UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

VIRGINIA RIDDLE and JOHNNY RIDDLE,	)	Case No.: _____
Plaintiffs,	)	
v.	)	JURY TRIAL DEMANDED
BOSTON SCIENTIFIC CORPORATION (D/B/A MANSFIELD SCIENTIFIC, INC.) & MICROVASIVE, INC.),	)	
Defendants.	)	

PLAINTIFF'S ORIGINAL COMPLAINT FOR DAMAGES

Comes now the Plaintiffs, VIRGINIA RIDDLE and JOHNNY RIDDLE, (hereafter referred to as "Plaintiff" or "Plaintiffs") by and through counsel, and bring this action for damages suffered by Plaintiffs as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the below described "Pelvic Mesh Products."

Plaintiffs allege as follows:

PARTIES

1. Plaintiffs are citizens of Albany, Kentucky, located in Clinton County.

2. Boston Scientific Corporation (d/b/a Mansfield Scientific, Inc. &

Microvasive, Inc.), hereafter referred to as “Boston Scientific” or “Defendant(s),” is a Delaware corporation with its corporate headquarters in Massachusetts. At all times material hereto, Boston Scientific was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce through the United Stated, either directly or indirectly, its medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse. All acts and omissions of Boston Scientific as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

3. This Court has diversity subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a): "The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between (1) citizens of different states." Damages to plaintiff are estimated in good faith to exceed the sum or value of $75,000, exclusive of interest and costs.

4. This Court has jurisdiction over the non-resident Defendants because they have done business and have continuing contacts in the States of Kentucky and West Virginia.

5. Venue is proper pursuant to the Judicial Panel on Multidistrict Litigation’s Order of February 7, 2012, where the Judicial Panel on

Multidistrict Litigation transferred to this Court a number of actions involving pelvic floor repair systems manufactured by the Defendants. Venue is proper pursuant to this Order and for the purposes of pretrial proceedings pursuant to Pretrial Order #1 by this Court dated February 29, 2012.

FACTUAL BACKGROUND

6. Boston Scientific was engaged in the business of placing, designing, manufacturing, marketing, packaging, labeling and selling such devices, including the Advantage Transvaginal Mid-Urethral Sling System, Solyx SIS System, Pinnacle Pelvic Floor Repair Kit, Lynx Mid-Urethral Sling System, Obtryx Transobturator Mid-Urethral Sling System, Uphold Vaginal Support System, Prefyx Pre-Pubic System, and other devices. Defendants' products are hereafter referred to as the "Pelvic Mesh Products."

7. 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 to the Food, Drug and Cosmetics Act. Section 510(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.

8. 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.

9. Moreover, these Pelvic Mesh Products contain a non-absorbable synthetic material, such as polypropylene or polyester mesh, intended for the treatment of stress urinary incontinence and pelvic organ prolapse. 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 Defendant's 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.

10. Defendant's 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.

11. The Defendant has 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 products.

12. At all times relevant to this action, Defendant 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, Defendant 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.

13. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, Defendant's 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 injure 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;

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.

14. The Defendant has consistently underreported and withheld

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

15. Despite the chronic underreporting of adverse events associated with the Defendant's 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.

16. 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 Defendant is one of the manufacturers of the products that are the subject of the notification.

17. 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." (Emphasis in the original). 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 Defendant and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use or labeling.

18. Defendant has 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 Defendant's 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 Defendant 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 Defendant actively and intentionally misled and continues 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 Plaintiffs.

19. Defendant 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.

20. Defendant 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.

21. 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 Defendant's Pelvic Mesh Products.

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

23. Defendant 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 Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

24. 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 Defendant, and in the condition directed by and expected by the Defendant.

25. Plaintiff and her physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse, or alter the Products in an unforeseeable manner.

26. The injuries, conditions, and complications suffered by women who have been implanted with Defendant's 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.

27. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendant's Pelvic Mesh, 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.

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

29. These representations were made by Defendant with the intent of inducing the medical community, Plaintiff and the public, to recommend, prescribe, dispense, and purchase the 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.

30. Defendant failed to undertake their duties to properly know the qualities of their products and in representations to Plaintiff and/or to Plaintiff's healthcare providers, 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 were not adequately tested and were known by Defendant;

c. 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;

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

e. That Defendant was 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;

f. 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;

g. That patients needed to be monitored more regularly than usual while using the Pelvic Mesh Products and that, in the event the products needed to be removed, that the procedures to remove them had a very high failure rate and/or needed tobe performed repeatedly. Thus:

h. That the Pelvic Mesh Products were manufactured negligently;

i. That the Pelvic Mesh Products were manufactured defectively; and

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

31. Defendant was under a duty to disclose to Plaintiff and her physicians, the defective nature of the Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury

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

33. Defendant's 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 Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Products.

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

35. Defendant 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.

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

37. As a result of Defendant's research and testing or lack thereof, Defendant 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 Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

38. Defendant 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.

39. The information distributed to the public, the medical community, the FDA and Plaintiff by Defendant 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.

40. Defendant 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.

41. Defendant 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.

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

43. Defendant's 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.

44. Defendant 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.

45. These representations, and others made by Defendant, 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. These representations, and others made by Defendant, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, andwere made in order to induce Plaintiff, and her respective healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase,

rely, use, and request the Pelvic Mesh Products and their healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

46. Defendant 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 products known to be dangerous and defective, and/or not as safe as other alternatives. Defendant utilized direct-to- consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

47. At the time the representations were made, Plaintiff and her 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 Defendant, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

48. 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 Defendant's products.

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

50. At all times relevant to this action, Defendant 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.

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

52. In doing so the Defendant 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.

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

54. The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendant 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.

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

PLAINTIFF'S EXPERIENCE AND INJURIES

56. On or about April 7, 2010, Plaintiff Virginia Riddle was implanted with a Boston Scientific Solyx SIS System, which was designed, manufactured, packaged, labeled and sold by Defendants.

57. The Pelvic Mesh Products were implanted in Plaintiff with the intention of treating the Plaintiff for stress urinary incontinence and/or pelvic organ prolapse, uses for which Defendants marketed and sold the products. At all times, the Pelvic Mesh Products that were implanted in Plaintiff were being used for the purposes that Defendants marketed the products.

58. After, and as a result of the implantation of the Pelvic Mesh Products, Plaintiff suffered serious bodily injuries, including, but not limited to, extreme pain, vaginal erosion, dyspareunia, abdominal and pelvic pain,

recurrence of urinary incontinence, additional surgery and/or other injuries. These injuries would not have occurred but for the defective nature of the products implanted and/or Defendants' wrongful conduct.

59. As a result of having the Pelvic Mesh Products implanted into her, Plaintiff has experienced significant mental and physical pain and suffering, has required additional surgery and/or medical treatment, and she has sustained permanent injury.

60. As a result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendant, Plaintiff was injured in her health, strength, and activity, sustaining injury to her person, all of which injuries have caused Plaintiff severe mental and physical pain and suffering. Plaintiff is informed and believes, and alleges thereon, that such injuries will result in some permanent disability to her person. As a result of such injuries, Plaintiff has suffered general damages.

61. As a further result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendant, Plaintiff was required to and did employ health care providers and incurred, medical, hospital and incidental expenses; further, Plaintiff is informed and believes, and alleges thereon, that Plaintiff will be required to incur additional medical, hospital, and incidental expenses thereto, all according to proof.

62. As a further result of the aforesaid conduct and defective products manufactured, sold, distributed, advertised, and promoted by Defendant Plaintiff has suffered a loss of earnings and earning capacity and will continue

to suffer a loss of future earnings, according to proof.

FIRST CAUSE OF ACTION

[Strict Product Liability- Failure to Warn]

63. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

64. Defendant manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiff to be used for treatment of vaginal prolapse, stress urinary incontinence and rectocele.

65. 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 their uses were specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used by Plaintiff in a way reasonably foreseeable to Defendant. Defendant failed to provide warnings of such risks and dangers to Plaintiff as described herein.

66. 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.

67. In doing the acts herein described, Defendant acted with oppression, fraud and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendant and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendant.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

SECOND CAUSE OF ACTION

[Strict Liability]

68. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

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

70. Alternatively, Pelvic Mesh Products manufactured and/or supplied by Defendant were defective in design or formulation, inadequate warning or instruction and/or inadequate post-marketing warnings or instructions in that when they were placed in the stream of commerce, they were unreasonably

dangerous, they were more dangerous than an ordinary consumer would expect and more dangerous than other forms of stress urinary incontinence, pelvic organ prolapse and rectocele repair.

71. As a result of the defective unreasonably dangerous condition of these products manufactured and/or supplied by Defendant, Plaintiff was caused to suffer the herein described injuries and damages.

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

73. Defendant thereby acted with fraud, malice, oppression and a conscious disregard for the Plaintiff's and the general public's safety, who accordingly request that the trier of fact, in the exercise of sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendant for its conduct, in an amount sufficiently large to be an example to others and deter Defendant and others from engaging in similar conduct in the future. The aforesaid wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of Defendant.

WHEREFORE, Plaintiff prays for judgment against Defendant, as hereinafter set forth.

THIRD CAUSE OF ACTION

[Negligence]

74. Plaintiff hereby incorporates by reference, as if fully set forth

herein, each and every allegation contained in Paragraphs 1-74, inclusive, of this Complaint.

75. Defendant and its representatives were manufacturers and/or distributors of Pelvic Mesh Products. At all times herein, Defendant 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 products. Defendant so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied aforesaid product, that it was dangerous and unsafe for the use and purpose for which it was intended, that is, urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele repair in Plaintiff and others similarly situated. As a result of the carelessness and negligence of Defendant, Plaintiff had the Pelvic Mesh Products described herein implanted in the manner intended by Defendant, and, as a result, Plaintiff suffered the injuries and damages described herein.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

FOURTH CAUSE OF ACTION

[Breach of Implied Warranty]

76. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and

further allege as follows:

77. Defendant impliedly warranted that the Pelvic Mesh Products, which Defendant designed, manufactured, assembled, promoted and sold to Plaintiff was merchantable and fit and safe for ordinary use. Defendant 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 rectocele.

78. Defendant's 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 Plaintiff to severe and permanent injuries. Therefore, Defendant breached the implied warranties of merchantability and fitness for a particular purpose when its synthetic mesh system was sold to Plaintiff, in that the Pelvic Mesh Products are defective and has eroded and caused dense scarring and otherwise failed to function as represented and intended.

79. As a result of Defendant's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff has sustained and will continue to sustain the injuries and damages described herein and are therefore entitled to compensatory damages.

80. After Plaintiff was made aware that her injuries were a result of the aforesaid Pelvic Mesh Products, Defendant had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiff prays for judgment against Defendant as

hereinafter set forth.

FIFTH CAUSE OF ACTION

[Breach of Express Warranty]

81. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

82. Defendant expressly warranted to Plaintiff and/or her 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.

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

84. As soon as the true nature of the products, and the fact that the warranty and representations were false, were ascertained, said Defendant had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

SIXTH CAUSE OF ACTION

[Fraud]

85. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

86. Defendant falsely and fraudulently represented to Plaintiff, her physicians, and to members of the general public that the aforesaid products were safe, effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. The representations by said Defendant were, in fact, false. The true facts include, but are not limited to, that the aforesaid products were not safe to be used for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse, or rectocele repair, and were, in fact, dangerous to the health and body of Plaintiff.

87. When the Defendant made these representations, it knew that they were false. Defendant made said representations with the intent to defraud and deceive Plaintiff, and with the intent to induce Plaintiff to act in the manner herein alleged, that is to use the aforementioned product for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse, or rectocele repair.

88. At the time Defendant made the aforesaid representations, Plaintiff took the actions herein alleged; Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In

reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid products as herein described. If Plaintiff had known the actual facts, she would not have taken such action. The reliance of Plaintiff and her physicians upon Defendant's representations were justified because said representations were made by individuals and entities who appeared to be in a position to know the true facts.

89. As a result of Defendant's fraud and deceit, Plaintiff was caused to sustain the herein described injuries and damages.

90. In doing the acts herein alleged, the Defendant acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendant and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendant.

91. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the Pelvic Mesh Products as described herein. Defendants did not disclose this information to the Plaintiff, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Pelvic Mesh Products Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

SEVENTH CAUSE OF ACTION

[Fraud by Concealment]

92. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

93. At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid Pelvic Mesh Products, that is, that said products were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely they were to cause serious consequences to users including permanent and debilitating injuries. Defendant made the affirmative representations as set forth above to Plaintiff and her physicians and the general public prior to the date Pelvic Mesh Products were implanted in Plaintiff, while concealing material facts.

94. At all times herein mentioned, Defendant, willfully, and maliciously concealed facts as set forth above from Plaintiff and her physicians, and therefore, Plaintiff, with the intent to defraud as herein alleged.

95. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for correction of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele. Defendant's representations were a substantial

factor in Plaintiff utilizing the Pelvic Mesh Products for correction of her medical conditions.

96. As a result of the concealment of the facts set forth above, Plaintiff sustained injuries as hereinafter set forth.

97. In doing the actions herein alleged, Defendant acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages, and to Defendant's wealth, and sufficiently large to be an example to others, and to deter this Defendant, and others from engaging in similar conduct in the future..

98. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the Pelvic Mesh Products as described herein. Defendants did not disclose this information to the Plaintiff, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Pelvic Mesh Products Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

99. Plaintiff hereby incorporates by reference, as if fully set forth

herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

100. At all relevant times herein, Defendant represented to Plaintiff and her 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.

101. The Defendant 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.

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

103. The representations by said Defendant to Plaintiff were false, and thereby caused Plaintiff's injuries described herein.

104. Defendant’s fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the

use of the Pelvic Mesh Products as described herein. Defendants did not disclose this information to the Plaintiff, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Pelvic Mesh Products Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

WHEREFORE, Plaintiff prays for judgment against Defendant as hereinafter set forth.

NINTH CAUSE OF ACTION

[Loss of Consortium]

105. Plaintiffs hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

106. As a direct and proximate result of the failure of the Pelvic Mesh Products, Plaintiff JOHNNY RIDDLE, Plaintiff's husband, has been and will continue to be deprived of the consortium, society, comfort, protection, and service of Plaintiff, thereby causing and continuing to cause JOHNNY RIDDLE economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering. Plaintiff JOHNNY RIDDLE'S injuries and damages are permanent and will continue into the future. The Plaintiffs seek general, compensatory, special and punitive damages from the Defendant as alleged herein.

WHEREFORE, Plaintiffs pray for judgment against Defendant as

hereinafter set forth.

PUNITIVE DAMAGES

107. Plaintiff incorporates by reference all paragraphs of this complaint as if fully set forth herein.

108. Defendants knew or should have known that the pelvic mesh products were defective and presented and unreasonable risk of harm to plaintiff.

109. Defendants' conduct as described in this complaint, for which plaintiff is entitled to recover compensatory damages, manifested a conscious indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the pelvic mesh products, including plaintiff, justifying the imposition of punitive damages. Defendants acted in a grossly negligent manner by failing to reveal and/or warn regarding the safety issues associated with their pelvic mesh products.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands a trial by jury, judgment against defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, and any other relief, monetary

or equitable, to which she is entitled.

1. Compensatory damages in an amount to be determined by the jury to Plaintiffs for past, present and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, all mental and emotional pain, medical expenses, loss of income, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits in an amount to be ascertained through discovery and to be determined by the jury.

3. All ascertainable economic damages.

4. Punitive and treble damages.

5. Reasonable attorneys' fees and costs as allowed by law.

6. Such other relief and this Court deems just and proper.

Dated this 11th day of July, 2012

Respectfully submitted,

/s/ Lee L. Coleman

_____

Lee L. Coleman

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