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

COMPLAINT

Plaintiff, Maureen Bustin ("Plaintiff"), 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 a product liability action brought by Plaintiff ("Plaintiff") for injuries arising out of the Proceed Ventral Patch ("Proceed" or "Ethicon Multi-Layered Hernia Mesh").

2. Defendants manufactured and supplied to doctors a nine-layer hernia mesh patch known as the Proceed Ventral Patch.

3. The Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Plaintiff.

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 nine layers, degradation of polymers due to exposure to gamma radiation, non-conforming subcomponents, or some other mechanism renders the Ethicon Multi-Layered Hernia Mesh a defective product.

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

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. Plaintiff currently resides in Reading, Pennsylvania and is a citizen and resident of Pennsylvania.

8. Plaintiff underwent hernia repair surgery on December 2, 2013 at St. Joseph Medical Center in Reading, Pennsylvania. At that time, the Ethicon Multi-Layered Hernia Mesh

product that Defendants manufactured, designed, distributed, and warranted was implanted into Plaintiff. Her surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

9. 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.

10. 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 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 Ethicon Multi-Layered Hernia Mesh, the hernia repair mesh product 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 comprising the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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 any response related to these adverse events.

16. Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial business activity within the State of New Jersey, Middlesex County.

b. Defendants' hernia mesh products, including the subject Ethicon Multi-Layered Hernia Mesh, were designed, manufactured, and placed into the stream of commerce in the State of New Jersey by 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.

17. At all material times, Defendants developed, manufactured, advertised, promoted, marketed, sold, and/or distributed the defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically to Plaintiff and Plaintiff's implanting physician or his practice group, or to the hospital where the Ethicon Multi-

Layered Hernia Mesh was implanted.

18. Plaintiff's claims and causes of action are only 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.

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

20. Ethicon knowingly markets to, and derives income from, patients across the United States, including the State of New Jersey from the sale of the Ethicon Multi-Layered Hernia Mesh device.

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

FACTS COMMON TO ALL COUNTS

22. A defectively designed, manufactured and marketed Proceed Ventral Patch left the hands of Defendants in its defective condition, and was delivered into the stream of commerce. Eugene M. Shaffer, M.D., implanted the Proceed Ventral Patch in Plaintiff's abdomen to repair an umbilical hernia on or about December 2, 2013 at St. Joseph Medical Center in Reading, Pennsylvania. Plaintiff was implanted with a Proceed Ventral Patch, ref: PVPM, lot: GA8DHWZ0.

23. According to the medical records, on April 24, 2017 Plaintiff underwent revision surgery to repair a recurrent incisional hernia. During this surgery it was discovered that the hernia

sac contained incarcerated omentum and the previously placed mesh had become densely adherent to the omentum. Portions of the mesh were subsequently removed, and a partial omentectomy was performed. Portions of omentum and fused mesh were sent to pathology.

24. Plaintiff experienced and/or continues to experience severe pain, hernia recurrence, nausea, vomiting, diarrhea, chills, inflammation, loss of appetite, weight loss, stress and anxiety which have impaired her activities of daily living.

25. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants warranted would not occur because of the Proceed design and composition.

26. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the Ethicon Multi-Layered Hernia Mesh, Plaintiff has suffered and continues to suffer injuries and damages, including: past, present and future physical and mental pain and suffering; physical disability; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.

27. Defendants were the designers, manufacturers, marketers, sellers, distributors and suppliers of the Ethicon Multi-Layered Hernia Mesh at all material times.

28. Defendants warranted the Ethicon Multi-Layered Hernia Mesh as safe and effective for use and placed the device into the United States stream of commerce.

29. 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 Defendants set out to design the Proceed Ventral Patch in 2006, and even before Defendants set out to design the Proceed Surgical Mesh predicate device in 2003.

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

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

32. Before 2003, Defendants were aware that utilizing Oxidized Regenerated Cellulose in their mesh products would result in dense adhesions in the presence of blood or fibrinous exudate.

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

34. Before 2003, Defendants were aware that any exposure to gamma radiation would weaken and embrittle the polypropylene of the Ethicon Multi-Layered Hernia Mesh.

35. Before 2006, Defendants were aware that adding Vicryl and other additional layers to the Proceed Surgical Mesh to create the Proceed Ventral Patch, would increase the intensity and duration of inflammation and foreign body response (FBR), thus increasing fibrinous exudate.

36. Before placing the 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 that 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.

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

38. Defendants sterilized the Proceed with gamma radiation, despite long-standing

knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma radiation.

39. The Proceed Ventral Patch is made of the following, starting with the component 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)
- PDS film layer
- PDS reinforcing element
- PDS ring
- PDS film layer
- Vicryl
- PDS film layer

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

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

42. Defendants sterilize the Proceed with gamma radiation.

43. Gamma radiation degrades, weakens, and embrittles the polypropylene base of the Proceed.

44. Decades before the release of the Ethicon Multi-Layered Hernia Mesh, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed gamma radiation.[1]

45. The embrittled polypropylene of the Ethicon Multi-Layered Hernia Mesh increases its propensity to tear away from the securing devices, such as sutures or tacks.

46. The polypropylene base is the only permanent, non-resorbable portion of the Ethicon Multi-Layered Hernia Mesh.

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

47. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Multi-Layered 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]

48. For decades, the medical community had concerns 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.

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

50. Despite significant evidence to the 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.

51. The following studies have investigated complications associated with the Proceed:

> a. In 2006, a study out of The Netherlands evaluating the use of new prosthetic meshes for ventral hernia repair was published in Surgical Endoscopy. **Proceed showed significantly less incorporation… Proceed composite has a smooth surface designed to prevent adhesion formation. However, it is less smooth than other composite meshes with antiadhesive barriers. Furthermore, the barrier applied is oxidized cellulose, which may not prevent mesh adhesions as effectively as anticipated or as reported previously.**
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> Burger, J.W. et al, *Evaluation of New Prosthetic Meshes for Ventral Hernia Repair*. Surg Endosc. 20:1320 – 1325 (2006). DOI: 10.1007/s00464-005-0706-4.
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> b. In 2009, a study out of The Netherlands on adhesions prevention during hernia mesh repair was published in the Annals of Biomedical Engineering. **The uncoated Prolene meshes were found to invoke a moderate inflammatory response in their immediate vicinity,**

[2] Ethicon Multi-Layered Hernia Mesh Ventral Patch Instructions for Use, RMC 8550915, Status 9/08.
[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).

characterized by the presence of active macrophages. A stronger inflammatory response was observed with the Proceed meshes, presumably due to ongoing phagocytosis of the oxidizing regenerated cellulose and polydioxanone coating… Most remarkable were adhesions with Proceed. Although adhesion scores were the lowest at day 7, they increased by day 30 and exceeded adhesion scores of NVP/BMA-coated Prolene mesh and Prolene.

Emans, P. et al, *Polypropylene Meshes to Prevent Abdominal Herniation. Can Stable Coatings Prevent Adhesions in the Long Term?* Annals of Biomedical Engineering. 37(2):410 – 418 (2009). DOI: 10.1007/s10439-008-9608-7.

c. In 2009, a study out of Saint Louis, Missouri measuring adhesions and mesh contraction was published by Surgical Innovation. The data was previously presented at the American Hernia Society, Third International Hernia Congress on June 9, 2006. **The highest degrees of mesh contraction occurred with DualMesh and Proceed… Proceed exhibited the greatest surface area of adhesion coverage and the highest-grade adhesions.**

Pierce, R. et al, *120-Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Bioabsorbable Barrier Macroporous Mesh After Intraperitoneal Placement*. Surg Innov. (2009). DOI: 10.1177/1553350608330479.

d. In 2010, a study out of Saint Louis, Missouri on adhesion related complications associated with intraperitoneal mesh was published in Surgical Endoscopy. **Nevertheless, there appears to be some differentiation in the adhesion characteristics of the absorbable-barrier-coated meshes… We noticed a similar increase in the adhesion tenacity score of PROCEED in a preclinical study of intraperitoneal placement f absorbable-barrier-coated meshes in a rabbit model.**

Jenkins, E. et al, *Prospective Evaluation of Adhesion Characteristics to Intraperitoneal Mesh and Adhesiolysis-Related Complications During Laparoscopic Re-Exploration After Prior Ventral Hernia Repair*. Surg Endosc. 24:3002 – 3007. DOI: 10.1007/s00464-010-1076-0.

e. In 2010, a study out of Belgium on the lack of convincing data in medical literature regarding to use of intraperitoneal hernia mesh was published in The World Journal of Hernia and Abdominal Wall Surgery. The content of the paper was presented during the 32nd International Congress of the European Hernia Society, in Istanbul, on October 6-8, 2010. **After release of the omental adhesions, we found the [Proceed] mesh to have shrunk and folded up, to a dimension of approximately 3.0 cm in**

diameter. This means a shrinkage from a circle of diameter 6.4 cm (surface: 3.14 x 3.2^2 = 32.2 cm^2) to a "circle" of diameter 3.0 cm (surface: 3.14 x 1.5^2 = 7.1 cm^2), equivalent to a mesh surface shrinkage of 77.9%... There is a complete lack of convincing data on these mesh devices in the medical literature.

Muysoms, F.E. et al, *Complications of Mesh Devices for Intraperitoneal Umbilical Hernia Repair: A Word of Caution*. Journal of Hernia. 15:463-468 (2011). DOI: 10.1007/s10029-010-0692-x.

f. In 2012, a study out of Saint Louis, Missouri on the effectiveness of barrier hernia mesh was published in Surgical Endoscopy. **This study also demonstrated increased adhesion formation for all of the barrier mesh prostheses between 7 and 30 days, which the authors attributed to increased inflammation related to the degradation and resorption of the barrier layer components, which were ongoing between 7 and 30 days. This effect was most pronounced in PROCEED Surgical Mesh materials, which again highlights the influence that the chemistry of the particular barrier components may have over the inflammatory response and subsequent adhesion formation.**

Deeken, C. et al, *A Review of the Composition, Characteristics, and Effectiveness of Barrier Mesh Prostheses Utilized for Laparoscopic Ventral Hernia Repair*. Surg Endosc. 26:566-575 (2012). DOI: 10.1007/s00464-011-1899-3.

g. In 2014, a study out of Belgium on the Proceed Ventral Patch (PVP) was published in The World Journal of Hernia and Abdominal Wall Surgery. **Polypropylene meshes, like the PVP, have demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4 cm in diameter is in sufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP in hernias of 2cm or more.**

Bontinck, J. et al, *Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias*. Journal of Hernia. 18:671 – 680 (2014). DOI: 10.1007/s10029-013-1140-5.

h. In 2015, a study out of Belgium on the Proceed (PP/ORC) was published in The World Journal of Hernia and Abdominal Wall Surgery. **In our opinion, there are several factors contributing to the extensive FBR and shrinkage/mesh contraction of the PP/ORC device. First, the composition of the PP/ORC device out of nine different layers will lead**

to a more extensive FBR. Second, absorption of 8 of these 9 layers will create a severe inflammatory reaction as, e.g.. shown with vicryl mesh absorption, also being one of the components of the PP/ORC device. A third possible explanation is delamination of the device.

Reynvoet, E. et al, *Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model*. Journal of Hernia. 19:955 – 963 (2015). DOI: 10.1007/s10029-015-1368-3.

i. In 2016, a study out of Bosnia and Herzegovina was published by The Royal Belgian Society for Surgery. **The extent of [adhesion] site involvement after 28 days was statistically significantly greater in the Proceed group.**

Delibegovic, S. et al, *Formation of Adhesions After Intraperitoneal Applications of TiMesh: Experimental Study on a Rodent Model*. The Royal Belgian Society for Surgery. (2016). DOI 10.1080/00015458.2016.1179513

j. In 2016, a study out of Germany on the adhesion prevention efficacy of Proceed (PCM) was published in International Journal of Medical Sciences. **PCM does not provide significant adhesion prevention.**

Winny, M. et al, *Adhesions Prevention Efficacy of Composite Meshes Parietex, Proceed, and 4DryField PH Covered Polypropylene Meshes in an IPOM Rat Model*. Int. J. Med. Sci. 13:936 – 941 (2016). DOI: 10.7150/ijms.16215.

k. In 2017, a Proceed (PVP) randomized controlled trial out of The Netherlands was published in the World Journal of Surgery. **At this point, PVP device usage shows an easier and faster operating procedure. Nevertheless, this advantage is outweighed by the significantly higher incidence of early re-operations due to early complications.**

Ponten, J.E. et al, *Mesh Versus Patch Repair for Epigastric and Umbilical Hernia (MORPHEUS Trial); One-Year Results of a Randomized Controlled Trial*. World J. Surg. (2017). DOI: 10.1007/s00268-017-4297-8.

l. In 2017, a study out of Brazil was published on adhesions and collagen formation following mesh implantation. **The study follow-up time, 90 days, was established because there were no articles in the literature with prolonged follow-up… What we can formulate is that absorption of the regenerated oxidized cellulose exposes the polypropylene layer to the abdominal visceral content and that this consequently led to the adhesions found… The adhesion formation is a complex process and is basically started by the tissue injury process**

> **which breaks down the balance between coagulation and fibrinolysis. Fibrin deposition results in a matrix where the fibroblasts produce extracellular matrix. The end process generates various degrees of adhesion… In the present study, type III collagen was expressed more in the coated group and based on the result of the research this could increase hernia formation.**
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> Rossi, L. et al, *Peritoneal Adhesions Type I, III and Total Collagen on Polypropylene and Coated Polypropylene Meshes: Experimental Study in Rats*. ABCD Arq Bras Cir Dig 30(2):77 – 82 (2017). DOI: 10.1590/0102-6720201700020001.

THE FDA'S 510(k) CLEARANCE PROCESS

52. 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 had approved for sale before 1976, when the MDA was enacted.

53. No clinical testing is required under this process.

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

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

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

57. 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.**

58. 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 it 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."

59. Defendants cleared the Proceed Ventral Patch, 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.

60. 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.**

61. The first 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 adhesion barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

62. 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.

63. Defendants applied for 510(k) clearance for the Proceed Ventral Patch in December of 2006. Defendants do not mention in the 510(k) application for the Proceed Ventral Patch that the mesh is intended to act as a resorbable adhesion barrier. After 510(k) clearance, Defendants marketed and continue to market the Proceed Ventral Patch as a resorbable adhesion barrier. Even the Proceed IFU notes "The ORC side of the patch provides a bioresorbable layer that physically separates the polypropylene mesh form underlying tissue and organ surfaces while minimizing tissue attachment to the polypropylene mesh during the critical wound healing period."

FAILURE TO WARN OF THE DANGERS ASSOCIATED WITH PROCEED

64. Defendants marketed the Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs).

65. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing

problems or defects in its devices through communications, e-mails, letters, recalls, warnings in product inserts, and/or through its product representatives, who communicate, interact and work with surgeons.

66. The nine layers of the Proceed Ventral Patch 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.

67. Defendants downplayed the intensity of the inflammatory reaction caused by Vicryl by stating in the Proceed Instructions for Use (IFU) that the Vicryl elicits "only a mild tissue reaction during absorption."

68. Defendants state in the Proceed Ventral Patch IFU that "The PROLENE Soft Mesh components are 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 the 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 non-reactive 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 the 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 IFU has a section for contraindications, which lists "None known."

71. The Proceed IFU has a section for adverse reactions, which lists "Potential adverse reactions are those typically associated with surgically implantable materials…" The polypropylene base of the Proceed carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the nine layers of the Proceed Ventral Patch 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. The Proceed IFU notes that "Selected mesh size should allow for adequate overlap of the fascial defect on all sides." The IFU never defines what constitutes "adequate overlap." Defendants are aware that the Proceed shrinks over time, with reports of the Proceed Ventral Patch shrinking as much as 77%.

73. Defendants failed to warn that the Proceed will elicit a fibrinous exudate.

74. Defendants failed to warn that the Proceed creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

75. Defendants never performed any clinical trials and/or studies before marketing the Ethicon Multi-Layered Hernia Mesh.

76. Defendants did not fully and/or adequately test the configuration of its new, nine-layer hernia mesh patch design with ORC, polypropylene, Vicryl, and six layers of PDS, that was

implanted into Plaintiff.

77. Although the United States does not have a complete and accurate database to track problems with hernia mesh implants, controlled studies have investigated the problems with the Ethicon Multi-Layered Hernia Mesh.

78. A single center study was conducted in Belgium, where three surgeons implanted only the Proceed in 101 patients between April 2009 and December 2011. The Proceed was able to be visualized by ultrasound in 47 patients. Of those 47 patients, 10 were noted to have mesh contraction. The Proceed "was removed during the operation in four patients and important centripetal contraction of the mesh, diminishing the surface area, was observed in all cases." The authors concluded the Proceed has "demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence and in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4cm in diameter was insufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP (Proceed Ventral Patch) in hernias of 2 cm or more." The authors go on to note that their study is likely underpowered as "Most recurrences after ventral hernia repair occur within 2 years after the operation. Since our study had a mean follow-up of 16 months, it is likely that a longer follow-up would yield a higher recurrence rate."[4]

79. In 2015, another study in Belgium confirmed "massive shrinkage" with the Proceed. The authors concluded that "This can however not be considered the ideal indication for a mesh device repair with a suggested mesh overlap of at least 5 cm for incisional hernias."[5]

[4] J. Bontinck, Single Centre Observational Study to Evaluate the Safety and Efficacy of the Ethicon Multi-Layered Hernia Mesh Ventral Patch to Repair Small Ventral Hernias, 18 Hernia 671, Clinical.Trials.gov: NCT01307696 (2013).

[5] E. Reynvoet, Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model, 19 Hernia

80. 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.

81. 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.

82. Despite these reassurances, the defective design and manufacture of the 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.

83. Defendants were aware that the ORC layer was ineffective in preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the nine-layer mesh would contract massively over time. Nonetheless, Defendants employed the design in the Proceed Ventral Patch in reckless disregard for the safety of patients, including Plaintiff.

84. 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.

85. From the time Defendants first began selling the Ethicon Multi-Layered Hernia Mesh in the United States through today, product labeling and the product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the Ethicon Multi-Layered Hernia Mesh, specifically its propensity to massively shrink, the increased in duration and intensity of inflammation, and the elevated rate of adhesions, bowel

955 (2015).

complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN UNDER NEW JERSEY PRODUCT LIABILITY ACT (NJ PLA)

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, the Ethicon Proceed 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 Ethicon Proceed.

89. Defendants expected the Ethicon Proceed Devices 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 her implanting physician, without substantial change in their condition.

90. At the time the Ethicon Proceed left Defendants' possession and the time the Ethicon Proceed 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:

- the Ethicon Proceed was not reasonably safe as intended to be used;
- the Ethicon Proceed had an inadequate design for the purpose of hernia repair;

- the Ethicon Proceed contained unreasonably dangerous design defects, including a large pore ORC layer that is ineffective at preventing adhesion formation to the underlying polypropylene;
- the Ethicon Proceed is unreasonably dangerous, due to the degraded state of the polypropylene utilized, which has been exposed to gamma irradiation;
- the Ethicon Proceed contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs the inflammatory response;
- the Ethicon Proceed was not appropriately or adequately tested before distribution; and
- the Ethicon Proceed 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.

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

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

93. Had the Defendants properly and adequately tested the Ethicon Proceed, they would have discovered that the ORC layer was ineffective at preventing adhesion formation to the

polypropylene; multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene was too weak; and that these defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, a pronounced foreign body response, among other complications.

94. The Ethicon Proceed, 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 form 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.

95. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings or the Ethicon Proceed, 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.

96. 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*. (hereinafter "NJ PLA").

COUNT II: STRICT PRODUCTS LIABILITY – FAILURE TO WARN UNDER NJ PLA

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

98. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Ethicon Proceed; and directly advertised or marketed the product to the FDA, health care

professionals, and consumers, including Plaintiff. Therefore, Defendants had a duty to warn of the risks associated with the use of the Ethicon Proceed.

99. Defendants distributed and sold the Ethicon Proceed in its original form of manufacture, which included the defects described in this Complaint.

100. The Ethicon Proceed was expected to and did reach Plaintiff and her implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

101. Each Ethicon Proceed 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.

102. At all material times, Plaintiff was a person Defendants should have considered to be subject to the harm caused by the defective nature of the Ethicon Proceed.

103. The Ethicon Proceed was implanted in Plaintiff, and used in a manner for which it was intended.

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

105. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting physician, of the true risks of the Ethicon Proceed, 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.

106. Defendants failed to timely and reasonably warn of material facts regarding the

safety and efficacy of the Ethicon Proceed. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Ethicon Proceed, or no consumer, including Plaintiff, would have purchased and/or consented to the use of the Ethicon Proceed.

107. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Proceed.

108. The Ethicon Proceed, 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 the Ethicon Proceed 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 the Ethicon Proceed.

109. The Ethicon Proceed, 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 the Ethicon Proceed 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.

110. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

111. Plaintiff and her physician used the Ethicon Proceed for its intended purpose, *i.e.*, hernia repair.

112. Plaintiff could not have discovered any defect in the Ethicon Proceed through the exercise of due care.

113. 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.

114. Neither Plaintiff, nor her implanting physician had substantially the same knowledge about the Ethicon Proceed as Defendants.

115. Defendants reasonably should have known the Ethicon Proceed was unsuitable to repair a hernia defect in patients like Plaintiff.

116. 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.

117. 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: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT UNDER NJ PLA

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

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

120. The Ethicon Proceed Defendants manufacture 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 the Ethicon Proceed 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 Ethicon Proceed as a safe and effective absorbable barrier hernia mesh.

121. 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.

122. 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 IV: NEGLIGENCE-
PURSUANT TO NEW JERSEY PRODUCT LIABILITY ACT, NEW JERSEY COMMON LAW AND PENNSYLVANIA COMMON AND STATUTORY LAW

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

124. 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 the Ethicon Proceed, they failed to do so.

125. Defendants knew, or in the exercise of reasonable care should have known, that the Ethicon Proceed was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff in whom the Proceed was

implanted. They also knew or should have known that Plaintiff and her physicians were unaware of the dangers and defects inherent in the Ethicon Proceed.

126. 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 the Ethicon Proceed, Plaintiff suffered injuries and damages as summarized in this Complaint.

127. Defendants are 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.*

128. Defendants are similarly liable in tort to Plaintiff for their wrongful conduct, including but not limited to negligent marketing and negligent misrepresentations, pursuant to New Jersey common law.

129. Defendants are liable in tort to Plaintiff for their wrongful conduct, including but not limited to their negligent marketing and negligent design of the Proceed product, pursuant to any and all applicable Pennsylvania common or statutory law.

COUNT V: BREACH OF IMPLIED WARRANTY UNDER NJ PLA AND PENNSYLVANIA COMMON AND STATUTORY LAW

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

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

132. When the Ethicon Proceed was implanted in Plaintiff to treat her hernia, the Proceed was being used for the ordinary purposes for which it was intended.

133. Plaintiff, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Proceed implanted in her.

134. Contrary to such implied warranties, the Ethicon Proceed was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Proceed 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 the Proceed.

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

136. 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*.

137. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable Pennsylvania common law or statutes.

COUNT VI: BREACH OF EXPRESS WARRANTY UNDER NJ PLA AND PENNSYLVANIA COMMON AND STATUTORY LAW

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

139. At all relevant times, Defendant manufactured, distributed, advertised, promoted, and sold the Ethicon Proceed.

140. At all relevant times, Defendant intended the Ethicon Proceed 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.

141. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Ethicon Proceed. Therefore, Plaintiff was a foreseeable user of Defendants' Ethicon Proceed.

142. Plaintiff and/or her implanting physician were at all relevant times in privity with Defendants.

143. Defendants' Ethicon Proceed was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

144. Defendants breached various express warranties with respect to the Ethicon Proceed, including the following particulars:

- Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that the Ethicon Proceed was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Ethicon Proceed.
- Defendants represented to Plaintiff and her physicians and healthcare providers that their Ethicon Proceed was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Ethicon Proceed was not safer than alternatives available on the market; and
- Defendants represented to Plaintiff and her physicians and healthcare providers that the Ethicon Proceed was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Ethicon Proceed.

145. In reliance upon Defendants' express warranty, Plaintiff was implanted with

Defendants' Ethicon Proceed as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

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

147. 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 the Ethicon Proceed.

148. Defendants breached their express warranties to Plaintiff in that the Ethicon Proceed was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

149. 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.

150. 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.*

151. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable Pennsylvania common law or statutes.

COUNT VII: PUNITIVE DAMAGES UNDER PENNSYLVANIA COMMON AND STATUTORY LAW, NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq.*) and NEW JERSEY PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1, *et seq.*)

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

153. 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 the 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 the Ethicon Multi-Layered Hernia Mesh, despite available information demonstrating that the 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 the Ethicon Multi-Layered Hernia Mesh or provided proper training and instruction to physicians regarding use of the 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 the Ethicon Multi-Layered Hernia Mesh.

154. Defendants were or should have been in possession of evidence demonstrating that the Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, Defendants

continued to market the Ethicon Multi-Layered Hernia Mesh by providing false and misleading information with regard to its safety and efficacy.

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

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

157. Defendants are 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.* and New Jersey common law.

158. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to *N.J.S.A.* 2A:15-5.9, *et seq.*

159. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to any and all Pennsylvania common law and in tort to Plaintiff for their wrongful conduct pursuant to the applicable Pennsylvania common law.

WHEREFORE, Plaintiff 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 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, listed on Exhibit A. 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, Michael G. Daly is hereby designated as trial counsel on behalf of Plaintiff.

/s/ Marc D. Grossman
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Dated: April 23, 2019

EXHIBIT A

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; and Benton, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3317-18.

SUMMONS

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Attorney(s) for Plaintiff Maureen Bustin

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

Maureen Bustin

Plaintiff(s)

vs.

Johnson & Johnson, et al.

Defendant(s)

CIVIL ACTION SUMMONS

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.

/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 4/23/2019

Name of Defendant to Be Served: Ethicon, Inc.

Address of Defendant to Be Served: Route 22 West, Somerville, NJ 08876

SUMMONS

Attorney(s) Marc Grossman
Office Address 100 Garden City Plaza, Suite 500
Town, State, Zip Code Garden City, NY 11530

Telephone Number (516) 741-5600
Attorney(s) for Plaintiff Maureen Bustin

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

Maureen Bustin

Plaintiff(s)

vs.

Johnson & Johnson, et al.

Defendant(s)

CIVIL ACTION SUMMONS

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.

/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 4/23/2019

Name of Defendant to Be Served: Johnson & Johnson

Address of Defendant to Be Served: One Johnson & Johnson Plaza, New Brunswick, New Jersey

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-003141-19

Case Caption: BUSTIN MAUREEN VS ETHICON, INC.
Case Initiation Date: 04/23/2019
Attorney Name: MARC DAVID GROSSMAN
Firm Name: SANDERS PHILLIPS GROSSMAN, LLC
Address: 100 GARDEN CITY PLAZA, STE 500
GARDEN CITY NY 11530
Phone:
Name of Party: PLAINTIFF : Bustin, Maureen
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PROCEED MESH/PATCH
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: See exhibit A
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:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO

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)

04/23/2019
Dated

/s/ MARC DAVID GROSSMAN
Signed