IN RE PELVIC MESH/ GYNECARE LITIGATION	: SUPERIOR COURT OF NEW JERSEY : ATLANTIC COUNTY – LAW DIVISION : : MASTER DOCKET NO. L-6341-10 : : CIVIL ACTION : J&J Litigation, Case No. 291 : : : **MASTER LONG FORM COMPLAINT** : **AND JURY DEMAND**

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any previously filed Complaint, and any Short-Form Complaint hereafter filed. Accordingly, Plaintiffs allege as follows:

I. PARTIES

A. Plaintiffs

1. The Plaintiffs include women residing within and outside of New Jersey who had Defendants' Pelvic Mesh Products (defined below) inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

2. The Plaintiffs also include the spouses and intimate partners of the aforesaid women, as well as others with standing to file claims arising from the Defendants' Pelvic Mesh Products.

B. Defendants

3. Defendant, Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

4. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

5. Defendant, Ethicon Women's Health and Urology is a division of Ethicon, Inc. located in Somerville, New Jersey.

6. Defendant, Gynecare is a division of Ethicon, Inc. located in Somerville, New Jersey.

7. Defendants, JOHN DOES 1-20 (fictitious names) are entities and/or persons who are liable to Plaintiffs, but who have not yet been identified despite reasonable due diligence on the part of the Plaintiffs.

II. DEFENDANTS' PELVIC MESH PRODUCTS

8. In or about October, 2002, the Defendants began to 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 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

mesh hernia 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. In or about September, 2005, the Defendants began to market and sell a product known as Prolift, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift include by reference all variations.

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

12. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple variations including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include by reference all variations.

13. The products known as Prolene Mesh, Gynemesh,, Prolift, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

14. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

III. FACTUAL BACKGROUND

15. Defendants' 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 for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

16. The Defendants have marketed and sold the Defendants' Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Products.

17. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, 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 Plaintiffs. In a study published based on a multi-center randomized controlled trial in August, 2010 in the Journal of the American

College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion rate with the Prolift, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs." Numerous studies published in influential medical journals have reached similar conclusions.

18. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

19. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Products were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiffs.

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

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

22. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

23. The Defendants' Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants.

24. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

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

26. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive 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, and injuries to Plaintiffs' intimate partners.

27. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, the Defendants have, and continue to manufacture, market, and sell the Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Products, both prior to and after the marketing and sale of the Products.

IV. ASSERTION OF CLAIMS PURSUANT TO NEW JERSEY LAW

COUNT I

PRODUCT LIABILITY ACT – DEFECTIVE MANUFACTURE AND DESIGN (N.J.S.A. 2A:58C-1, et seq.)

28. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

29. The Defendants' Pelvic Mesh Products, were in certain instances, defectively and improperly manufactured, rendering the products deficient, and unreasonably dangerous and hazardous to certain Plaintiffs.

30. The Defendants' Pelvic Mesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

31. The Pelvic Mesh Products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

32. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold, and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiffs and others.

33. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, damages pursuant to the Wrongful Death Act and Survivors' Act (N.J.S.A. 2A:31-1, et seq. and 2A:15-3), punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II

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

35. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

36. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products.

37. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products, given the Plaintiffs' conditions and need for information.

38. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

39. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks

and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

40. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, damages pursuant to the Wrongful Death Act and Survivors' Act (N.J.S.A. 2A:31-1, et seq. and 2A:15-3), punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

V. ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF STATES OTHER THAN NEW JERSEY

42. Plaintiffs reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

43. Certain Plaintiffs were prescribed, purchased and/or were injured as a result of implantation of the Defendants' Pelvic Mesh Products outside of New Jersey (the "Non-New Jersey Plaintiffs"). To the extent the Court chooses to apply the laws of states other than New Jersey for the Non-New Jersey Plaintiffs, Plaintiffs hereby place Defendants on notice of their intention to plead and assert all claims available under the laws of foreign states.

COUNT III

STRICT LIABILITY

f) Idaho Products Liability Reform Act (the ILPRA"), Idaho Code §§ 6-1401, *et seq.*;

g) Indiana Products Liability Act ("IPLA"), Ind. Code Ann. § 34-20-1-1 *et seq.*;

h) Kansas Product Liability Act, Kan. Stat. Ann. § 60-3302, *et seq.* (2005);

i) Kentucky Product Liability Act, Ky. Rev. Stat. Ann. § 411.300 *et seq.*;

j) Louisiana Product Liability Act, La. Rev. Stat. Ann. § 9:2800.51 *et seq.*;

k) Maine Revised Statutes, 14 M.R.S. § 221*et seq.*

l) Mississippi Product Liability Act, Miss. Code Ann. § 11-1-63 (1993) *et seq.*

m) Montana Code. Anno. § 27-1-719, *et seq*

n) Texas. Civil Practice & Remedies Code, § 82.001, *et seq.*;

o) Washington Product Liability Act, Laws of 1981, ch. 27 §§ 1-7, Wash. Rev. Code §§ 7.72.010-.060

48. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT IV

NEGLIGENCE

49. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

50. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Products, and recruitment and training of physicians to implant the Pelvic Mesh Products.

51. Defendants breached their duty of care to the Plaintiffs, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Products.

52. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT V

NEGLIGENCE CLAIMS UNDER THE APPLICABLE LAWS OF CONNECTICUT

53. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

54. Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, labeling, sale and distribution of the Defendants' Pelvic Mesh Products, including a duty to assure that the Products did not cause unreasonable, dangerous side-effects to users.

55. Defendants failed to exercise ordinary care in the design, manufacture, marketing, labeling, sale, and distribution, quality assurance, quality control, and distribution of the Defendants' Pelvic Mesh Products in that Defendants knew or should have known that the Defendants' Pelvic Mesh Products created a high unreasonable risk of harm.

56. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

COMMON LAW FRAUD

57. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

58. Defendants falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiffs, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective.

59. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

60. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiffs, and the public, and also inducing the medical community, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiffs.

61. In representations to Plaintiffs and/or to Plaintiffs' healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a) That the Defendants' Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the risk of adverse events with the Defendants' Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c) The Defendants' Pelvic Mesh Products were not adequately tested;

d) That the limited clinical testing revealed the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f) That Defendants were aware of dangers in the Defendants' Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g) That the Defendants' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h) That patients needed to be monitored more regularly than usual while using the Defendants' Pelvic Mesh Products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

i) That the Defendants' Pelvic Mesh Products were manufactured negligently;

j) That the Defendants' Pelvic Mesh Products were manufactured defectively;

k) That the Defendants' Pelvic Mesh Products were designed negligently, and designed defectively;

62. Defendants were under a duty to disclose to Plaintiffs and their physicians, the defective nature of the Defendants' Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

63. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Defendants' Pelvic Mesh Products.

64. Defendants' concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiffs into reliance and cause Plaintiffs to use the Defendants' Pelvic Mesh Products.

65. At the time these representations were made by Defendants, and at the time Plaintiffs used the Pelvic Mesh Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

66. Defendants knew and had reason to know that the Defendants' Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Defendants' Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

67. In reliance upon these false representations, Plaintiffs were induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and

damages. Defendants knew or had reason to know that Plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Defendants' Pelvic Mesh Products, as described in detail herein.

68. Plaintiffs reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Defendants' Pelvic Mesh Products.

69. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring Plaintiffs, the public, and Plaintiffs' healthcare providers and physicians, that the Defendants' Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs, and the public at large.

70. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiffs, Plaintiffs' healthcare providers, and the United States Food and Drug Administration ("FDA").

71. The information distributed to the public, the medical community, the FDA, and Plaintiffs, by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other

commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendants' Pelvic Mesh Products.

72. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the Defendants' Pelvic Mesh Products specifically that the Products did not have dangerous and/or serious adverse health safety concerns, and that the Defendants' Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

73. Defendants intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

74. Defendants chose to over-promote the purported safety, efficacy and benefits of the Defendants' Pelvic Mesh Products instead.

75. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiffs; to gain the confidence of the public, the medical community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Defendants' Pelvic Mesh Products.

76. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Defendants' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

in the use of the Defendants' Pelvic Mesh Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover the false representations of Defendants, nor would Plaintiffs with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

83. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Defendants' Pelvic Mesh Products, Plaintiffs would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

84. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiffs.

85. As a proximate result of the Defendants' conduct Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT VII

FRAUDULENT CONCEALMENT

86. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

87. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

88. Plaintiffs from Alabama, Arizona, California, Colorado, Delaware, Georgia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin and any other states that recognize such a cause of action bring this fraudulent concealment claim under the common law.

89. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Products were defective and unreasonably unsafe for their intended purpose.

90. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiffs, their physicians and the medical community that their Pelvic Mesh Products were defective, unsafe, unfit for the purposes intended, and that they were not of merchantable quality.

91. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a) Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;

b) Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiffs.

92. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

93. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that their healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products, and Plaintiffs justifiably acted or relied upon, to their detriment, the concealed and/or non-disclosed facts as evidenced by their purchase of the Defendants' Pelvic Mesh Products.

94. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Defendants' Pelvic Mesh Products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Defendants' Pelvic Mesh Products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia, Restatement (Second) of Torts* § 550 (1977).

95. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT VIII

CONSTRUCTIVE FRAUD

96. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

97. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs and their physicians.

98. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Pelvic Mesh Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Pelvic Mesh Products, as compared to other products and forms of treatment.

99. For example, scientists in the recent study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

100. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

101. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the

Defendants' Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Defendants' representations.

102. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

103. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT IX

NEGLIGENT MISREPRESENTATION

104. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

105. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

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

107. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

108. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

109. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

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

COUNT X

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

110. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

111. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

112. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Products sold and distributed by Defendants.

113. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.