UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PATRICIA HOWARD	:	
	:	
Plaintiff,	:	Civil Action No. _____
	:	
v.	:	
	:	
ETHICON, INC. and JOHNSON & JOHNSON,	:	COMPLAINT AND DEMAND FOR JURY TRIAL
	:	
Defendants.	:	
	:	

Plaintiff Patricia Howard (hereafter as "Plaintiff"), by and through her counsel of record, Fitzgerald Law Group, brings this action against Defendants Ethicon, Inc. and Johnson & Johnson (hereafter collectively as "Defendants") related to the design, manufacture, marketing, distribution and sale of Defendants' pelvic mesh products (further defined below) for personal injuries suffered as a proximate result of Plaintiff's use of Defendants' pelvic mesh products. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct and in support allege as follows:

JURISDICTION & VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and all Defendants.

2. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants researched, designed, tested, manufactured, labeled, packaged, marketed, distributed,

advertised and sold the pelvic mesh product which caused Plaintiff injury as alleged herein within this judicial district and because Defendants are subject to personal jurisdiction within the State of Maine.

TAG-ALONG ACTION

3. This is a potential tag-along action and, in accordance with 28 U.S.C. § 1407, it should be transferred to the United States District Court for the Southern District of West Virginia for inclusion in *In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (Hon. Joseph R. Goodwin).

PARTIES

4. Plaintiff Patricia Howard is an adult individual and at all times relevant was a resident and citizen of Dover-Foxcroft, Maine

5. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Within Johnson & Johnson 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." The Ethicon Franchise was charged by Johnson & Johnson with the research, design, testing, development, manufacture, packaging, labeling, training, promotion, marketing, advertising and/or selling of the pelvic mesh product at issue in this case. The companies which comprise the Ethicon Franchise are controlled by Johnson & Johnson and include, but are not limited to, Ethicon, Inc., Ethicon LLC, Ethicon, Ltd. At all times relevant, Johnson & Johnson tested, studied, researched, designed, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the pelvic mesh product at issue in this case in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

6. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson with its principal place of business in Somerville, New Jersey. At all times relevant to this action, Ethicon,

Inc. tested, studied, researched, designed, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the pelvic mesh product at issue in this case in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

DEFENDANTS' PELVIC MESH PRODUCTS

7. At all times relevant, Defendants were engaged in the business of researching, designing, manufacturing, testing, training, packaging, labeling, marketing, promoting, advertising and/or selling pelvic mesh devices throughout the United States and worldwide, including but not limited to, Prolene Mesh, Prolene Soft Mesh, Gynemesh, Gynemesh PS, TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact, TVT Abbrevo, Prolift, Prolift +M, and Prosima.

8. In or about October 2002, Defendants began to manufacture, market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references herein to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

9. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' Prolene hernia mesh product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

10. On or about January l, 2005, without seeking clearance from the United States Food and Drug Administration ("FDA"), the Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift System was and is offered as an anterior,

posterior, or total repair system, and all references to the Prolift and/or Prolift System include by reference all variations.

11. In or about May 2008, the Defendants began to manufacture, market and sell a product known as the Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M System was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M and/or Prolift +M System include by reference all variations.

12. In or about March 2010, Defendants began to manufacture, market and sell a product known as Prosima System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prosima was and is offered as an anterior, posterior, or total repair system, and all references to Prosima include by reference all variations.

13. The Defendants also manufacture, market and sell a pelvic mesh product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to, the TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT-Exact and TVT-Abbrevo. All references to TVT include by reference all variations.

SPECIFIC FACTUAL ALLEGATIONS

14. On or about April 2, 2009, Plaintiff Howard underwent a surgical procedure at St. Joseph's Hospital for the treatment of stress urinary incontinence. During surgery, a Gynecare TVT-Secur pelvic mesh device (hereafter "the Product") was implanted by Plaintiff's urogynecological surgeon.

15. Subsequently, as a direct and proximate result of the defective nature of the Product as stated herein, Plaintiff began experiencing complications and injuries attributable to the Product.

16. Had Plaintiff and/or Plaintiff's urogynecological surgeon been properly warned by Defendants about the risks of the Product, Plaintiff's urogynecological surgeon would not have implanted the Product in Plaintiff, and Plaintiff would not have agreed to have the Product implanted.

17. As a direct, proximate and legal consequence of her use of the Product, and its defects and failures as stated herein, Plaintiff Howard has suffered and continues to suffer permanent and debilitating injures and damages which require ongoing medical care. As a further direct, proximate and legal consequence of her use of the Product, Plaintiff Howard has sustained and will sustain future damages, including but not limited to, additional surgeries; cost of medical care; rehabilitation; home health care; economic loss; mental and emotional distress; 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.

GENERAL FACTUAL ALLEGATIONS

18. Surgical mesh products have been used to repair abdominal hernias since the 1950s.

19. In the 1970s, gynecologists began using surgical mesh products designed for abdominal hernia repair to surgically repair prolapsed organs.

20. In the 1990s, gynecologists began using surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").

21. Medical device manufacturers, including Defendants, began to modify the surgical mesh used in hernia repair to be used as products specifically intended to correct POP an SUI.

22. Today, Defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools.

23. Defendants sought and obtained clearance from the FDA to market the Product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act which 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 at any time with regard to the Product.

24. Defendants' pelvic mesh products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. Pelvic mesh products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

25. On October 20, 2008, the FDA issued a Public Health Notification that described over 1,000 adverse events that had been reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the mesh manufacturers by name, a review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database indicates that the Defendants named herein are manufacturers of the pelvic mesh products that are the subject of the FDA notification.

26. On July 13, 2011, the FDA issued a Safety Communication stating that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in original).

27. The FDA Safety Communication also stated, "*Mesh 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).

28. Also in July, 2011, the FDA advised physicians and healthcare practitioners that it continues to evaluate the serious complications and consequences associated with implantation of surgical mesh through transvaginal placement to treat SUI.

29. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct-to-consumer advertising in the form of patient brochures, instructions for use, or the packaging and labeling associated with the Product.

30. In fact, at the time Defendants began marketing each of its pelvic mesh products, Defendants were aware that its pelvic mesh products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

31. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that the transvaginal mesh should be recalled because it offers no significant benefits but exposes patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

32. In early September 2011, the FDA Advisory Panel convened to discuss safety concerns with pelvic mesh products in general. As a result of the meeting, the FDA has called for more clinical studies and tougher regulation on mesh devices and manufacturers, such as the Defendants. The Advisory Panel also informed the FDA that they agreed on the need for more safety studies of the implants as well as labeling changes to warn of potential risks. A representative of Defendants' global regulatory department attended the Advisory Panel meeting.

33. 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.

34. 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."

35. Plaintiff's pelvic mesh-related injuries are the type of and consistent with the mesh-related complications reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

36. 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. 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."

37. 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" (the "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."

38. The FDA summarized its findings from its review of adverse event reporting and the medical 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).

39. The 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."

40. 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."

41. 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."

42. On January 3, 2012, the FDA contacted Defendant and ordered Defendant to conduct post-marketing surveillance to address numerous questions regarding adverse event rates, safety and efficacy of Defendants' pelvic mesh products.

43. At all times relevant, Defendants knew or should have known about the Product's risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

44. Defendants' pelvic mesh products, including the Product at issue in this case, contain polypropylene. Despite claims that polypropylene is inert, the scientific evidence demonstrates that pelvic mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products, including Plaintiff. This negative immune response promotes degradation and fragmentation of the polypropylene mesh, as well as inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the Product, such as those experienced by Plaintiff.

45. 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."

46. The Product at issue in this case was unreasonably susceptible to degradation and fragmentation inside the body, shrinkage and contraction inside the body, and the "creep" or the gradual elongation and deformation of the mesh inside the body when subject to prolonged tension.

47. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and directly to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and treatment procedures, and other competing pelvic mesh products.

48. Defendants have marketed and sold pelvic mesh products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and advertising strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants have also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of pelvic mesh products. Defendants' further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out pelvic mesh products for implantation into their bodies.

49. For example, Defendants described in its patient brochures, instructions for use, and other marketing materials, that the known complications for its pelvic mesh products were consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare"

and "small" when, in fact, Defendants knew or should have known that the complications were neither rare nor small, but common, permanent, and debilitating.

50. At all times relevant, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the pelvic mesh products and advertised, promoted, marketed, sold and distributed the pelvic mesh products as safe and effective medical devices when, in fact, Defendants knew 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, catastrophic and permanent injuries.

51. Contrary to Defendants" representations and marketing to the medical community and to the patients themselves, the Product has a high rate of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating revision or removal operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

52. The specific nature of the Product's design defects include, but are not limited to, the following:

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

b. the design of the Product 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 Product, including, but not limited to, the propensity of the Product 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 Product, which, when placed in women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

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

f. the inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, and walking); and

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

53. The Product is also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers on numerous subjects including, but not limited to, the following:

a. the Product's propensities to contract, retract, and/or shrink inside the body;

b. the Product's propensities for degradation, fragmentation and/or creep;

c. the Product's 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 Product;

f. the risk of chronic infections resulting from the Product;

g. the risk of permanent vaginal or pelvic scarring as a result of the Product;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Product;

k. the hazards associated with the Product;

l. the Product's defects described herein;

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

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

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

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

q. revision or removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain and infection.

54. Defendants have underreported information about the propensity of the Product to fail and cause injury and complications, and have made unfounded representations regarding the safety and efficacy of the Product through various communication means and media.

55. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.

56. Defendants failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product even exists.

57. At all times relevant, feasible and suitable alternatives to the Product have existed that do not present the same frequency or severity of risks as the Product.

58. The Product was 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 although inadequately the implanting physician.

59. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product.

60. The Product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendants' possession, and in the condition directed by and expected by Defendants.

61. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' pelvic mesh products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs. In many cases, women have been forced to undergo intensive medical treatment, including but not limited to, operations to locate and remove or revise the 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.

62. The medical and scientific literature studying the effects of polypropylene mesh, such as the Product, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Product.

63. Removal of contracted, eroded and/or infected mesh can require multiple surgical procedures and results in scarring fragile, compromised pelvic tissue and muscles.

64. At all relevant times, Defendants continued to promote the Product as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy of the Product.

65. 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 Product.

66. At all relevant times, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

67. The Product as researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, distributed, and sold by Defendants, was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of a lack of safety.

68. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone extensive medical treatment and/or corrective surgery, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

69. At all times relevant, the officers and/or directors of Defendants participated in, authorized and/or directed the production and promotion of the Product when they knew of the hazards and dangerous propensities of the Product, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

70. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

71. At all times relevant, Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, distributed, and sold the Product.

72. At all times relevant, the Product were expected to and did reach Plaintiff and her physician without substantial change in its condition as manufactured, distributed and sold by Defendants.

73. At all times relevant, the Product were "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

74. At no time did Plaintiff or her physician have reason to believe that the Product were in a condition not suitable for its proper and intended use.

75. Plaintiff and her physician used the Product in the manner in which the Product were intended to be used, making such use reasonably foreseeable to Defendants.

76. At all times relevant, the dangerous propensities of the Product were known to Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing, at the time they distributed, supplied, or sold the Product and such dangerous propensities of the Product were not known or reasonably knowable to ordinary physicians, including Plaintiff's physician, who would be expected to use the Product.

77. The Product as researched, designed, tested, manufactured, packaged, labeled marketed, promoted, advertised, distributed, and sold by Defendants were "defective" and "unreasonably dangerous", as Defendants failed to provide appropriate, adequate and sufficient warnings and instructions to render the Product reasonably safe for its ordinary, intended, and reasonably foreseeable use.

78. Defendants consciously disregarded the increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the Product; and continuing to market, promote, sell and defend the Product.

79. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Product's propensities to contract, retract, and/or shrink inside the body;

b. the Product's propensities for degradation, fragmentation and/or creep;

c. the Product's 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 Product;

f. the risk of chronic infections resulting from the Product;

g. the risk of permanent vaginal or pelvic scarring as a result of the Product;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Product;

k. the hazards associated with the Product;

l. the Product's defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Product are no more effective than feasible available alternatives;

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

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

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

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

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

80. At all times relevant, Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, distributed, supplied, and sold the Product in a defective and dangerous condition, as described herein, to healthcare providers, including Plaintiff's physician.

81. After receiving notice of numerous bodily injuries resulting from the Product, Defendants failed to provide post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Product or to those women who have been implanted with the Product advising that the Product was causing an

unreasonably high rate of infections, abscesses, erosions, extrusions, and/or other painful complications as described herein. Further, Defendants failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion, or other complications as described herein.

82. The lack of sufficient instructions and warnings was a substantial factor in causing Plaintiff's injuries, losses and damages as described herein.

83. As a direct, foreseeable and proximate result of Defendants' wrongdoing as described herein, including the lack of sufficient instructions or warnings for the Product, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

84. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

85. At all times relevant, Defendants researched, designed, tested, manufactured, formulated, labeled, marketed, promoted, advertised, distributed, and sold the Product.

86. At all times relevant, the Product were expected to and did reach Plaintiff and her physician without substantial change in its condition as manufactured, distributed and sold by Defendants.

87. At all times relevant, the Product was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

88. At no time did Plaintiff or her physician have reason to believe that the Product was in a condition not suitable for its proper and intended use.

89. Plaintiff and her physician used the Product in the manner in which the Product was intended to be used, making such use reasonably foreseeable to Defendants.

90. At all times relevant, the dangerous propensities of the Product was known to Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing, at the time they distributed, supplied, or sold the Product and such dangerous propensities of the Product was not known or reasonably knowable to ordinary physicians, including Plaintiff's physician, who would be expected to use the Product.

91. The Product as researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, advertised, distributed, and sold by Defendants was defective in design because when it left Defendants' control it was unreasonably dangerous and was also more dangerous than an ordinary consumer would expect.

92. The Product as researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, advertised, distributed, and sold by Defendants was defective in design because when it left Defendants' control its foreseeable risks outweighed any alleged benefits.

93. Specifically, the Product implanted in Plaintiff was defective in design by virtue of but not limited to the following respects:

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

b. the design of the Product 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 Product, including, but not limited to, the propensity of the Product 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 Product, 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 Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Product, 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); and

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

94. At all times relevant, practical, technically feasible, and safer alternative designs that would have prevented the harms described herein without substantially impairing the reasonably anticipated or intended function of the Product was available to Defendants as demonstrated by the existence of other types of treatment for POP and SUI available on the market which were as or more efficacious and had a more established safety profile and considerably lower risk profile than the Product.

95. At all times relevant, Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, advertised, distributed, and sold the Product in a defective and dangerous condition, as described herein, to healthcare providers, including Plaintiff's physician.

96. The defective design of the Product was a substantial factor in causing Plaintiff's injuries, losses and damages as described herein.

97. As a direct, foreseeable and proximate result of Defendants' wrongdoing as described herein, including the defective design of the Product, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

98. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

99. At all times relevant, Defendants researched, designed, tested, manufactured, formulated, labeled, marketed, promoted, distributed, and sold the Product.

100. At all times relevant, the Product was expected to and did reach Plaintiff and her physician without substantial change in its condition as manufactured, distributed and sold by Defendants.

101. At all times relevant, the Product was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

102. At no time did Plaintiff or her physician have reason to believe that the Product was in a condition not suitable for its proper and intended use.

103. Plaintiff and her physician used the Product in the manner in which the Product was intended to be used, making such use reasonably foreseeable to Defendants.

104. At all times relevant, the dangerous propensities of the Product was known to Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing, at the time they distributed, supplied, or sold the Product and such dangerous propensities of the Product was not known or reasonably knowable to ordinary physicians, including Plaintiff's surgeon, who would be expected to use the Product.

105. The Product as researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, advertised, distributed, and sold by Defendants was defective in manufacture when it left Defendants' custody and control.

106. The manufacturing defects associated with the Product was a substantial factor in causing Plaintiff's injuries, losses and damages as described herein.

107. As a direct, foreseeable and proximate result of Defendants' wrongdoing as described herein, including the Product's manufacturing defects, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
NEGLIGENCE

108. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

109. At all times relevant hereto, it was Defendants' duty to use reasonable care in the design, research, testing, manufacture, packaging, labeling, marketing, promotion, advertising, distribution, and sale of the Product.

110. At all times relevant, Defendants failed to exercise reasonable care by committing one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising, and distributing the Product without thorough and adequate pre-market and post-market testing of the Product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing the Product while negligently and intentionally concealing and failing to disclose information which demonstrated the risk of serious harm associated with the use of the Product;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the Product was safe for its intended use;

d. Failing to disclose to regulatory agencies, the medical community, including Plaintiff's physician, and consumers that Defendants knew and had reason to know that the Product was indeed unreasonably unsafe and unfit for use by reason of the Product's defects and risks of harm to its users;

e. Failing to warn and disclose to Plaintiff, the medical community, including Plaintiff's physician, and consumers that the risks of harm were unreasonable and that there were safer and effective alternative treatment options available to Plaintiff and other patients;

f. Failing to provide adequate warnings, instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would, use the Product;

g. Advertising, marketing and recommending the use of the Product while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of the Product;

h. Representing that the Product was safe for its intended use when in fact; Defendants knew or should have known the Product was not safe for their intended purpose;

i. Continuing to manufacture and sell the Product with the knowledge that the Product was unreasonably unsafe and dangerous;

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of the Product so as to avoid the risk of serious harm associated with the use of the Product;

k. Failing to ensure the Product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of the Product and that use of the Product created a high risk of developing serious complications attributable to the Product;

l. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine and monitor the safety of the Product.

111. The reasons that Defendants' negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

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

b. the design of the Product 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 Product, including, but not limited to, the propensity of the Product 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 Product, 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 Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Product, 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); and

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

112. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers about numerous material subjects including, but not limited to, the following:

a. the Product's propensities to contract, retract, and/or shrink inside the body;

b. the Product's propensities for degradation, fragmentation and/or creep;

c. the Product's 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 Product;

f. the risk of chronic infections resulting from the Product;

g. the risk of permanent vaginal or pelvic scarring as a result of the Product;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Product;

k. the hazards associated with the Product;

l. the Product's defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Product are no more effective than feasible available alternatives;

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

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

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

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

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

113. Defendants knew or had reason to know that the Product caused an increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of

harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the Product and continuing to market, promote, sell and defend the Product.

114. Defendants' negligent acts and omissions were a substantial factor in causing Plaintiffs' injuries, losses, and damages, as described herein.

115. As a direct and proximate result of Defendants' negligent acts and omissions, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

116. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

117. Defendants through their marketing programs, aggressive direct-to-consumer advertising campaigns, promotional activities, product packaging and labeling, and other written and verbal assurances expressly warranted to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purpose.

118. Plaintiff and her physician chose to use the Product based upon Defendants' express warranties and representations regarding the safety and fitness of the Product.

119. Plaintiff and her physician reasonably relied upon to their detriment Defendants' express warranties and guarantees that the Product was safe, merchantable, and reasonably fit for its intended purpose when deciding to use the Product.

120. Defendants breached their express warranties because the Product implanted in Plaintiff were unreasonably dangerous and defective and did not conform to the express warranties.

121. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body thereby causing her injuries.

122. As a direct and proximate result of Defendants' negligent acts and omissions, including their breach of express warranties, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

123. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

124. The Product was sold by Defendants with implied warranties of merchantability and of fitness for its intended purpose: namely that Plaintiff could use the Product without the risk of serious injury.

125. Plaintiff and her implanting physician relied upon the implied warranties of merchantability and of fitness for its intended purpose when deciding to use the Product.

126. Defendants breached the implied warranties of merchantability and of fitness for its intended purpose because the Product implanted in Plaintiff were neither merchantable nor suited for their intended use as warranted.

127. Defendants' breach of the implied warranties of merchantability and of fitness for its

intended purpose resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body thereby causing her injuries.

128. As a direct and proximate result of Defendants' negligent acts and omissions, including their breach of the implied warranties of merchantability and of fitness for its intended purpose, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

129. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

130. At the time Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, promoted, advertised, distributed, and sold the Product for use by Plaintiff, Defendants knew or should have known of the use for which the Product was intended and the serious risks and dangers associated with such use of the Product.

131. Defendants owed a duty to physicians and to the ultimate end-users of the Product, including Plaintiff, to accurately and truthfully represent the risks of the Product.

132. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's physicians, the medical community, Plaintiff, and the public about the risks of the Product, which Defendants knew or in the exercise of diligence should have known.

133. Among Defendants' numerous material misrepresentations and misleading omissions

to Plaintiff, Plaintiff's physicians and the general public are Defendants 'assurances to doctors that the Product was safe, that the Product were the best pelvic mesh device on the market for the treatment of POP and SUI, had an excellent safety and tolerance record and a low and acceptable risk profile. Defendants did not reveal (and instead concealed) their knowledge of the serious complications with the Product during their meetings with physicians.

134. Despite their knowledge of the serious problems with the Product, Defendants urged their sales representatives to continue marketing the Product and distributed medical literature and other communications to physicians in an effort to mislead them and the general public about the safety of the Product.

135. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent misrepresentations, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION

136. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

137. Defendants, having undertaken to research, design, test, manufacture, package, label, market, promote, distribute, advertise and sell the Product, owed a duty to provide accurate and complete information to Plaintiff, physicians, and the public about the Product.

138. However, Defendants misled Plaintiff, physicians, and the public into believing that the Product was safe and effective for its intended use; engaged in deceptive, misleading and unconscionable promotional and sales methods to convince health care professionals and patients to use the Product, even though Defendants knew or should have known that the Product was unreasonably unsafe. Defendants also failed to warn health care professionals and the public about the safety risks of the Product they designed, marketed and sold.

139. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Product was safe for human use and had no unacceptable side effects.

140. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Product. Defendants, through promotional and marketing practices as well as the publication of medical literature, deceived physicians, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from physicians, the FDA and the general public, including Plaintiff, regarding the safety of the Product.

141. Defendants expressly denied that the Product created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Product.

142. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding the Product all the while undertaking a major advertising campaign to sell the Product. Defendants received reports of the Product defects from various sources, including those mentioned above, and intentionally withheld this information, while continuing to sell the Product.

143. Further, even as Defendants disclosed some information regarding risks of the

Product, the disclosures were incomplete and misleading.

144. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Product. Defendants failed to fully inform physicians, patients, including Plaintiff, and the public of the true risks with the Product's use that were known to Defendants, and continued to assure physicians and patients that the Product was safe for its intended purpose and continued to promote and sell the Product.

145. Through the materials they disseminated, Defendants falsely and deceptively misrepresented and omitted a number of material facts regarding the Product.

146. Defendants possessed evidence demonstrating that the Product caused serious adverse side effects. Nevertheless, Defendants continued to market the Product by providing false and misleading information with regard to their safety to Plaintiff and Plaintiff's physicians.

147. Among Defendants' numerous material misrepresentations and misleading omissions to Plaintiff, Plaintiff's physicians and the general public are Defendants' assurances that the Product had an excellent safety profile. Defendants made such statements even after they became aware that the Product was associated with serious complications as described herein.

148. Despite their knowledge of the serious problems with the Product, Defendants urged their sales representatives to continue marketing the Product, and distributed medical literature and other communications to physicians in an effort to mislead them and the general public about the safety of the Product.

149. Defendants engaged in all the acts and omissions stated herein with the intent that Plaintiff's physician and Plaintiff would rely on the misrepresentations, deceptions and concealment in deciding to use the Product rather than an available, alternative treatment.

150. Plaintiff and Plaintiff's physicians justifiably relied to their detriment on Defendants' intentional and fraudulent material misrepresentations and omissions as stated herein. This reliance

proximately caused Plaintiff's injuries and damages as described herein.

151. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' intentional and fraudulent misrepresentations and omissions, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

NINTH CAUSE OF ACTION
CONSTRUCTIVE FRAUD

152. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

153. At the time Defendants sold the Product to Plaintiff, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the Product, which knowledge was not possessed by Plaintiff or her physicians, and Defendants thereby held a position of superiority over Plaintiff and her physicians.

154. Through their unique knowledge and expertise regarding the defective nature of the Product, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff and her physician that they had knowledge of the truth of the representation that the Product was safe and effective for its intended use and was not defective.

155. Defendants' representations to Plaintiff, her physician, the medical community, and the public were unqualified statements made to induce Plaintiff and her physician to purchase and use

the Product, and Plaintiff and her physicians relied upon the statements when using the Product.

156. Defendants have made numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physician and the general public. Among these misrepresentations are Defendants' assurances that the Product was safe and effective for its intended use and had an excellent safety profile. Defendants made such statements even after they became aware of the serious complications with the Product.

157. Despite their knowledge of the serious problems with the Product, Defendants urged their sales representatives to continue marketing the Product, and distributed medical literature and other communications to physicians in an effort to mislead them and the general public about the risks of the Product.

158. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and Plaintiff's physician and engaged in constructive fraud in their relationship with Plaintiff and Plaintiff's physician. Plaintiff and Plaintiff's physician reasonably relied on Defendants' representations to their detriment as described herein.

159. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants engaging in constructive fraud in their relationship with Plaintiff and her physicians, Plaintiff was implanted with the Product and has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; economic loss; and mental and emotional distress for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

160. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

161. Defendants' failure to document or follow up on the known defects in the Product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

162. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the Product's defects, Defendants continued to represent its Product as safe for its intended use.

163. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with the Product. Because of Defendants' concealment of the true character, quality and nature of the Product, Defendants are estopped from relying on any statute of limitations defense.

164. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information about the Product to Plaintiff, physicians and the public.

165. Defendants' acts before, during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or cause thereof.

166. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

167. Defendants' conduct, as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiffs' Complaint.

ELEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

168. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

169. Plaintiff is entitled to punitive damages because the Defendants' breaches of their duties to Plaintiff were deliberate, intentional, and/or motivated by malice or ill will to Plaintiff.

170. Defendants intentionally misled Plaintiff, her health care providers, the medical community, and the public at large by making false representations about the safety of the Product.

171. Defendants intentionally downplayed, understated and/or misrepresented their actual knowledge of the potential for serious injury with the use of the Product despite available information demonstrating that the Product was likely to cause serious injuries to consumers.

172. Defendants were in possession of evidence demonstrating that the Product caused serious injuries to consumers. Nevertheless, Defendants continued to market the Product by providing false and misleading information to the Plaintiff and the general public with regard to the safety and efficacy of the devices.

173. Defendants' outrageous actions as described herein were performed willfully, intentionally, and with malice in their disregard for the rights of the Plaintiff and the general public.

174. Accordingly, Plaintiff seeks and is entitled to punitive or exemplary damages in an amount to be determined at trial.

TWELFTH CAUSE OF ACTION
UNJUST ENRICHMENT

175. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

176. Defendants are, and at all times were, the manufacturer, seller, and/or supplier of the Product.

177. Plaintiff paid for the Product for the purpose of treating her pelvic organ prolapse

and/or stress urinary incontinence.

178. Defendants accepted payment from Plaintiff for the purchase of the Product.

179. Plaintiff has not received the safe and effective Product for which she paid. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving products of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

180. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

THIRTEENTH CAUSE OF ACTION
VIOLATION OF UNFAIR OR DECEPTIVE TRADE PRACTICES AND/OR CONSUMER PROTECTION ACT(S)

181. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

182. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in their research, design, test, manufacture, formulate, label, market, promote, distribute and sale of the Product.

183. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Product and would not have been injured as described here and incurred related medical costs.

184. Specifically, Plaintiff and her physicians were misled by the deceptive conduct as described herein.

185. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of:

a. 5 M.R.S.A. §§ 205-A *et seq.*

186. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the Product that she would not have paid had Defendants not engaged in unfair and deceptive conduct.

187. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices in violation of:

a. 5 M.R.S.A. §§ 205-A *et seq.*

188. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell the Product. Each aspect of Defendants' conduct combined to artificially create sales of the Product.

189. The medical community relied upon Defendants' misrepresentations and omissions in determining which antibiotic to utilize.

190. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

191. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for the Product. As a direct and proximate result of Defendants' violations the unfair trade practices and/or consumer protection acts described herein, Plaintiff has sustained economic losses and other damages for which she is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

CONDITIONS PRECEDENT

192. All conditions precedent to Plaintiff's right to recover herein and to Defendants' liability have been performed or have occurred.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, as follows:

a. Compensatory damages in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

b. Special damages in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, and pain and suffering;

c. Double or triple damages as allowed by law;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

f. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: July 13, 2016

Respectfully submitted,

/s/ Kevin M. Fitzgerald
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