IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CAROLYN LEWIS, KENNETH LEWIS, AUGUSTINA BROWN-SINGLETARY, ANDRE SINGLETARY-SMITH, KARIN HARRISON, ROBERT HARRISON, PATRICIA HEADRICK, DARRELL HEADRICK, KATIE USZLER, NICK USZLER, KELLY YOUNG, and KENNETH YOUNG,	)	
Plaintiffs,	)	CIVIL ACTION FILE
v.	)	NO. _____
JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, GYNECARE, and AMERICAN MEDICAL SYSTEMS, INC.,	)	
Defendants.	)	

ORIGINAL COMPLAINT

COME NOW, Plaintiffs Carolyn Lewis, Kenneth Lewis, Augustina Brown-Singletary, Andre Singletary-Smith, Karin Harrison, Robert Harrison, Patricia Headrick, Darrell Headrick, Katie Uszler, Nick Uszler, Kelly Young, and Kenneth Young, and file their Original Complaint, complaining of Defendants Johnson & Johnson, Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare, and American Medical Systems, Inc., and in support thereof, respectfully show the Court as follows:

PARTIES

1. Plaintiffs Carolyn Lewis and Kenneth Lewis are married and are citizens of the State of Texas.

2. Plaintiffs Augustina Brown-Singletary and Andre Singletary-Smith are married and are citizens of the State of Virginia.

3. Plaintiffs Karin Harrison and Robert Harrison are married and are citizens of the State of Wisconsin.

4. Plaintiffs Patricia Headrick and Darrell Headrick are married and are citizens of the State of Illinois.

5. Plaintiffs Katie Uszler and Nick Uszler are married and are citizens of the State of Wisconsin.

6. Plaintiffs Kelly Young and Kenneth Young are married and are citizens of the State of Nevada.

7. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in Somerville, 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.

8. Defendant Ethicon, Inc. ("Ethicon") is a wholly-owned subsidiary of J&J located in Somerville, New Jersey. 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.

9. Defendant Ethicon Women's Health and Urology ("Ethicon WHU") is a division of Ethicon located in Somerville, New Jersey. All acts and omissions of Ethicon WHU 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.

10. Defendant Gynecare ("Gynecare") is a division of Ethicon located in Somerville, New Jersey. All acts and omissions of Gynecare 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.

11. Defendant American Medical Systems, Inc. ("AMS") is a Delaware corporation with its corporate headquarters and principal place of business in Minnetonka, Minnesota. All acts and omissions of AMS 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.

JURISDICTION AND VENUE

12. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

13. Defendants have significant contacts with this federal judicial district such that they are subject to the personal jurisdiction of the Court in this district.

14. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

THE PELVIC MESH PRODUCTS

15. Defendants' Pelvic Mesh Products ("Pelvic Mesh Products") are as follows:

a. Gynecare TVT;

b. Gynecare TVT-O;

c. Gynecare TVT Secur;

d. Gynecare Prolift;

e. Gynecare Prolift+M; and

f. AMS Monarc Subfascial Hammock.

16. J&J, Ethicon, Ethicon WHU, and Gynecare designed, manufactured, packaged, labeled, marketed, sold, and distributed the Gynecare TVT, the Gynecare TVT-O, the Gynecare TVT Secur, the Gynecare Prolift, and the Gynecare Prolift+M, including that which was implanted in Plaintiff(s) as indicated in the paragraphs that follow.

17. AMS designed, manufactured, packaged, labeled, marketed, sold, and distributed the AMS Monarc Subfascial Hammock, including that which was implanted in Plaintiff(s) as indicated in the paragraphs that follow.

18. The Pelvic Mesh Products contain monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth below is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

19. Defendants sought and obtained FDA clearance to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for

safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Pelvic Mesh Products.

20. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original). The FDA Safety Communication also stated, "*[m]esh contraction* (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA…. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

21. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…. Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

22. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

23. The injuries of the female Plaintiffs as will be more fully set forth in each Plaintiff's Fact Sheet to be served in this civil action are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

24. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

25. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

26. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" ("White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

27. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

28. The FDA White Paper further stated that "these products are associated with serious adverse events…. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

29. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

30. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

31. Defendants knew or should have known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

32. Defendants knew or should have known that the Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

33. The scientific evidence shows that the material from which the Pelvic Mesh Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products, including the female Plaintiffs identified herein.

34. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the female Plaintiffs identified herein.

35. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Pelvic Mesh Products were unreasonably susceptible to degradation and fragmentation inside the body.

36. The Pelvic Mesh Products were unreasonably susceptible to shrinkage and contraction inside the body.

37. The Pelvic Mesh Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

38. The Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

39. Defendants omitted the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as safe medical devices when Defendants knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, including the female Plaintiffs identified herein, catastrophic injuries.

40. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Pelvic Mesh Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the female Plaintiffs identified herein, making them defective under the law.

41. The specific nature of the Pelvic Mesh Products' defects includes, but is not limited to, the following:

a. the use of polypropylene and collagen material in the Pelvic Mesh Products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (*e.g.*, intercourse, defecation, walking);

g. the propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

h. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

42. The Pelvic Mesh Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiffs identified herein and/or their health care providers of subjects including, but not limited to, the following:

a. the Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. the Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Pelvic Mesh Products;

f. the risk of chronic infections resulting from the Pelvic Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. the hazards associated with the Pelvic Mesh Products;

l. the Pelvic Mesh Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

43. Defendants have underreported information about the propensity of the Pelvic Mesh Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

44. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

45. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

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

47. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

48. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Pelvic Mesh Products and the aftercare of patients implanted with the Pelvic Mesh Products.

49. The Pelvic Mesh Products implanted in the female Plaintiffs identified herein were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

50. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Pelvic Mesh Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

51. In many cases, including in the case of the female Plaintiffs identified herein, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

52. The medical and scientific literature studying the effects of the Pelvic Mesh Products, like that of the product(s) implanted in the relevant female Plaintiffs identified herein, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Pelvic Mesh Products.

53. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

54. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

55. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products.

56. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the female Plaintiffs identified herein and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

57. The Pelvic Mesh Products as designed, manufactured, distributed, sold, and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

58. As a result of having the Pelvic Mesh Products implanted in them, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo further medical treatment and procedures, and have suffered financial or economic loss, including, but

not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

PLAINTIFF-SPECIFIC INFORMATION

59. Plaintiff Carolyn Lewis provides the following additional information specific to her case:

a. Plaintiff Carolyn Lewis was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's TVT (Lot No. 3348119, Reference No. 810041B).

b. The Pelvic Mesh Products were implanted on November 20, 2009 by Muriel Boreham, M.D. at Baylor Medical Center in Dallas, Texas.

60. Plaintiff Augustina Brown-Singletary provides the following additional information specific to her case:

a. Plaintiff Augustina Brown-Singletary was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's TVT (Lot No. 3405460, Reference No. 810081L).

b. The Pelvic Mesh Products were implanted on July 26, 2010 by Howard Wiles, III, M.D. at Bon Secours St. Francis Medical Center in Midlothian, Virginia.

61. Plaintiff Karin Harrison provides the following additional information specific to her case:

a. Plaintiff Karin Harrison was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's TVT (Lot No. 3030237, Reference No. 810041B) and Gynecare's Prolift (Lot No. 2931387, Reference No. PFRT01).

b. The Pelvic Mesh Products were implanted on September 5, 2007 by Dennis Miller, M.D. at Columbia St. Mary's Hospital in Milwaukee, Wisconsin.

62. Plaintiff Patricia Headrick provides the following additional information specific to her case:

a. Plaintiff Patricia Headrick was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's TVT (Lot No. 3500124, Reference No. 810081).

b. The Pelvic Mesh Products were implanted on May 24, 2011 by Stephanie Skelly, M.D. at Red Bud Regional Hospital in Red Bud, Illinois.

63. Plaintiff Katie Uszler provides the following additional information specific to her case:

a. Plaintiff Katie Uszler was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's TVT-O (Lot No. 3227750, Reference No. 810081) and Gynecare's TVT Secur (Lot No. 3515538, Reference No. TVTS).

b. The Gynecare TVT-O was implanted on February 27, 2009 by Lata Gupta, M.D. at Aurora Medical Center in Kenosha, Wisconsin. The Gynecare TVT Secur was implanted on September 28, 2011 by Anthony Park, M.D. at Aurora Medical Center in Kenosha, Wisconsin.

64. Plaintiff Kelly Young provides the following additional information specific to her case:

a. Plaintiff Kelly Young was implanted with the following Pelvic Mesh Products, about which she is making a claim: Gynecare's Prolift+M (Lot No. 3380027, Reference No. PFRT02) and AMS's Monarc Subfascial Hammock (Lot No. 659669047, Reference No. 72403830)

b. The Pelvic Mesh Products were implanted on August 5, 2010 by Basia Yakaitis, M.D. at University Medical Center in Las Vegas, Nevada.

CAUSES OF ACTION

Count I: Negligence

65. Paragraphs 1-64 of this Complaint are hereby incorporated by reference as if fully set forth herein.

66. Defendants had a duty to individuals, including the female Plaintiffs identified herein, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Products.

67. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Products. Defendants breached their aforementioned duty by:

a. failing to design the Pelvic Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products were implanted, including the female Plaintiffs identified herein;

b. failing to manufacture the Pelvic Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products were implanted, including the female Plaintiffs identified herein;

c. failing to use reasonable care in the testing of the female Plaintiffs identified herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products were implanted, including the female Plaintiffs identified herein;

d. failing to use reasonable care in inspecting the Pelvic Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products were implanted, including the female Plaintiffs identified herein; and

e. otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Pelvic Mesh Products.

68. The reasons that Defendants' negligence caused the Pelvic Mesh Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and

causing pain upon normal daily activities that involve movement in the pelvis (*e.g.*, intercourse, defecation);

g. the propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

h. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

69. Defendant also negligently failed to warn or instruct the female Plaintiffs identified herein and/or their health care providers of subjects including, but not limited to, the following:

a. the Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. the Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Pelvic Mesh Products;

f. the risk of chronic infections resulting from the Pelvic Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. the hazards associated with the Pelvic Mesh Products;

l. the Pelvic Mesh Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

70. As a direct and proximate result of Defendants' negligence, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo further

medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

Count II: Strict Liability – Design Defect

71. Plaintiffs incorporate by reference paragraphs 1-64 of this Complaint as if fully set forth herein.

72. The Pelvic Mesh Products implanted in the female Plaintiffs identified herein were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Pelvic Mesh Products' design defects include, but are not limited to:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Pelvic Mesh Products, including, but not limited to, the propensity of the Pelvic Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Pelvic Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Pelvic Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Pelvic Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (*e.g.*, intercourse, defecation);

g. the propensity of the Pelvic Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

h. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

73. As a direct and proximate result of the Pelvic Mesh Products' aforementioned defects as described herein, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

74. Defendants are strictly liable to the female Plaintiffs identified herein for designing, manufacturing, marketing, labeling, packaging, and selling a defective product(s).

Count III: Strict Liability – Manufacturing Defect

75. Plaintiffs incorporate by reference paragraphs 1-64 of this Complaint as if fully set forth herein.

76. The Pelvic Mesh Products implanted in the female Plaintiffs identified herein were not reasonably safe for their intended uses and were defective as described herein as a matter of law

with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the female Plaintiffs identified herein.

77. As a direct and proximate result of the Pelvic Mesh Products' aforementioned defects as described herein, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

78. Defendants are strictly liable to the female Plaintiffs identified herein for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

Count IV: Strict Liability – Failure to Warn

79. Plaintiffs incorporate by reference paragraphs 1-64 of this Complaint as if fully set forth herein.

80. The Pelvic Mesh Products implanted in the female Plaintiffs identified herein were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. the Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Pelvic Mesh Products;

f. the risk of chronic infections resulting from the Pelvic Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

k. the hazards associated with the Pelvic Mesh Products;

l. the Pelvic Mesh Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Pelvic Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

81. As a direct and proximate result of the Pelvic Mesh Products' aforementioned defects as described herein, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

82. Defendants are strictly liable to the female Plaintiffs identified herein for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

Count V: Breach of Express Warranty

83. Plaintiffs incorporate by reference paragraphs 1-64 of this Complaint as if fully set forth herein.

84. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Pelvic Mesh Products were safe and reasonably fit for their intended purposes.

85. The female Plaintiffs identified herein and/or their healthcare providers chose the Pelvic Mesh Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Pelvic Mesh Products.

86. The female Plaintiffs identified herein, individually and/or by and through their physician, reasonably relied upon Defendants' express warranties and guarantees that the Pelvic Mesh Products were safe, merchantable, and reasonably fit for their intended purposes.

87. Defendants breached these express warranties because the Pelvic Mesh Products implanted in the female Plaintiffs identified herein were unreasonably dangerous and defective as described herein and not as Defendants had represented.

88. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product(s) in the body of the female Plaintiffs identified herein, placing said Plaintiffs' health and safety in jeopardy.

89. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

Count VI: Breach of Implied Warranty

90. Plaintiffs incorporate by reference paragraphs 1-64 of this Complaint as if fully set forth herein.

91. Defendants impliedly warranted that the Pelvic Mesh Products were merchantable and were fit for the ordinary purposes for which they were intended.

92. When the Pelvic Mesh Products were implanted in the female Plaintiffs identified herein to treat their pelvic organ prolapse and/or stress urinary incontinence, the Pelvic Mesh Products were being used for the ordinary purposes for which they were intended.

93. The female Plaintiffs identified herein, individually and/or by and through their physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Pelvic Mesh Products implanted in them.

94. Defendants breached these implied warranties of merchantability because the Pelvic Mesh Products implanted in the female Plaintiffs identified herein were neither merchantable nor suited for their intended uses as warranted.

95. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of the female Plaintiffs identified herein, placing said Plaintiffs' health and safety in jeopardy.

96. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the female Plaintiffs identified herein have experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, and have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

Count VII: Loss of Consortium

97. Plaintiffs incorporate by reference paragraphs 1-96 of this Complaint as if fully set forth herein.

98. As a direct and proximate result of the above-described injuries sustained by the female Plaintiffs identified herein, where applicable, their husbands identified herein suffered a loss of their respective wife's consortium, companionship, society, affection, services and support.

Count VIII: Punitive Damages

99. Plaintiffs incorporate by reference paragraphs 1-98 of this Complaint as if fully set forth herein.

100. Defendants sold the Pelvic Mesh Products to the healthcare providers of the female Plaintiffs identified herein and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area.

101. Defendants sold the Pelvic Mesh Products to the health care providers of the female Plaintiffs identified herein (as well as other health care providers in the state of implantation and throughout the United States) in spite of their knowledge that the Pelvic Mesh Products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the female Plaintiffs identified herein and numerous other women.

102. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Pelvic Mesh Products' failures to perform as intended, which led to the severe and debilitating injuries suffered by the female Plaintiffs identified herein and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Pelvic Mesh Products' designs or the processes by which the Pelvic Mesh Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Pelvic Mesh Products as safe and effective.

103. Defendants knew the Pelvic Mesh Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in

an effort to cure the conditions proximately related to the use of the Pelvic Mesh Products, as well as other severe and personal injuries which were permanent and lasting in nature.

104. Defendants withheld material information from the medical community and the public in general, including the female Plaintiffs identified herein, regarding the safety and efficacy of the Pelvic Mesh Products.

105. Defendants knew and recklessly disregarded the fact that the Pelvic Mesh Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

106. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Pelvic Mesh Products.

107. Notwithstanding the foregoing, Defendants continue to aggressively market the Pelvic Mesh Products to consumers, without disclosing the true risks associated with the Pelvic Mesh Products.

108. Defendants knew of the Pelvic Mesh Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including the female Plaintiffs identified herein.

109. Defendants continue to conceal and/or fail to disclose to the public, including the female Plaintiffs identified herein, the serious complications associated with the use of the Pelvic Mesh Products to ensure continued and increased sales of the Pelvic Mesh Products.

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

JURY TRIAL DEMAND

111. Plaintiffs hereby respectfully request a trial by jury and submit the appropriate fee herewith.

PRAYER

112. WHEREFORE, Plaintiffs demand a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney's fees, interest, and any other relief, monetary or equitable, to which they are entitled.

Dated: July 25, 2012

Respectfully Submitted,

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