UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

TANYA DAVIS, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	)	CAUSE NO. 1:22-cv-818 **JURY TRIAL DEMANDED**

COMES NOW, the Plaintiff, Tanya Davis, by and through her counsel, hereby submits the following Complaint for Damages against Defendant Boston Scientific Corporation. Plaintiff states and alleges as follows in support thereof:

PARTIES, JURISDICTION, VENUE

1. At the time of her vaginal mesh implant, Plaintiff, Tanya Davis, was a resident and citizen of Attica, Indiana in Fountain County, Indiana. Currently, Plaintiff, Tanya Davis, is a resident and citizen of Providence, Kentucky in Webster County, Kentucky.

2. Defendant Boston Scientific Corporation (hereinafter "BSC") is a Delaware corporation with its principal place of business located at 300 Boston Scientific Way, Marlborough, Massachusetts 01752. Defendant may be served through its registered agent, Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, Indiana 46204.

3. Defendant BSC is and has been, at all times relevant herein, engaged in the research, development, design, manufacture, marketing, advertising, sale, distribution, and delivery into commerce, including interstate commerce in Indiana and all other States of the Union,

of the Obtryx II Transobturator Mid-Urethral Sling System (hereinafter "Obtryx II") (referred to as "product" or "products" hereinafter).

4. Defendant designed, manufactured, marketed, promoted, and sold the Obtryx II that was implanted into Plaintiff's body and is the subject of this action.

5. Upon information and belief, at all times herein mentioned, the employees of the Defendant herein, its subsidiaries, affiliates, and other related entities, as well as the employees of Defendant's subsidiaries, affiliates, and other related entities, were the agents, servants, and employees of Defendant, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to an act or transaction of Defendant, such allegations shall be deemed to mean that the principals, officers, employees, agents and/or representation of the Defendant herein committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendant herein while actively engaged in the scope of their duties.

6. The Court has jurisdiction this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs. Additionally, this Court has personal jurisdiction over BSC because, at all times relevant to this Complaint, BSC has conducted regular business in Indiana, by selling, marketing, promoting, and distributing its products to the medical community therein, including but not limited to the Obtryx II. BSC's contacts with the State of Indiana have been significant, continuous, systematic, and direct.

7. Venue in this district is appropriate under 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in this district and the Indianapolis Division. Specifically, the surgical implantation of the Obtryx II, about which Plaintiff complains herein,

occurred at St. Vincent Williamsport Hospital located at 412 North Monroe St., Indiana 47993, and BSC's sales employees, directors, managers, and agents marketed, promoted, sold, and otherwise distributed the Obtryx II in the State of Indiana.

8. All of the acts and omissions of BSC, as described herein, were committed by BSC's agents, servants, employees and/or owners who were acting within and during the scope of their respective agencies, services, employments, and/or ownership, and this Court has personal jurisdiction over the parties and subject matters herein; and venue properly lies with this Court.

FACTUAL BACKGROUND

10. The Obtryx II was designed, manufactured, marketed, promoted, and sold by BSC as a medical and/or surgical product or product for the treatment of stress urinary incontinence (SUI). Stress urinary incontinence is a condition wherein a leakage of urine occurs during moments of physical activity that increase abdominal pressure, such as coughing, sneezing, laughing and/or exercise.

11. BSC and its employees and agents marketed, advertised, and promoted the Obtryx II to the medical community, including Plaintiff's medical providers, as a safe, effective, and reliable medical product for the treatment of SUI.

12. BSC's Obtryx II contains monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material, as implanted in the Plaintiff, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with this product. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendant's collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction.

Defendant's collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal and/or human tissue. The collagen is harsh upon the female pelvic tissue. When mesh is inserted in the female body according to the manufacturer's instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

13. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgical repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including BSC, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, BSC sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendant, including the Obtryx II, are considered Class II medical products.

14. Defendant sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Product Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical product if the product is deemed "substantially equivalent" to other predicate products marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by BSC with regard to the Obtryx II.

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

16. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening, and vaginal pain." (emphasis in original).

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

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

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

19. The injuries of the Plaintiff, as will be more fully established in discovery, are reported in the FDA Safety Communication and in the ACOG/AUGST Joint Committee Opinion.

20. The FDA Safety Community further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

21. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of

Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

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

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

24. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

25. As is known to BSC, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

26. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates

that serious complications can occur … [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

27. Defendant did not, and has not, adequately studied the extent of the risks associated with the Obtryx II product. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

28. Defendant knew or should have known about the risks and complications associated with the Obtryx II product, as identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

29. Defendant knew or should have known that the Obtryx II unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

30. The scientific evidence shows that the material from which the Obtryx II is made is biologically incompatible with human tissue and promotes and negative immune response in a large subset of the population implanted with this product, including the Plaintiff.

31. The negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the Plaintiff.

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

33. The Obtryx II was unreasonably susceptible to shrinkage and contraction inside the body. Defendant should have known of this serious risk and warned physicians and patients.

34. The Obtryx II was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

35. To this day, the Obtryx II has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical product, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

36. A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support. POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

37. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Obtryx II, and advertised, promoted, marketed, sold, and distributed the product as a safe medical product when Defendant knew or should have known that the product was not safe for its intended purposes, and that the product would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

38. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the products have high rates of failure, injury, and complications,

fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

39. The specific nature of the defects of the Obtryx II include, but are not limited to, the following:

a) The use of polypropylene and collagen in the product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries:

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

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

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

f) The inelasticity of the product, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted,

and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g) The propensity of the product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the product, which is causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

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

40. The Obtryx II is also defective due to Defendant's failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a) The product's propensity to contract, retract, and/or shrink inside the body;

b) The product's propensity for degradation, fragmentation and/or creep;

c) The product's inelasticity preventing proper mating with the pelvic floor

and vaginal region;

d) The frequency and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the product;

f) The risk of chronic infections resulting from the product;

g) The risk of permanent vaginal or pelvic scarring as a result of the product;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the product;

i) The need for corrective or revision surgery to adjust or remove the product;

j) The severity of complications that could arise as a result of implantation of the product;

k) The hazards associated with the product;

l) The product's defects described herein;

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

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

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

p) That use of the product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) That removal of the product due to complications may involve multiple

surgeries and may significantly impair the patient's quality of life; and

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

41. Defendant underreported and continues to underreport information about the propensity of the product to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the products through various means and media.

42. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude, and frequency of the risks attendant to the product.

43. Defendant failed to design and establish a safe, effective procedure for removal of the product, or to determine if a safe, effective procedure for removal of the product exists.

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

45. The product was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the product, and trained the implanting physicians.

46. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the product and the aftercare of patients implanted with the product.

47. The product implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant.

48. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the product, including, but are not limited to, erosion,

mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

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

50. The medical and scientific literatures studying the effects of the product, like that of the product implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the product.

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

52. At all relevant times herein, Defendant continued to promote the product as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

53. In doing so, Defendant failed to disclose the known risks and failed to warn or known of scientifically knowable dangers and risk associated with the product, including the magnitude and frequency of these risks.

54. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff and the public on notice of the dangers and the adverse events caused by implantation of the product.

55. The product as designed, manufactured, distributed, sold, and/or supplied by Defendant was defective as marketed due to the inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

56. As a result of having the product implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering; has sustained permanent injury; has undergone medical treatment and will likely undergo further medical treatment and procedures; has suffered financial and economic loss, including but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

57. On May 3, 2018, Plaintiff was implanted with product Obtryx II System, Lot Number 21889878 for the treatment of stress urinary incontinence.

58. Plaintiff's implant procedure was performed at St. Vincent Williamsport Hospital, 412 North Monroe St., Williamsport, Indiana 47993 by Mahesh Goel, M.D.

59. The product implanted in Plaintiff was in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

60. Plaintiff and her physician foreseeably used and implanted the products properly and appropriately and did not misuse or alter these products in any unforeseeable manner.

61. Neither Plaintiff nor her physicians and/or healthcare providers were warned that the Obtryx II was unreasonable dangerous or of the risks of the product, outlined herein, even when used exactly as intended and instructed by Defendant. To the contrary, Defendant promoted and sold the type of product implanted in the Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did incorporate Defendant's products.

62. On information and belief, Plaintiff's implanting physician would have advised Plaintiff of the risks of the products, including the Obtryx II, and considered these risks in the risk-benefit analysis.

63. As a direct and proximate cause of having the Obtryx II product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, including pelvic pain and dyspareunia, abdominal pain, urinary problems, prolapse and incontinence; and has undergone medical treatment and will likely undergo further medical treatment and procedures; has suffered financial or economic loss, including but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

64. As a further direct and proximate result of being surgically implanted with the Obtryx II product, the Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and pain that may be permanent.

65. Plaintiff developed complications, including but not limited to, pelvic pain and dyspareunia, as a result of the product and the dangers associated with the product, as described herein, and underwent a removal procedure on May 14, 2020, for removal of the vaginal mesh.

66. Plaintiff's removal surgery was performed by Mahesh Goel, St. Vincent Williamsport Hospital, 412 Monroe St., Williamsport, IN 47993.

FIRST CAUSE OF ACTION
(Negligence - Ind. Code § 34-20-1-1, *et. seq.*)

67. Plaintiff realleges and incorporates Paragraphs 1 through 66 of this Complaint as if each were set forth fully and completely herein.

68. At all times herein mentioned, Defendant was engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using,

supplying, selling, marketing, warranting, packaging, and advertising the Obtryx II pelvic mesh product at issue in this case.

69. Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in the pursuit of the activities mentioned above, and Defendant breached said duty of care.

70. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation or use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Obtryx II pelvic mesh product, and to adequately test and warn of the risk and dangers of the Obtryx II pelvic mesh product, both before and after sale.

71. Further, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in the education and training of physicians regarding the risks, benefits, and implantation of its pelvic mesh products.

72. Additionally, Defendant owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Obtryx II manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Obtryx II pelvic mesh product to perform as intended or as an ordinary consumer would expect.

73. Defendant further breached its duty of care in the testing of its products, including the Obtryx II pelvic mesh product at issue in this case, by failing to conduct adequate testing to ensure that the products were reasonably safe for implantation in the female pelvic area prior to

releasing the products into the market, failing to conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA Adverse Event databases for their potential significant for Defendant's products, including the Obtryx II pelvic mesh product at issue in this case.

74. Defendant breached the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the products, including Plaintiff herein. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging, and selling the products at issue herein. Defendant breached the aforementioned duties in that Defendant negligently and carelessly designed, licensed, inspected or failed to inspect, tested or failed to test, inadequately warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Obtryx II product in that said product caused, directly and proximately, the injuries of Plaintiff through failure of the products to perform as intended or as an ordinary consumer would expect. Defendant breached the aforementioned duty by, among other things:

a) Failing to design the product at issue herein so as to avoid an unreasonable risk of harm to women in whom the product at issue herein was implanted, including Plaintiff;

b) Failing to manufacture the product at issue herein so as to avoid an unreasonable risk of harm to women in whom the product at issue herein was implanted, including Plaintiff;

c) Failing to use reasonable care in the testing of the product at issue herein

so as to avoid an unreasonable risk of harm to women in whom the product at issue herein was implanted, including Plaintiff;

d) Failing to use reasonable care in inspecting the product at issue herein so as to avoid an unreasonable risk of harm to women in whom the product at issue herein was implanted, including Plaintiff;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the product at issue herein;

f) Failing to use reasonable care in studying the product at issue herein to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life-threatening complications that were known or knowable; and

g) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the product at issue herein.

75. Defendant also negligently failed to warn, train, and instruct Plaintiff and/or her health care providers of subjects including but not limited to, the following:

a) The use of polypropylene and collagen in the product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries:

c) Biomechanical issues with the design of the product, including, but not

limited to, the propensity of the products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

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

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

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

g) The propensity of the product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the product, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

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

76. Defendant also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a) The product's propensity to contract, retract, and/or shrink inside the body;

b) The product's propensity for degradation, fragmentation and/or creep;

c) The product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The frequency and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the product;

f) The risk of chronic infections resulting from the product;

g) The risk of permanent vaginal or pelvic scarring as a result of the product;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the product;

i) The need for corrective or revision surgery to adjust or remove the product;

j) The severity of complications that could arise as a result of implantation of the product;

k) The hazards associated with the product;

l) The product's defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the

product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

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

77. As a direct and proximate result of Defendant's negligent design, marketing, physician training, and testing of its products, including the Obtryx II pelvic mesh product at issue in this case, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and economic damages.

78. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have jurisdiction.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

SECOND CAUSE OF ACTION
(Strict Liability – Defective Design)

(Ind. Code § 34-20-1-1, *et. seq.)*

79. Plaintiff realleges and incorporates by reference Paragraphs 1 through 78 of this Complaint as if each were set forth fully and completely herein.

80. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

81. Defendant was and is engaged in the business of selling its pelvic mesh products, including the Obtryx II pelvic mesh product, in the State of Indiana.

82. Defendant is a manufacturer and/or supplier of pelvic mesh products, specifically the Obtryx II pelvic mesh product at issue herein, and is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing its pelvic mesh products, specifically the Obtryx II pelvic mesh product, into the stream of commerce.

83. The pelvic mesh product at issue herein, the Obtryx II device, was designed, marketed, manufactured, and distributed by the Defendant and was defective and not reasonably safe due to its improper, inadequate, and defective design.

84. The Obtryx II pelvic mesh product manufactured, designed, marketed, promoted, and sold by Defendant was expected to, and did, reach Plaintiff without substantial change in the condition in which they were sold and in the condition directed by and expected by Defendant. The Obtryx II pelvic mesh product was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale, and distribution, and at the time they left the possession of the Defendant.

85. Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the pelvic mesh products,

including the Obtryx II pelvic mesh product at issue herein, and Plaintiff was an expected user or consumer of the pelvic mesh products.

86. Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

87. The pelvic mesh product at issue herein that was implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh products, like Plaintiff.

88. Defendant's pelvic mesh products, specifically the Obtryx II pelvic mesh product, manufactured and/or supplied by Defendant, was defective in design or formulation in that, when it left the hands of Defendant, and it was unreasonably dangerous, taking into consideration the expectations of a reasonable consumer under the circumstances.

89. The Obtryx II pelvic mesh product at issue herein that was implanted into Plaintiff, was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the products at the time the products were designed, manufactured, packaged, labeled, and/or sold. There were also safer alternative designs for the Obtryx II device.

90. The Obtryx II pelvic mesh product at issue herein that was implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to its design. These design defects include, but are not limited to, the following:

a) The use of polypropylene and collagen in the product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the product to be inserted into and through an area of the

body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries:

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

d) The use and design of arms and anchors in the product, which, when placed in the women, is likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

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

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

g) The propensity of the product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the product, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

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

91. As designed, Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, were and are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

92. Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, are not reasonably, safe, and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that they should not have been marketed.

93. Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to their characteristics.

94. Defendant has intentionally and recklessly designed, marketed, labeled, sold, and distributed its pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this

case, with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placings its economic interests above the health and safety of Plaintiff.

95. At all relevant times, feasible, safer mesh-related alternative designs to the Obtryx II pelvic mesh product existed, such as the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Boston Scientific's Repliform® or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinlyidene fluoride (PVDF) alternative, a retropubic mini-sling, such as the TFS device from TFS Surgical, a retropubic sling comprised of Dynamesh or other PVDF alternative, or a retropubic mini-sling comprised of DynaMesh or other PVDF alternative.

96. With respect to Plaintiff in particular, flaws with the Obtryx II mesh product's design, including but not limited to the use of polypropylene mesh in the Obtryx II pelvic mesh product, the weight and pore size of the polypropylene mesh used in the product, and the implantation design of the product, caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well as entrapment, aggravation, irritation, and/or compression of Plaintiff's obturator and/or pudendal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from pelvic pain and dyspareunia, abdominal pain, urinary problems, prolapse and incontinence, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

97. As a direct and proximate result of the wrongful acts and omissions of Defendant, Plaintiff has suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

98. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

THIRD CAUSE OF ACTION
(Strict Liability – Product Defective Due to Inadequate Warning or Instruction)
(Ind. Code § 34-20-1-1, *et. seq.*)

99. Plaintiff realleges and incorporates by reference Paragraphs 1 through 98 of this Complaint as if each were set forth fully and completely herein.

100. Defendant supplied the Obtryx II pelvic mesh product that was implanted in Plaintiff.

101. Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Obtryx II pelvic mesh product at issue herein.

102. The Obtryx II pelvic mesh product was manufactured, designed, marketed, labeled, and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

103. Defendant's Obtryx II pelvic mesh product is defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of risks associated with the use of their product.

104. In their DFU's, as well as the marketing materials they prepared and disseminated to patients and healthcare providers, Defendant omitted critical information regarding the risks and potential complications of the Obtryx II pelvic mesh product at issue in this case. Specifically, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following:

a) The use of polypropylene and collagen in the product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries:

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

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

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

f) The inelasticity of the product, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted,

and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g) The propensity of the product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the product, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

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

m) The product's propensity to contract, retract, and/or shrink inside the body;

n) The product's propensity for degradation, fragmentation, and/or creep;

o) The product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

p) The frequency and manner of mesh erosion or extrusion;

q) The risk of chronic inflammation resulting from the product;

r) The risk of chronic infections resulting from the product;

s) The risk of permanent vaginal or pelvic scarring as a result of the product;

t) The risk of recurrent, intractable pelvic pain and other pain resulting from the product;

u) The need for corrective or revision surgery to adjust or remove the product;

v) The severity of complications that could arise as a result of implantation of the product;

w) The hazards associated with the product;

x) The product's defects described herein;

y) Treatment of pelvic organ prolapse and stress urinary incontinence with the product is no more effective than feasible available alternatives;

z) Treatment of pelvic organ prolapse and stress urinary incontinence with the product exposes patients to greater risk than feasible available alternatives;

aa) Treatment of pelvic organ prolapse and stress urinary incontinence with the product makes future surgical repair more difficult than feasible available alternatives;

bb) Use of the product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

cc) Removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

dd) Complete removal of the product may not be possible and may not result in complete resolution of the complications, including pain.

105. Further, Defendant failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case. Defendant also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers regarding the inadequate research and testing of the pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, and the complete lack of a safe, effective procedure for removal of the pelvic mesh products. Defendant intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of Defendant's pelvic mesh products, including the Obtryx II pelvic mesh product at issue in his case, understating the risks and exaggerating the benefits in order to advance its own financial interests, with wanton and willful disregard for Plaintiff's rights and health.

106. Had Defendant properly and adequately warned and instructed Plaintiff and her healthcare providers with regard to the Obtryx II pelvic mesh product's risks and potential complications, upon information and belief, Plaintiff would not have been recommended implantation of the Obtryx II pelvic mesh product, and Plaintiff would not have proceeded with implantation of the Obtryx II pelvic mesh product, thus avoiding the injuries Plaintiff has alleged herein.

107. As a proximate result of Defendant's design, manufacture, labeling, marketing, sale, and distribution of the pelvic mesh products, including the Obtryx II pelvic mesh product at issue in this case, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and economic damages.

108. Defendant, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

109. As a direct and proximate result of Defendant's failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Obtryx II pelvic mesh product at issue herein.

110. As a further direct and proximate result of the wrongful acts and omissions of Defendant, Plaintiff suffered severe injuries, emotional distress, and economic damages.

111. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

Punitive Damages

112. Plaintiff realleges and incorporates by reference Paragraphs 1 through 111 of this Complaint as if each were set forth fully and completely herein.

113. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint were malicious, willful, wanton, intentionally, oppressive, and fraudulent. Defendant committed these acts with a conscious disregard for the rights of Plaintiff and for the primary purpose of increasing Defendant's profits from the sale and distribution of the pelvic mesh products. Defendant's outrageous and unconscionable conduct warrants an aware of exemplary and punitive damages.

114. Prior to the manufacturing, sale, and distribution of the Obtryx II pelvic mesh product to Plaintiff and Plaintiff's healthcare providers, Defendant knew that said product was in a defective condition and users would experience and did experience severe injuries. Further, Defendant knew that the product presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendant unreasonably subjected Obtryx II users to the risk of injury from using the pelvic mesh products.

115. Despite its knowledge, Defendant, for the purpose of enhancing its profits, knowingly and deliberately failed to remedy the known defects in the Obtryx II pelvic mesh products and failed to warn of the extreme risk of injury occasioned by said defects inherent in the Obtryx II pelvic mesh products. Defendant intentionally proceeded with the manufacturing, sale, distribution, and marketing of the Obtryx II pelvic mesh products, knowing that these actions would expose users to serious danger in order to advance Defendant's pecuniary interest and monetary profits.

116. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

DEMAND FOR JURY TRIAL

117. Plaintiff hereby demands a trial by jury as to all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1) Compensatory damages in excess of the jurisdictional amount;

2) Economic damages in the form of medical, incidental, and hospital

expenses, out of pocket expenses, lost wages, and other economic damages in an amount to be determined at trial of this action;

3) Punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of its conduct and to deter similar conduct in the future;

4) Attorneys' fees, expenses, and costs of the action; and

5) Such further relief as the Court deems necessary, just, and proper.

Dated this 27th day of April 2022.

Respectfully submitted

/s/ Jonathan A. Knoll
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