UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI KANSAS CITY DIVISION

OSSIE BLACKSTON and JOHN BLACKSTON, Plaintiffs, v. ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, and JOHNSON & JOHNSON, Defendants.	)	**CASE NO. 4:12-cv-483** **COMPLAINT AND JURY DEMAND**

Plaintiffs OSSIE and JOHN BLACKSTON, for their Complaint against Defendants ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, AND JOHNSON & JOHNSON states as follows:

PARTIES

1. Plaintiffs Ossie and John Blackston are residents of the county of Baltimore in the state of Maryland. All references herein to "Plaintiff" shall refer to Plaintiff Ossie Blackston.

2. Defendants Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare and Johnson & Johnson (hereinafter referred to collectively as "Defendants") develop technology to diagnose and treat conditions related to the pelvic health of women. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging,

labeling, and selling such devices, including the Prolene Mesh/Prolene Soft Mesh, Gynemesh, TVT, TVT-O, TVT-S, TVT Exact, TVT Abbrevo, Prolift, Prolift +M mesh and other pelvic mesh products unknown at the present (hereinafter collectively referred to as "Pelvic Mesh Products"). Defendants manufacture, market, advertise, promote and sell Pelvic Mesh Products worldwide.

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. At all relevant times, Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed in the stream of commerce the Pelvic Mesh Products, including the Pelvic Mesh Products at issue in this lawsuit.

8. At all times mentioned herein, Defendants acted, by and through their agents, representatives and employees who acted within the scope and course of their agency and employment.

9. At all relevant times, the defendant, Johnson & Johnson, was and still is a foreign corporation authorized to do business in the State of Missouri.

10. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, was and still is a business entity actually doing business in the State of Missouri.

11. At all times hereinafter mentioned, the defendant, Johnson & Johnson, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

12. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

13. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

14. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

15. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

16. At all relevant times, the defendant, Ethicon, Inc., was and still is a foreign corporation authorized to do business in the State of Missouri.

17. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., was and still is a business entity actually doing business in the State of Missouri.

18. At all times hereinafter mentioned, the defendant, Ethicon, Inc., is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

19. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

20. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

21. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

22. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., expects or should reasonably expect its acts to have

consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

23. At all relevant times, the defendant, Ethicon Women's Health & Urology, was and still is a foreign corporation authorized to do business in the State of Missouri.

24. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, was and still is a business entity actually doing business in the State of Missouri.

25. At all times hereinafter mentioned, the defendant, Ethicon Women's Health & Urology, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

26. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

27. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

28. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

29. That at all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

30. At all relevant times, the defendant, Gynecare, was and still is a foreign corporation authorized to do business in the State of Missouri.

31. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, was and still is a business entity actually doing business in the State of Missouri.

32. At all times hereinafter mentioned, the defendant, Gynecare, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

33. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

34. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

35. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, regularly does and solicits business and engages in a persistent

course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

36. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

JURISDICTION AND VENUE

37. This Court has jurisdiction over this action by virtue of 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 a complete diversity of citizenship between Plaintiff and each defendant. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)-(c) by virtue of the fact that Johnsons and Johnson products are sold to and consumed by individuals in the State of Missouri thereby subjecting defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

38. This Court has jurisdiction over the Defendants because the Defendants are licensed to do business in all states of the United States of America including the State of Missouri. At all relevant times, Defendants were engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion , and/or distribution of Pelvic Mesh Products, including the Gynecare TVT mesh, for ultimate sale and/or use in the United States of America, including the State of Missouri, as well as in various foreign jurisdictions. Defendants are thus amenable to the jurisdiction of this Court.

39. Venue is proper pursuant to 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and all defendants are subject to personal jurisdiction in the Judicial District of the Western District of Missouri.

DEFENDANTS' PELVIC MESH PRODUCTS

40. In or about October 2002, 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 and Gynecare TVT.

41. 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.

42. In or about September 2005, 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.

43. In or about February 2007, Defendants began to market and sell a product known as TVT mesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The TVT mesh was and is offered as an anterior, posterior, or total repair system, and all references to the TVT mesh include by reference all variations.

44. In or about May 2008, 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.

45. The Defendants also marketed and sold 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.

46. The products known as Prolene Mesh, Gynemesh, Prolift, Prolift+M, TVT mesh and TVT, as well as any as yet identified 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.

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

FACTUAL ALLEGATIONS

48. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 501(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

49. The Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. The Pelvic Mesh Products are represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks. It is 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 vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

50. Moreover, these Pelvic Mesh Products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

51. 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 vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

52. The Defendants have marketed and sold the 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, 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. Also utilized are documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the Pelvic Mesh Products.

53. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device 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.

54. 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 Plaintiff, making them defective under the law. The defects stem from any or all of the following:

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

b. the design of the Pelvic Mesh Devices to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus 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 mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

d. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injury major nerve routes in the pelvic region;

e. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

f. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike; and

g. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

55. Upon information and belief, 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 Pelvic Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

56. Despite the chronic underreporting of adverse events associated with the Defendants' Pelvic Mesh Products and the underreporting of events associated with similarly designed competitor products, enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

57. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic Mesh Products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Products that are the subject of the notification.

58. On July 13, 2011, the FDA issued a Safety Communication:" UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated

analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were “not rare.” These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits was more effective than traditional non mesh repair of pelvic organ prolapse. The FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." 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 labeling.

59. On September 8-9, 2011 the FDA held advisory committee meetings to address the issues and concerns surrounding the Pelvic Mesh Products, including the product at issue in this lawsuit.

60. Defendants have known that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the 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 Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff.

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

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

63. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

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

65. The Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

66. The Pelvic Mesh Products implanted into the Plaintiff 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.

67. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse, or alter the Pelvic Mesh Product in an unforeseeable manner.

68. 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), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic 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.

69. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh Products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

70. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

71. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, 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 an indifference to the health, safety, and welfare of Plaintiff.

72. Defendants failed to undertake their duties to properly know the qualities of their Pelvic Mesh Products and in representations to Plaintiff and/or to Plaintiff's

healthcare providers, to and concealed and intentionally omitted the following material information:

a. That the 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 Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Pelvic Mesh Products were not adequately tested and were known by Defendants;

d. That the limited clinical testing revealed the 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 failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in the 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 Pelvic Mesh Products were dangerous and caused 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 Pelvic Mesh Products and that in the event the Pelvic Mesh Products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

i. That the Pelvic Mesh Products were manufactured negligently;

j. That the Pelvic Mesh Products were manufactured defectively;

k. That the Pelvic Mesh Products were designed negligently, and designed defectively.

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

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

75. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Pelvic Mesh Products.

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

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

78. In reliance upon these false representations, Plaintiff was 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 Plaintiff and Plaintiff's 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 Pelvic Mesh Products, as described in detail herein.

79. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the 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, Plaintiff, and the public at large.

80. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

81. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, 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 Pelvic Mesh Products.

82. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Pelvic Mesh Products specifically, that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Pelvic Mesh Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

83. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

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

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

86. Upon information and belief, 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 Pelvic Mesh Products did not present serious health risks.

87. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

88. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and Plaintiff's healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Pelvic Mesh Products and her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

89. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of Pelvic Mesh Products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

90. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff

discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

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

92. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

93. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

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

95. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

96. At all relevant times herein, 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 Pelvic Mesh Products system including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

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

98. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Pelvic Mesh Products when they knew of the hazards and dangerous propensities of said Pelvic Mesh Products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

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

100. 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 defects, Defendants continued to represent its Pelvic Mesh Products as safe for their intended use.

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

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

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

104. 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 Plaintiff.

PLAINTIFF'S EXPERIENCE AND INJURIES

105. On May 7, 2009, Plaintiff Ossie Blackston was implanted with Pelvic Mesh Products, including the Gynecare TVT mesh sling at Franklin Square Hospital in Baltimore, Maryland. The Gynecare TVT mesh sling was designed, manufactured, packaged, labeled and sold by Defendants.

106. The Pelvic Mesh Product was implanted in Plaintiff with the intention of treating the Plaintiff for stress urinary incontinence, uterovaginal prolapse and cystocele, uses for which Defendants marketed and sold the Pelvic Mesh Products.

107. At all times, the Pelvic Mesh Product that was implanted in Plaintiff was being used for the purposes that Defendants marketed the Pelvic Mesh Products.

108. Following implantation of the Gynecare TVT mesh, Plaintiff suffered of persistent pelvic pain and was seen by her physician with complaints of pelvic pain, stress urinary incontinence, infection and bleeding . Subsequently, it was discovered that the Gynecare TVT mesh which was implanted on May 7, 2009 had begun to erode through the vaginal wall. Following this discovery, Plaintiff underwent surgical extraction of the exposed portion of the Gynecare TVT mesh on February 18, 2010 at Greater Baltimore Medical Center in Baltimore, Maryland.

109. On or about August 2011, Plaintiff saw for the first time, information about product safety and defect issues associated with the implantation of Pelvic Mesh Products. After seeing this information, Plaintiffs suspected for the first time that the Pelvic Mesh Product that had been implanted into Plaintiff Ossie Blackston may have been defective and that she may have sustained an injury as a result of having had Defendants' defective Pelvic Mesh Product implanted into her.

110. As a result of having the Gynecare TVT mesh Pelvic Mesh Product implanted into her, Plaintiff has experienced significant mental and physical pain and suffering, has required additional surgery and medical treatment and has sustained permanent injury.

111. As a result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured in her health, strength, and activity, sustaining injury to her person, all of which injuries have caused and will continue to cause her severe mental and physical pain and suffering disability, impairment, loss of enjoyment of life, inability to engage in chosen and necessary activities. Plaintiff is informed and believes, and alleges thereon, that such injuries will result in some permanent disability to her person.

112. As a further result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiffs were required to and did employ health care providers and incurred, medical, hospital and incidental expenses; further, Plaintiffs are informed and believe, and allege thereon, that Plaintiffs will be required to incur additional medical, hospital, and incidental expenses thereto, all according to proof.

FIRST CAUSE OF ACTION

STRICT PRODUCT LIABILITY - FAILURE TO WARN

113. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

114. Defendants, manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiff to be used for treatment of pelvic organ prolapse, stress urinary incontinence or cystocele.

115. At all times mentioned herein, the Pelvic Mesh Products were and are, dangerous and presented a substantial danger to patients who were implanted with the Pelvic Mesh Devices, and these risks and dangers were known or knowable at the time of

distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed to pelvic reconstruction patients because its uses were specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used in a way reasonably foreseeable to Defendants by Plaintiff. Defendants failed to provide warnings of such risks and dangers to Plaintiff as described herein.

116. As a result of the implantation of the Pelvic Mesh Products Plaintiff suffered debilitating injuries including mesh erosion, hardening, chronic pain and worsening dyspareunia, and recurrent incontinence leading to the need for dangerous and serious vaginal surgery.

SECOND CAUSE OF ACTION

STRICT LIABILITY

117. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

118. The Pelvic Mesh Products were manufactured and/or supplied by the Defendants, and were placed into the stream of commerce by the Defendants in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with its design of formulation.

119. Alternatively, Pelvic Mesh Products manufactured and/or supplied by the Defendants were defective in design or formulation, inadequate warning or instruction and/or inadequate post-marketing warnings or instructions in that when it was placed in the stream of commerce, it was unreasonably dangerous, it was more dangerous than an

ordinary consumer would expect and more dangerous than other forms of stress urinary incontinence, pelvic organ prolapse or cystocele repair.

120. As a result of the defective unreasonably dangerous condition of these Pelvic Mesh Products manufactured and/or supplied by the Defendants, Plaintiffs were caused to suffer the herein described injuries and damages.

121. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by Pelvic Mesh Products

THIRD CAUSE OF ACTION

NEGLIGENCE

122. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

123. Defendants, and their representatives, were manufacturers and/or distributors of Pelvic Mesh Products. At all times herein, Defendants had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell the aforesaid product

124. Defendants breached their duty to properly manufacturer, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and see the aforesaid Pelvic Mesh Products, as set forth herein.

125. As a result of Defendants' breach of their duty to Plaintiffs, Plaintiffs suffered injuries as set forth herein.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

126. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

127. Defendants impliedly warranted that the Pelvic Mesh Products, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs was merchantable and fit and safe for ordinary use. Defendants further impliedly warranted that its Pelvic Mesh Products were fit for the particular purpose of correcting urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and cystocele.

128. Defendants' Pelvic Mesh Products were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries. Therefore, Defendants breached the implied warranties of merchantability and fitness for a particular purpose when it's synthetic mesh system was sold to Plaintiffs, in that the Pelvic Mesh Products are defective and has eroded and caused dense scarring and otherwise failed to function as represented and intended.

129. As a result of Defendants' breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiffs have sustained and will continue to sustain the injuries and damages described herein and is therefore entitled to compensatory damages.

130. After Plaintiffs were made aware that Plaintiffs' injuries were a result of the aforesaid Pelvic Mesh Products, Defendants had ample and sufficient notice of the breach of said warranty.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

131. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

132. Defendants expressly warranted to Plaintiffs and/or their authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that the defective Pelvic Mesh Products were safe, effective, fit and proper for their intended use.

133. Plaintiffs and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiffs and was unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiffs to sustain damages and injuries herein alleged.

134. As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, said Defendants had ample and sufficient notice of the breach of said warranty.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

135. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

136. At all relevant times herein, Defendants represented to Plaintiffs and Plaintiff's physicians that the Pelvic Mesh Products were safe to use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele knowing

that the Pelvic Mesh Products were defective and capable of causing the injuries described herein.

137. The Defendants made the aforesaid representations with no reasonable ground for believing them to be true when Defendants' own data showed the Pelvic Mesh Products to be defective and dangerous when used in the intended manner.

138. The aforesaid representations were made to the physician(s) prescribing the Pelvic Mesh Products prior to the date it was prescribed to Plaintiffs and used by Plaintiff's physicians with the intent that Plaintiffs and Plaintiff's physician(s) rely upon such misrepresentations about the safety and efficacy of the Pelvic Mesh Products. Plaintiffs and Plaintiff's physicians did reasonably rely upon such representations that the aforesaid product was safe for use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele.

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

139. Plaintiffs repeat and reallege all allegations contained in all paragraphs above as if fully set forth herein.

140. As a direct and proximate result of Defendant's negligence and conduct, as detailed above, plaintiff John Blackston was caused to lose the consortium and society of his spouse, plaintiff Ossie Blackston.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together

with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general damages in a sum within the jurisdiction of this Court;

2. For medical, hospital, and incidental expenses, according to proof;

3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For such other relief as the Court deems just and proper.

Dated: April 27, 2012

By: /s/ Jeffrey M. Kuntz

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JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all issues.

By: /s/ Jeffrey M. Kuntz

Jeffrey M. Kuntz
WAGSTAFF & CARTMELL, LLP
Attorney for Plaintiffs

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI KANSAS CITY DIVISION

OSSIE BLACKSTON and JOHN BLACKSTON, Plaintiffs, v. ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, and JOHNSON & JOHNSON, Defendants.	)	**CASE NO. 4:12-cv-483** **COMPLAINT AND JURY DEMAND**

Plaintiffs OSSIE and JOHN BLACKSTON, for their Complaint against Defendants ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, AND JOHNSON & JOHNSON states as follows:

PARTIES

1. Plaintiffs Ossie and John Blackston are residents of the county of Baltimore in the state of Maryland. All references herein to "Plaintiff" shall refer to Plaintiff Ossie Blackston.

2. Defendants Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare and Johnson & Johnson (hereinafter referred to collectively as "Defendants") develop technology to diagnose and treat conditions related to the pelvic health of women. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging,

labeling, and selling such devices, including the Prolene Mesh/Prolene Soft Mesh, Gynemesh, TVT, TVT-O, TVT-S, TVT Exact, TVT Abbrevo, Prolift, Prolift +M mesh and other pelvic mesh products unknown at the present (hereinafter collectively referred to as "Pelvic Mesh Products"). Defendants manufacture, market, advertise, promote and sell Pelvic Mesh Products worldwide.

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. At all relevant times, Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed in the stream of commerce the Pelvic Mesh Products, including the Pelvic Mesh Products at issue in this lawsuit.

8. At all times mentioned herein, Defendants acted, by and through their agents, representatives and employees who acted within the scope and course of their agency and employment.

9. At all relevant times, the defendant, Johnson & Johnson, was and still is a foreign corporation authorized to do business in the State of Missouri.

10. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, was and still is a business entity actually doing business in the State of Missouri.

11. At all times hereinafter mentioned, the defendant, Johnson & Johnson, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

12. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

13. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

14. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

15. At all times hereinafter mentioned, upon information and belief, the defendant, Johnson & Johnson, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

16. At all relevant times, the defendant, Ethicon, Inc., was and still is a foreign corporation authorized to do business in the State of Missouri.

17. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., was and still is a business entity actually doing business in the State of Missouri.

18. At all times hereinafter mentioned, the defendant, Ethicon, Inc., is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

19. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

20. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

21. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

22. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon, Inc., expects or should reasonably expect its acts to have

consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

23. At all relevant times, the defendant, Ethicon Women's Health & Urology, was and still is a foreign corporation authorized to do business in the State of Missouri.

24. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, was and still is a business entity actually doing business in the State of Missouri.

25. At all times hereinafter mentioned, the defendant, Ethicon Women's Health & Urology, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

26. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

27. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

28. At all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, regularly does and solicits business and engages in a persistent course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

29. That at all times hereinafter mentioned, upon information and belief, the defendant, Ethicon Women's Health & Urology, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

30. At all relevant times, the defendant, Gynecare, was and still is a foreign corporation authorized to do business in the State of Missouri.

31. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, was and still is a business entity actually doing business in the State of Missouri.

32. At all times hereinafter mentioned, the defendant, Gynecare, is engaged in the business of designing, manufacturing, advertising, marketing, and selling Pelvic Mesh Products including the Gynecare TVT mesh, and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

33. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, committed a tortuous act inside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

34. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, committed a tortuous act outside the State of Missouri, which caused injury to Plaintiff inside the State of Maryland.

35. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, regularly does and solicits business and engages in a persistent

course of conduct in the State of Missouri, deriving substantial revenue from goods and products consumed in the State of Missouri.

36. At all times hereinafter mentioned, upon information and belief, the defendant, Gynecare, expects or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

JURISDICTION AND VENUE

37. This Court has jurisdiction over this action by virtue of 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 a complete diversity of citizenship between Plaintiff and each defendant. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)-(c) by virtue of the fact that Johnsons and Johnson products are sold to and consumed by individuals in the State of Missouri thereby subjecting defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

38. This Court has jurisdiction over the Defendants because the Defendants are licensed to do business in all states of the United States of America including the State of Missouri. At all relevant times, Defendants were engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion , and/or distribution of Pelvic Mesh Products, including the Gynecare TVT mesh, for ultimate sale and/or use in the United States of America, including the State of Missouri, as well as in various foreign jurisdictions. Defendants are thus amenable to the jurisdiction of this Court.

39. Venue is proper pursuant to 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and all defendants are subject to personal jurisdiction in the Judicial District of the Western District of Missouri.

DEFENDANTS' PELVIC MESH PRODUCTS

40. In or about October 2002, 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 and Gynecare TVT.

41. 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.

42. In or about September 2005, 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.

43. In or about February 2007, Defendants began to market and sell a product known as TVT mesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The TVT mesh was and is offered as an anterior, posterior, or total repair system, and all references to the TVT mesh include by reference all variations.

44. In or about May 2008, 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.

45. The Defendants also marketed and sold 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.

46. The products known as Prolene Mesh, Gynemesh, Prolift, Prolift+M, TVT mesh and TVT, as well as any as yet identified 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.

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

FACTUAL ALLEGATIONS

48. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 501(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

49. The Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. The Pelvic Mesh Products are represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks. It is 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 vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

50. Moreover, these Pelvic Mesh Products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

51. 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 vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

52. The Defendants have marketed and sold the 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, 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. Also utilized are documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the Pelvic Mesh Products.

53. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device 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.

54. 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 Plaintiff, making them defective under the law. The defects stem from any or all of the following:

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

b. the design of the Pelvic Mesh Devices to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus 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 mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

d. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injury major nerve routes in the pelvic region;

e. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

f. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike; and

g. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

55. Upon information and belief, 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 Pelvic Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

56. Despite the chronic underreporting of adverse events associated with the Defendants' Pelvic Mesh Products and the underreporting of events associated with similarly designed competitor products, enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

57. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic Mesh Products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Products that are the subject of the notification.

58. On July 13, 2011, the FDA issued a Safety Communication:" UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated

analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were “not rare.” These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits was more effective than traditional non mesh repair of pelvic organ prolapse. The FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." 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 labeling.

59. On September 8-9, 2011 the FDA held advisory committee meetings to address the issues and concerns surrounding the Pelvic Mesh Products, including the product at issue in this lawsuit.

60. Defendants have known that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the 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 Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff.

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

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

63. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

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

65. The Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

66. The Pelvic Mesh Products implanted into the Plaintiff 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.

67. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse, or alter the Pelvic Mesh Product in an unforeseeable manner.

68. 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), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic 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.

69. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh Products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

70. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

71. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, 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 an indifference to the health, safety, and welfare of Plaintiff.

72. Defendants failed to undertake their duties to properly know the qualities of their Pelvic Mesh Products and in representations to Plaintiff and/or to Plaintiff's

healthcare providers, to and concealed and intentionally omitted the following material information:

a. That the 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 Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Pelvic Mesh Products were not adequately tested and were known by Defendants;

d. That the limited clinical testing revealed the 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 failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in the 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 Pelvic Mesh Products were dangerous and caused 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 Pelvic Mesh Products and that in the event the Pelvic Mesh Products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

i. That the Pelvic Mesh Products were manufactured negligently;

j. That the Pelvic Mesh Products were manufactured defectively;

k. That the Pelvic Mesh Products were designed negligently, and designed defectively.

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

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

75. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Pelvic Mesh Products.

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

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

78. In reliance upon these false representations, Plaintiff was 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 Plaintiff and Plaintiff's 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 Pelvic Mesh Products, as described in detail herein.

79. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the 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, Plaintiff, and the public at large.

80. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

81. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, 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 Pelvic Mesh Products.

82. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Pelvic Mesh Products specifically, that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Pelvic Mesh Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

83. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

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

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

86. Upon information and belief, 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 Pelvic Mesh Products did not present serious health risks.

87. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

88. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and Plaintiff's healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Pelvic Mesh Products and her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

89. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of Pelvic Mesh Products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

90. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff

discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

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

92. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

93. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

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

95. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

96. At all relevant times herein, 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 Pelvic Mesh Products system including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

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

98. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Pelvic Mesh Products when they knew of the hazards and dangerous propensities of said Pelvic Mesh Products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

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

100. 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 defects, Defendants continued to represent its Pelvic Mesh Products as safe for their intended use.

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

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

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

104. 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 Plaintiff.

PLAINTIFF'S EXPERIENCE AND INJURIES

105. On May 7, 2009, Plaintiff Ossie Blackston was implanted with Pelvic Mesh Products, including the Gynecare TVT mesh sling at Franklin Square Hospital in Baltimore, Maryland. The Gynecare TVT mesh sling was designed, manufactured, packaged, labeled and sold by Defendants.

106. The Pelvic Mesh Product was implanted in Plaintiff with the intention of treating the Plaintiff for stress urinary incontinence, uterovaginal prolapse and cystocele, uses for which Defendants marketed and sold the Pelvic Mesh Products.

107. At all times, the Pelvic Mesh Product that was implanted in Plaintiff was being used for the purposes that Defendants marketed the Pelvic Mesh Products.

108. Following implantation of the Gynecare TVT mesh, Plaintiff suffered of persistent pelvic pain and was seen by her physician with complaints of pelvic pain, stress urinary incontinence, infection and bleeding . Subsequently, it was discovered that the Gynecare TVT mesh which was implanted on May 7, 2009 had begun to erode through the vaginal wall. Following this discovery, Plaintiff underwent surgical extraction of the exposed portion of the Gynecare TVT mesh on February 18, 2010 at Greater Baltimore Medical Center in Baltimore, Maryland.

109. On or about August 2011, Plaintiff saw for the first time, information about product safety and defect issues associated with the implantation of Pelvic Mesh Products. After seeing this information, Plaintiffs suspected for the first time that the Pelvic Mesh Product that had been implanted into Plaintiff Ossie Blackston may have been defective and that she may have sustained an injury as a result of having had Defendants' defective Pelvic Mesh Product implanted into her.

110. As a result of having the Gynecare TVT mesh Pelvic Mesh Product implanted into her, Plaintiff has experienced significant mental and physical pain and suffering, has required additional surgery and medical treatment and has sustained permanent injury.

111. As a result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured in her health, strength, and activity, sustaining injury to her person, all of which injuries have caused and will continue to cause her severe mental and physical pain and suffering disability, impairment, loss of enjoyment of life, inability to engage in chosen and necessary activities. Plaintiff is informed and believes, and alleges thereon, that such injuries will result in some permanent disability to her person.

112. As a further result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiffs were required to and did employ health care providers and incurred, medical, hospital and incidental expenses; further, Plaintiffs are informed and believe, and allege thereon, that Plaintiffs will be required to incur additional medical, hospital, and incidental expenses thereto, all according to proof.

FIRST CAUSE OF ACTION

STRICT PRODUCT LIABILITY - FAILURE TO WARN

113. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

114. Defendants, manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiff to be used for treatment of pelvic organ prolapse, stress urinary incontinence or cystocele.

115. At all times mentioned herein, the Pelvic Mesh Products were and are, dangerous and presented a substantial danger to patients who were implanted with the Pelvic Mesh Devices, and these risks and dangers were known or knowable at the time of

distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed to pelvic reconstruction patients because its uses were specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used in a way reasonably foreseeable to Defendants by Plaintiff. Defendants failed to provide warnings of such risks and dangers to Plaintiff as described herein.

116. As a result of the implantation of the Pelvic Mesh Products Plaintiff suffered debilitating injuries including mesh erosion, hardening, chronic pain and worsening dyspareunia, and recurrent incontinence leading to the need for dangerous and serious vaginal surgery.

SECOND CAUSE OF ACTION

STRICT LIABILITY

117. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

118. The Pelvic Mesh Products were manufactured and/or supplied by the Defendants, and were placed into the stream of commerce by the Defendants in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with its design of formulation.

119. Alternatively, Pelvic Mesh Products manufactured and/or supplied by the Defendants were defective in design or formulation, inadequate warning or instruction and/or inadequate post-marketing warnings or instructions in that when it was placed in the stream of commerce, it was unreasonably dangerous, it was more dangerous than an

ordinary consumer would expect and more dangerous than other forms of stress urinary incontinence, pelvic organ prolapse or cystocele repair.

120. As a result of the defective unreasonably dangerous condition of these Pelvic Mesh Products manufactured and/or supplied by the Defendants, Plaintiffs were caused to suffer the herein described injuries and damages.

121. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by Pelvic Mesh Products

THIRD CAUSE OF ACTION

NEGLIGENCE

122. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

123. Defendants, and their representatives, were manufacturers and/or distributors of Pelvic Mesh Products. At all times herein, Defendants had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell the aforesaid product

124. Defendants breached their duty to properly manufacturer, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and see the aforesaid Pelvic Mesh Products, as set forth herein.

125. As a result of Defendants' breach of their duty to Plaintiffs, Plaintiffs suffered injuries as set forth herein.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

126. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

127. Defendants impliedly warranted that the Pelvic Mesh Products, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs was merchantable and fit and safe for ordinary use. Defendants further impliedly warranted that its Pelvic Mesh Products were fit for the particular purpose of correcting urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and cystocele.

128. Defendants' Pelvic Mesh Products were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries. Therefore, Defendants breached the implied warranties of merchantability and fitness for a particular purpose when it's synthetic mesh system was sold to Plaintiffs, in that the Pelvic Mesh Products are defective and has eroded and caused dense scarring and otherwise failed to function as represented and intended.

129. As a result of Defendants' breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiffs have sustained and will continue to sustain the injuries and damages described herein and is therefore entitled to compensatory damages.

130. After Plaintiffs were made aware that Plaintiffs' injuries were a result of the aforesaid Pelvic Mesh Products, Defendants had ample and sufficient notice of the breach of said warranty.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

131. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

132. Defendants expressly warranted to Plaintiffs and/or their authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that the defective Pelvic Mesh Products were safe, effective, fit and proper for their intended use.

133. Plaintiffs and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiffs and was unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiffs to sustain damages and injuries herein alleged.

134. As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, said Defendants had ample and sufficient notice of the breach of said warranty.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

135. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

136. At all relevant times herein, Defendants represented to Plaintiffs and Plaintiff's physicians that the Pelvic Mesh Products were safe to use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele knowing

that the Pelvic Mesh Products were defective and capable of causing the injuries described herein.

137. The Defendants made the aforesaid representations with no reasonable ground for believing them to be true when Defendants' own data showed the Pelvic Mesh Products to be defective and dangerous when used in the intended manner.

138. The aforesaid representations were made to the physician(s) prescribing the Pelvic Mesh Products prior to the date it was prescribed to Plaintiffs and used by Plaintiff's physicians with the intent that Plaintiffs and Plaintiff's physician(s) rely upon such misrepresentations about the safety and efficacy of the Pelvic Mesh Products. Plaintiffs and Plaintiff's physicians did reasonably rely upon such representations that the aforesaid product was safe for use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele.

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

139. Plaintiffs repeat and reallege all allegations contained in all paragraphs above as if fully set forth herein.

140. As a direct and proximate result of Defendant's negligence and conduct, as detailed above, plaintiff John Blackston was caused to lose the consortium and society of his spouse, plaintiff Ossie Blackston.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together

with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general damages in a sum within the jurisdiction of this Court;

2. For medical, hospital, and incidental expenses, according to proof;

3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For such other relief as the Court deems just and proper.

Dated: April 27, 2012

By: /s/ Jeffrey M. Kuntz

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JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all issues.

By: /s/ Jeffrey M. Kuntz

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