IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

LYNDA STEPP AND
JOE MIKE STEPP **PLAINTIFFS**

V. **CAUSE NO.:** 3:22-cv-166-HTW-LGI

ETHICON, INC. and
JOHNSON & JOHNSON **DEFENDANTS**

COMPLAINT
JURY TRIAL DEMANDED

COME NOW, Plaintiffs Lynda Stepp and Joe Mike Stepp, by and through counsel, and do hereby file their Original Complaint in the above-styled cause of action complaining of Defendants Ethicon, Inc., and Johnson & Johnson, and would respectfully show unto the Court as follows:

I.
PARTIES

1. Plaintiffs Lynda Stepp and Joe Mike Stepp are adult individual citizens residing in Neshoba County, Philadelphia, Mississippi. On March 5, 2012, Linda Stepp was implanted with Ethicon's Gynecare Prosima pelvic mesh product ("Prosima" or "Pelvic Mesh Product") by Dr. Ronnye Purvis, M.D. at Anderson Regional Medical Center in Meridian, Mississippi

2. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation that has its principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

3. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant J&J located in Somerville, New Jersey. Ethicon, Inc. is a corporation organized and existing under New Jersey

law, maintaining its principal place of business at 555 US Route 22, Somerville, New Jersey 08876.

4. J&J and Ethicon, Inc. are collectively referred to herein as "Ethicon" or "Defendants".

5. All acts and omissions of the above-referenced Defendants 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.

II.
JURISDICTION AND VENUE

6. Plaintiffs Lynda Stepp and Joe Mike Stepp were residents of the Southern District of Mississippi at the time of Plaintiff Linda Stepp's implant of the Ethicon device, which surgery occurred at Anderson Regional Medical Center in Meridian, Mississippi.

7. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

8. Defendants have significant contacts with this federal judicial district therefore they are subject to the personal jurisdiction of the Court in this district. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district and therefore, pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

9. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this court has *in personam* jurisdiction over Defendants Ethicon, Inc. and Johnson & Johnson, because they are present in the state of Mississippi such that requiring appearance does not offend traditional notions of fair play and justice

III.
FACTUAL BACKGROUND

10. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Prosima.

11. Surgical mesh, including mesh used in Prosima the pelvic mesh product, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse. Most pelvic mesh products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and/or collagen, including Prosima.

12. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder,drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

13. Defendants' Prosima pelvic mesh product is targeted for women who suffer from POP as a result of the weakening or damage caused to the walls of the vagina. This product 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 prolapse, pelvic organ prolapse and/or rectocele.

14. Defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Prosima product manufactured by Defendants is considered a Class III medical device.

15. The Prosima pelvic mesh product contains polypropylene mesh, a type of plastic. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response ina large subset of the population receiving Defendants' Prosima pelvic mesh product. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh. At all times material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical provider, the medical community, the FDA, and the public at large.

16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory responsein a large subset of the population implanted with Defendants' Prosima pelvic mesh product.This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation,chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. At all times material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical provider, themedical community, the FDA, and the public at large.

17. Furthermore, the Prosima pelvic mesh product containing collagen cause hyper-

inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' Prosima collagen-containing products disintegrate after implantation into thefemale pelvis. The collagen-containing products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material. Cross linked collagen is harsh upon the female pelvic tissues because it hardens the bodily tissues. At alltimes material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical provider, the medical community, the FDA, and the public at large.

18. When this Prosima pelvic mesh product is inserted in the female body according to Defendants' instructions, it creates a non-anatomic condition in the pelvis leadingto chronic pain and functional disabilities.

19. In 2002, the FDA cleared the first pelvic mesh products for use in the treatment of pelvic organ prolapse ("POP"). These products included the Prosima product manufactured, marketed, and distributed by Defendants. This product was approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing ofa medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Prosima pelvic mesh product.

20. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market pelvic mesh products, including Prosima, underSection 510(k) of the Medical Device Amendment. 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. This clearance process did not require Defendants to prove the safety or efficacy of the Prosima pelvic mesh product and, thus, aformal review of the safety and efficacy of the Prosima

pelvic mesh product was never conducted with regard to the product.

21. Defendants' Prosima pelvic mesh product was marketed to the medical community and directly to patients as safe, effective, reliable medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, pelvic organ prolapse, and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment,and other competing pelvic mesh products.

22. The Defendants have marketed and sold the Prosima pelvic mesh product to the medical community at large and directly to 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.

23. Defendants also utilized documents, patient brochures and websites, offering exaggerated and misleading expectations as to the safety and utility of the Prosima pelvic mesh product.[1], [2]

24. Defendants further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out this product for implantation into their bodies.

25. At all times material to this action, the Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising,and delivering, and introducing into interstate commerce, including, *inter alia*, within the United

[1] *See e.g.,* Sales Aid for the Prosima, attached hereto as **Ex. A**.
[2] *See e.g.,* Patient Brochure for the Prosima, attached hereto as **Ex. B**. (The documents attached hereto, despite being marked CONFIDENTIAL, have been admitted at public trials causing them to lose any confidential status. *In re Bard IVC Filters Prods. Liab. Litig*., No. MDL 15-02641-PHX DGC, 2019 U.S. Dist. LEXIS 6124 (D. Ariz. Jan. 11, 2019)).

States, either directly or indirectly through third parties, subsidiaries or related entities, their Gynecare Prosima pelvic mesh product.

26. Each Prosima product was cleared for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

27. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverseevents") that had been reported over a three-year period relating to pelvic mesh products, including the Prosima.

28. Although the FDA notice did not identify the transvaginal mesh manufacturersby name, the FDA's MAUDE database indicates that the Defendants are the manufacturers ofthe Prosima pelvic mesh product that is the subject of the notification.

29. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, including the products manufactured, marketed and distributed by Defendants like the Prosima. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare." (emphasis in the original). The FDA had also received increased reports of complications associated with pelvic mesh products used in POP cases, including the Prosima.

30. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) isa 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).

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

32. 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 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."

33. The FDA summarized its findings from its review of the adverse event reportsand 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 expose patients to greater risks."(Emphasis in original).

34. The White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance datathat fail to demonstrate improved clinical benefit over traditional non-mesh repair." 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 White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organprolapse." The polypropylene mesh used in devices for transvaginal POP repair is the same mesh used in the Prosima.

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

36. 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 Prosima transvaginal meshinside the body as a serious complication associated with transvaginal 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 interventionto correct the condition, and some of the pain appears to be intractable.

37. 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." The polypropylenemesh used in devices for transvaginal POP repair is the same mesh used in the Prosima.

38. As is known to the Defendants, 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, including Defendants, oftheir Prosima pelvic mesh product used to treat POP in January of 2012.

39. In September 2011, the FDA acknowledged the need for additional data andnoted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence".

40. Defendants did not, and have not, adequately studied the extent of the risks associated with the Prosima product. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks. In 2012, because of the safety concerns it was seeing, the FDA issued orders requiring Defendants to conduct postmarket surveillance studies on all of their POP devices, including Prosima. Rather than conduct the FDA-ordered long-term safety studies, J&J chose to instead stop selling Prosima.

41. On April 16, 2019, the FDA ordered all transvaginal POP device manufacturers, including Defendants, to stop selling and distributing POP products immediately. The FDA had not received sufficient evidence to assure that the probable benefits of these devices outweighed their probable risks, and concluded that transvaginal POP products do not have a reasonable assurance of safety and effectiveness. The FDA has not banned Defendants' Prosima as of the date of this filing. But, considering the Prosima utilizes the same, banned polypropylene mesh utilized in POP devices, the Prosima's claimed benefits do not outweigh its risks.

42. Defendants knew or should have known that the Prosima product unreasonably exposed patients, including Plaintiff, to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing their Prosima pelvic mesh product, Defendants were aware that their Prosima pelvic mesh product was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic

mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory responsein a large subset of the population implanted with Defendants' Prosima pelvic mesh product. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, causes new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

43. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in deviceconstruction."

44. Defendants knew or should have known about the Prosima's risks and complications identified in the FDA Safety Communications and the ACOG/AUGS Joint Committee Opinion.

45. Defendants also knew or should have known that: (1) some of the predicate products for the Prosima pelvic mesh product had high failure and complication rates, resulting in the recall of some of these predicate devices; (2) that there were and are differences between the Defendants' Prosima pelvic mesh product and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between theProsima pelvic mesh product and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the

Prosima pelvic mesh product was and is causing numerous patients severe injuries and complications.

46. The Defendants suppressed information related to the Prosima and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and patients. As a result, the Defendants actively and intentionallymisled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Prosima and the proceduresfor implantation were and are safe and effective, leading to the prescription for and implantation of the Prosima pelvic mesh product into Plaintiff.

47. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Prosima pelvic mesh product.

48. Defendants failed to design and establish a safe, effective procedure for removal of their Prosima pelvic mesh product. Therefore, in the event of a failure, injury, orcomplications, it is impossible to easily and safely remove the Prosima pelvic mesh product.Defendants' above-referenced failures continue to this day.

49. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared tothe Defendants' Prosima pelvic mesh product, including but not limited to a device that utilizes less polypropylene mesh and has larger pores, and/or a biologic device.

50. The Prosima pelvic mesh product was at all times utilized and implanted in amanner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the Prosima device and trained the implanting physicians.

51. Furthermore, the Defendants provided incomplete, insufficient and misleading training and information to physicians, in order to increase the number of physicians utilizing their Prosima pelvic mesh product, and thus increase the sales of the Prosima pelvic mesh product, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

52. Before Prosima was removed from the market, Defendants' Prosima pelvic mesh product was marketed to the medical community and to patients as a safe, effective and reliable medical device, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasiblealternative treatments of POP, and other competing products.

53. Defendants misrepresented, omitted and downplayed the known risks, dangers, adverse events, contraindications, defects and disadvantages of the Prosima product, and advertised, promoted, marketed, sold and distributed the Prosima product as a safe medical device when Defendants knew or should have known that the Prosima product was not safe for its intended purposes, and that the Prosima product would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Prosima product was made known to physicians, the magnitude and frequency/extent of these problems were not disclosed and were hidden from physicians, including Plaintiff's implanting physician.[3]

54. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, including Plaintiff and her implanting physician, the Prosima product has high rates of failure, injury, and complications, fails to perform as intended, requires

[3] *See* Gynecare Prosima Instructions For Use ("IFU") in circulation at the time of Plaintiff's implant surgery, attached hereto as **Ex. C**.

frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making it defective under the law.

55. The specific nature of the Prosima product's defects include, but are not limited to, the following:

a. the use of polypropylene in the Prosima product and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associatedintractable pain;

b. the design of the Prosima product to be inserted into and through anarea of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. biomechanical issues with the design of the Prosima product which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious andpermanent injury;

d. the propensity of the mesh design characteristics of the Prosima productfor plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof,

to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. the propensity of the Prosima product to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted, and causing discomfort and pain with normal daily activities that involvemovement in the pelvic region (e.g., intercourse, defecation, walking);

f. the propensity of the Prosima product for degradation or fragmentation over time, which causes an increased surface area that leads to enhancedchronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time;

g. the hyper-inflammatory responses to Prosima collagen leading to problems including chronic inflammatory response, chronic pain and fibrotic reaction as well as infections and other serious adverse events;

h. the propensity of the Prosima collagen product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

i. the harshness of Prosima collagen upon the female pelvic tissue, and the hardening of the product in the body; and

j. the inability of surgeons to effectively treat many of these conditions due

to the integration of the Prosima mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

56. The Prosima product is also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of known subject including but not limited to, the following[4]:

a. the Prosima product's propensities to contract, retract, and/or shrinkinside the body;

b. the Prosima product's propensities for degradation, fragmentation and/or migration;

c. the Prosima product's inelasticity preventing proper mating with thepelvic floor and vaginal region;

d. the frequency and manner of transvaginal mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Prosima product;

f. the risk of chronic infections resulting from the Prosima product;

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

h. the risk of de novo urinary dysfunction;

i. the risk of de novo dyspareunia or painful sexual relations, including pain or injury to partner;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the Prosima product;

k. the need for corrective or revision surgery to adjust or remove the Prosima product which in some cases is not feasible nor possible;

[4] *See* **Ex. C.**

l. the severity of complications that could arise as a result ofimplantation of the Prosima product;

m. the hazards associated with the Prosima product;

n. the Prosima product's defects described herein;

o. treatment of POP with the Prosima product is no more effective than feasible, available and safer alternatives;

p. treatment of POP with the Prosima product exposes patients to greater risk than feasible, available and safer alternatives;

q. treatment of POP with the Prosima product makes future surgical repair more difficult than feasible, available and safer alternatives;

r. use of the Prosima product puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. removal of the Prosima product due to complications may involvemultiple surgeries and may significantly impair the patient's quality of life; and

t. complete removal of the Prosima product may not be possible and may not result in complete resolution of the complications, including pain.

57. At the time of Plaintiff's injuries, the Defendants' Prosima pelvic mesh productwas defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings, labels, and instructions were deficient.

58. Defendants' Prosima pelvic mesh product is dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients, including Plaintiff, and her health care providers, including her implanting physician.

59. In support of the facts stated herein, Defendants' Prosima pelvic mesh productthat was implanted in Plaintiff was defective and unreasonably dangerous at the time it left Defendants' possession, custody or control.

60. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Prosima pelvic mesh product, Plaintiff has been injured and has sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment oflife, loss of care, comfort, and economic damages. As long as Defendants' Prosima pelvic mesh product remains implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above- referenced and new injuries until death.

61. Throughout the relevant time periods, it was known or knowable to Defendants that their Prosima pelvic mesh product caused large numbers of complications thatwere not rare. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated withthe Prosima device. It was known or knowable to Defendants that the safety and efficacy of their Prosima pelvic mesh product had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to Defendants that there was no evidence that their Prosima pelvic mesh product was safe and effective and, in fact the evidence that was known or knowable to Defendants was that their Prosima pelvic mesh product was not safe and effective. Defendants continued to represent that their Prosima pelvic mesh product was safe and effective.

62. Defendants' knowledge of the risks of its polypropylene mesh devises, including Prosima were admitted by Ethicon's corporate witnesses at the trial of *The People of the State of California v. Johnson & Johnson, et al*, Case No. 37-2016-00017889-CU-MC-CTL, Superior Court of the State of California, County of San Diego, Central Branch (January 30, 2020),

including its Medical Director, Dr. Piet Hinoul, In that case, Dr. Hinoul testified concerning issues of degradation, shrinkage/contracture and other known complications of Ethicon's mesh devices unrelated to the procedures to implant them.

Table 1: Hinoul Testimony on Known Mesh Risks

TVT Complications	POP/Prolift Complications	Mesh Properties
• Vaginal exposure (lifelong/recurring) • Erosion to organs (lifelong/recurring) • Contracture causing pain • Removal for pain/dyspareunia • Debilitating/life changing pain • Chronic groin pain • Pain to partner • Chronic pain • Chronic dyspareunia (8/7/19 Tr. 38:12-39:14, 40:28-41:3, 41:21-42:15, 44:25-45:12 [Dr. Hinoul].)	• Same as "TVT Complications" • Risks to young, sexually active women • Incapacitating pelvic pain • Dyspareunia • Large scale erosion that are difficult to treat • Distortion of vaginal cavity interfering with intercourse • Shrinkage leading to pelvic pain and dyspareunia (8/7/19 Tr. 68:1-10, 70:2-11, 79:28-80:4, 81:15-82:8 [Dr. Hinoul].)	• Chronic foreign body reaction • Shrinkage/contraction • Infection/biofilm • Inflammation • Not inert (8/7/19 Tr. 79:28-80:4, 82:14-26, 83:21-23, 84:19-85:17 [Dr. Hinoul].)

63. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their Prosima pelvic mesh product through the relevant time periods, Defendants failed to disclose this information to the Plaintiff, to her physicians or to the publicat large.

64. At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid Prosima product, that is, that said product was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to causeserious consequences to users including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants'Prosima pelvic mesh product.

65. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Prosima product because: (a) Defendants were in a superior position toknow the true quality, safety and efficacy of the Defendants' Prosima pelvic mesh product; (b) Defendants knowingly made false claims about the safety and quality of Defendants' Prosima pelvic mesh product in the documents and marketing materials Defendants providedto the FDA, physicians, and the general public; and (c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Prosima pelvic mesh productfrom Plaintiff and her implanting physician.

66. The facts concealed and/or not disclosed by Defendants to Plaintiff and her implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Prosima pelvic mesh product.

67. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously misrepresented and concealed facts, as set forth above, from Plaintiff and her physicians, and therefore, Plaintiff, with the intent to defraud as herein alleged.

68. Defendants intentionally misrepresented, concealed and/or failed todisclose the true defective nature of the Prosima product so that Plaintiff and her implanting physician would request and purchase the Defendants' Prosima pelvic mesh product, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Prosima pelvic mesh product, and Plaintiff justifiably acted or relied upon, to her detriment, the misrepresented, concealed and/or non-disclosed facts as evidenced by her purchase of Defendants' Prosima pelvic mesh product. Plaintiff's implanting physician justifiably acted or relied upon, the misrepresented, concealed and/or non-disclosed facts as evidenced by his practices or hospital's purchase of Defendants' Prosima pelvic mesh product.

69. 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 haveacted as they did, that is, would not reasonably rely upon said representations of safety and efficacy and utilized the Prosima pelvic mesh product for treatment of Plaintiff's POP.

70. Defendants' failure to disclose and misrepresent the above-referenced information was a substantial factor in Plaintiff's implanting physician selecting Defendants'Prosima pelvic mesh product and procedure for treatment of Plaintiff's POP. This failure to disclose also resulted in the provision of incorrect and incomplete information to the Plaintiff as a patient. As a direct and proximate result of this conduct, Plaintiff was injured. As long as Defendants' Prosima pelvic mesh product or a portion of it remains implanted in Plaintiff, Plaintiff will continue to suffer the above-referenced and new injuries until death.

71. On several occasions after Defendants placed their Prosima on the market and before Plaintiff's implant surgery, Defendants failed to disclose and misrepresented the above-referenced information (risks, adverse events, and contraindications) to Plaintiff and her implanting physician. These omissions andmisrepresentations continue to this day with respect to the continued marketing and sale of Defendants' pelvic mesh devices.

72. Defendants' above-referenced misrepresentations were made by Defendants' retained key opinion leaders, agents, employees, representatives, or any other person acting on behalf of Defendants. These statements were made to Plaintiff's implanting physician at the hospital where he conducted Plaintiff's implant surgery, his office or practice, any training or educational sessions offered by Defendants, and/or at any professional organization meetings or presentations. These details are within Defendants' knowledge and control.

73. Upon information and belief, Ronnye Purvis, M.D. recommended the Prosima pelvic mesh product to Plaintiff Lynda Stepp as appropriate and safe for the treatment of pelvic

organ prolapse. Consequently, Plaintiff consented to the implantation of the device.

74. On March 5, 2012, Plaintiff Lynda Stepp underwent rectocele repair surgery to address her pelvic organ prolapse at Anderson Regional Medical Center in Meridian, Mississippi. During this surgery, she was implanted with Ethicon's Gynecare Prosima Mesh (LOT: 3542404)) by Dr. Ronnye Purvis, M.D.

75. On August 11, 2021, at Merit Health River Oaks in Flowood, Mississippi, Plaintiff Lynda Stepp underwent surgery to remove the Ethicon Gynecare Prosima Mesh as it had eroded into surrounding tissue, causing significant pain and bodily injury. As a result of having the Gynecare Prosima Mesh implanted in her, Plaintiff Lynda Stepp has experienced significant mental and physical pain and suffering, to include dyspareunia, disabling pelvic and vaginal pain, infections and difficulties walking, has sustained permanent injury and scarring, 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.

IV.
DISOVERY RULE, ESTOPPEL, AND FRAUDULENT CONCEALMENT

76. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

77. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

78. Despite diligent investigation by Plaintiffs into the cause of Plaintiff Lynda Stepp's injuries, including consultations with Plaintiff's medical provider, the nature of Plaintiff's injuries and damages and their relationship to the Pelvic Mesh Product were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

79. The running of the statute of limitations in this cause is tolled during anytime in which Plaintiffs suffered under a legal disability.

80. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiffs the nature of Plaintiff Lynda Stepp's injury and the connection between the injury and Defendants' tortious conduct. Defendants had actual knowledge of the wrong, they concealed the wrong by making a misrepresentation or by remaining silent when they had a duty to speak, they had a fixed purpose to conceal the wrong, and Plaintiff Lynda Stepp and her physician reasonably relied on the misrepresentation or silence.

V.
CAUSES OF ACTION
COUNT I: MISSISSIPPI PRODUCTS LIABILITY ACT ("MPLA") – DESIGN DEFECT

81. Plaintiffs incorporate by reference each and every material fact of this Complaint as if fully set forth herein.

82. The Mississippi Products Liability Act ("MPLA") provides for recovery from an injury caused by a design defect. See Miss. Code Ann. § 11-1-63(a)(3).

83. The Prosima designed, marketed, manufactured and distributed by Defendants was

defective and not reasonably safe due to its improper, inadequate, and defective design.

84. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Prosima. Plaintiff Lynda Stepp was an expected user or consumer of the Prosima.

85. The Prosima was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to the Prosima implanted in Plaintiff were reasonably foreseeable to Defendants.

86. The Prosima implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

87. The Prosima implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

88. Plaintiff and her healthcare provider used the aforementioned Prosima in a manner that was reasonably foreseeable to Defendants. Neither Plaintiff, nor her health care provider, could have, by the exercise of reasonable care, discovered the device's defective conditions or perceived its unreasonable dangers prior to the implantation of the Prosima mesh device.

89. At the time of implantation of the Prosima in Plaintiff Lynda Stepp, there were feasible and suitable alternative designs for implantation as compared to the Defendants' Prosima mesh device including biologic materials, autologous grafts, allografts and xenografts that would have been safer alternative devices to the Defendants' Prosima. Additionally, there were larger pore, lighter weight mesh devices that would have been safer alternatives, including Defendants' own Ultrapro mesh.

90. If any of these safer alternative designs been used for Plaintiff Lynda Stepp, she would not have suffered the injuries as set forth herein, including degradation, stiffness, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges, as Plaintiff's injuries were caused by these specific design flaws of the Prosima mesh device. These safer alternative designs were capable of preventing Plaintiff's injuries and damages.

91. The above-referenced defective propensities of the Prosima are specifically linked to Plaintiff's above-referenced injuries, such that she underwent reasonable and necessary revision procedure due to her chronic pain and mesh erosion. If the Prosima mesh device that was implanted in Plaintiff did not exhibit the above-referenced defective propensities, there would have been no need to undergo revision procedure because there would have been no erosion, at a minimum. The above-referenced defective propensities of the Prosima device continues to cause Plaintiff injuries to this day.

92. As long as mesh from the Prosima mesh device that was implanted in Plaintiff remains in her body, it will continue to degrade, shrink, contract, deform, harden, and cause the ongoing injuries described herein.

93. The Prosima implanted in Plaintiff Lynda Stepp was not reasonably safe for its intended uses and was defective as described herein with respect to its design. The Pelvic Mesh Device's design defects include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Prosima and the immune reaction that results from such material, causing adverse reactions and injuries;

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

c. Biomechanical issues with the design of the Prosima, including, but not limited to, the propensity of the Prosima 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 Prosima, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

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

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

g. The propensity of the Prosima 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 products to disintegrate after implantation

in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen 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 Prosima in the body;

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; and

m. The failure to provide adequate instructions for use (IFU) and training.

94. As a direct and proximate result of the Pelvic Mesh Device's defective design, Plaintiffs suffered severe injuries, emotional distress, and economic damages.

95. WHEREFORE, Plaintiffs Lynda Stepp and Joe Mike Stepp demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT II:
MISSISSIPPI PRODUCTS LIABILITY ACT ("MPLA") –
FAILURE TO WARN

96. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

97. The MPLA provides for recovery from an injury caused by a product that was

defective because it failed to contain adequate warnings or instructions. *See* Miss. Code Ann. § 11-1-63(a)(2).

98. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Prosima mesh device.

99. The Prosima was expected to, and did, reach the intended consumers, handlers, and persons receiving the product, including Plaintiff Lynda Stepp, with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled and marketed by Defendants.

100. The Prosima was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff Lynda Stepp's physician and/or healthcare provider and all other consumers of the product, making the products unreasonably dangerous.

101. The Prosima implanted in Plaintiff Lynda Stepp was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings.[5] Specifically, Defendants did not provide Plaintiff's implanting surgeon, Dr. Ronnye Purvis, sufficient or adequate warnings regarding, among other subjects:

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

b. The Prosima's propensities for degradation, fragmentation, disintegration and/or creep;

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

d. The rate and manner of mesh erosion or extrusion;

[5] *See* **Ex. B**.

e. The risk of chronic inflammation resulting from the Prosima;

f. The risk of chronic infections resulting from the Prosima;

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

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

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

j. The severity of complications that could arise as a result of implantation of the Prosima, including permanent nerve damage;

k. The hazards associated with the Prosima;

l. The Prosima's defects described herein;

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

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

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

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

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

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

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Prosima.

102. Defendants were and are aware that its Prosima product, as described herein, degrades, contracts, shrinks, frays, cords, migrates, stiffens, hardens, is cytotoxic, causes chronic inflammation, loses pore size with tension, and/or otherwise deforms at all times

103. Defendants' Instructions for Use ("IFU") and pamphlets or commercial documents for the Prosima device were provided to Plaintiff's implanting physician. The IFU was deficient for failure to disclose the above-referenced risks, adverse events, and contraindications of the device that was implanted in Plaintiff. The IFU also failed to warn Plaintiff and her implanting physician of the nature, degree, extent, and occurrence of the above-referenced risks, adverse events, and contraindications of the device that was implanted in Plaintiff. Defendants' IFU for the Prosima device is defective, deficient, and/or insufficient.

104. Defendants' IFU for the Prosima device is defective, deficient, and/or insufficient because it does not warn of all injuries alleged by Plaintiff.

105. Defendants' IFU for the Prosima device is defective, deficient, and/or insufficient because it does not list known adverse events and risks that caused the injuries that Plaintiff sustained, including shrinkage or contraction, degradation, cytotoxicity, deformation, the fact that the product has sharp edges, is rough, etc.—some or all of which caused the injuries suffered by Plaintiff.

106. Defendants' Prosima IFU is deficient because it fails to detail the extent and frequency of known complications, including mesh erosion and extrusion, experienced by Plaintiff.

107. Defendants' defective, deficient, and/or insufficient IFU, pamphlets or commercial

documents, paid-for studies, training and presentation materials, for the Prosima device that was implanted in Plaintiff made this product unreasonably dangerous.

108. Defendants' defective, deficient, and/or insufficient IFU, pamphlets or commercial documents, paid-for studies, training and presentation materials, for the Prosima device that was implanted in Plaintiff proximately caused her above-referenced injuries.

109. Plaintiff's implanting physician, Dr. Purvis, relied, in part, on Defendants' defective, deficient, and/or insufficient IFU and pamphlets or commercial documents during his consent process with Plaintiff prior to implanting the Prosima device in her. Also, Plaintiff's implanting physician relied on written and/or oral information she received from Defendants before implanting this device in Plaintiff. Plaintiff's implanting physician would have conveyed the above-referenced information to Plaintiff during her consent process for the Prosima. Ultimately, the decision whether or not to have the Prosima implanted lies with the Plaintiff.

110. The Prosima is also defective since Defendants did not properly package or label the product to give reasonable warnings of danger about the Prosima when Defendants, by exercising reasonable diligence, could have made such warnings or instructions available to Plaintiff and her implanting physician.

111. If Defendants provided Plaintiff's implanting physician with adequate warnings in the Prosima's IFU or other materials provided, Plaintiff's implanting physician would have heeded those warnings.

112. If Plaintiff's implanting physician was adequately warned by being informed of all known risks, adverse events, and contraindications of the Prosima device, Plaintiff's implanting physician would have warned Plaintiff of the same.

113. Upon information and belief, Plaintiff's implanting physician would have changed

his consent process and/or not recommended Defendants' Prosima to Plaintiff if Defendants had given proper and adequate warnings to him.

114. Plaintiff was not properly consented to have the Prosima device implanted in her because Defendants did not inform her implanting physician of the above-referenced risks, adverse events, and contraindications of the device that was implanted in Plaintiff.

115. Plaintiff's implanting physician did not have independent knowledge of the above-referenced risks, adverse events, and contraindications of the Prosima device that was implanted in Plaintiff.

116. Defendants also have a post-implant and continuing duty to warn Plaintiff, her implanting physician and medical providers, the medical community, and/or the public at large of the Prosima product's known characteristics or defective propensities as described herein. Defendants breached and continue to breach these duties owed to Plaintiff, her implanting physician and medical providers, the medical community, and/or the public. These duties are continuing in nature and will only expire until Defendants' Prosima device is permanently removed from the bodies of all women who were implanted with this device, which is not likely to occur.

117. Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff Lynda Stepp, Plaintiff's healthcare provider, and the medical community. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare provider, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare provider were not adequately informed of the potential dangers and/or defects of the Prosima mesh device. Had Defendants properly disclosed the risks associated with the Prosima for transvaginal use, Plaintiff would not have agreed to treatment with this device.

118. As a direct and proximate result of the wrongful acts and omissions of Defendants as set forth hereinabove, Plaintiffs suffered severe injuries, emotional distress, and economic damages.

WHEREFORE, Plaintiffs Lynda Stepp and Joe Mike Stepp demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT III:
MPLA – FAILURE TO CONFORM TO REPRESENTATIONS

119. Plaintiffs incorporate by reference each and every material fact of this Complaint as if fully set forth herein.

120. The MPLA provides for recovery based on a failure to conform to representations. *See* Miss. Code Ann. § 11-1-63(a)(1)(4).

121. The Mississippi Supreme Court contemplates two separate and distinct claims for breach of express warranty and failure to conform to representations. *See Forbes v. General Motors Corp.,* 935 So.2d 869, 875 (Miss. 2006) (citation omitted).

122. Plaintiffs' failure to conform to representations claim is based, in part, on Defendants' statements based on past and present facts regarding the Prosima device that was implanted in Plaintiff.

123. Defendants made representations or promises to Plaintiff and her implanting physician that the Prosima would perform as intended by curing or alleviating Plaintiff's pelvic organ prolapse in the future, after it was implanted in Plaintiff.

124. Defendants made representations or promises to Plaintiff and her implanting provider that the Prosima would not degrade, deform, shrink, contract, or exhibit any of the defective propensities detailed herein in the future, after it was implanted in Plaintiff.

125. Defendants' representations regarding their Prosima pelvic mesh product did not conform, when they represented and continue to represent:

a. the design of the Prosima product so as to avoid an unreasonable risk of harm to women in whom the product was implanted, including the Plaintiff;

b. the manufacture of the Prosima product so as to avoid an unreasonable risk of harm to women in whom the product was implanted, including the Plaintiff;

c. the testing of the Prosima product so as to avoid an unreasonable risk of harm to women in whom the product was implanted, including the Plaintiff;

d. the inspecting the Prosima product to avoid an unreasonable risk of harm to women in whom the product was implanted, including the Plaintiff; and

e. otherwise misrepresenting the designing, manufacturing, marketing, labeling, packaging and/or selling of the Prosima product.

126. The Defendants' misrepresentations caused the Prosima product to be unreasonably dangerous and defective include, but are not limited to:

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

b. the design of the Prosima product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing

immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Prosima 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 propensity of the Prosima product for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

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

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

g. the propensity of the Prosima product to cause long standing inflammatory response altering the effective porosity of the mesh resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage and resulting neuromas; and

h. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the Defendants' Prosima instructions.

127. Defendants made the above-referenced express representations of material fact concerning the character, quality, and safety of their Prosima product, including misrepresenting that the Prosima is safe and effective; does not cause chronic injuries; and does not degrade, contract or shrink, fray, cord, curl, harden, lose particles, corrode, and/or otherwise deform.

128. The Prosima that was implanted in Plaintiff did not confirm to the above-referenced representations.

129. Plaintiff Lynda Stepp and her implanting physicians justifiably relied on the above-referenced representations regarding the Prosima device.

130. Plaintiff's justifiable reliance on the above-referenced representations is the direct and proximate cause of her pelvic-related injuries addressed herein.

131. The Defendants' Prosima pelvic mesh product is dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

132. Defendants had and have a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, the FDA, and the public, that the Prosima pelvic mesh products had not been adequately tested and found to be safe and effective for the treatment of pelvic organ prolapse. The representations made by Defendants, in fact, were false.

133. Defendants failed to exercise ordinary care in their representations concerning the Prosima pelvic mesh product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants misrepresented the Prosima pelvic mesh product's high risk of unreasonable, dangerous, adverse side effects. Defendants' above-referenced failures continue to this day with other similar pelvic mesh devices they manufacture, market and sell.

134. Defendants breached their duty in representing that the Defendants' Prosima pelvic mesh product has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community. Defendants' above-referenced breaches continue to this day with other similar pelvic mesh devices they manufacture, market and sell.

135. As a direct and proximate result of Defendants' failure to conform to representations, 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 or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages. As long as any portion of Defendants' Prosima pelvic mesh product remains implanted in Plaintiff, Plaintiff will continue to suffer the above-referenced and new injuries until death.

WHEREFORE, Plaintiffs Lynda Stepp and Joe Mike Stepp demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT IV:
LOSS OF CONSORTIUM

136. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

137. Plaintiff Joe Mike Stepp is the spouse of Plaintiff Lynda Stepp, and as a direct and proximate result of Defendants' conduct as described in this Complaint, the Spouse Plaintiff

alleges that his marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered. Additionally, Plaintiff Joe Mike Stepp has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

138. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Joe Mike Stepp has suffered the following injuries and damages:

a. Direct personal injury, as well as great emotional pain and mental anguish as a result of the implantation of the defective Prosima device described hereinabove;

b. Loss of household services sustained in the past;

c. Loss of household services that, in reasonable probability, Plaintiff Joe Mike Stepp will sustain in the future;

d. Loss of consortium sustained in the past; and

e. Loss of consortium that, in reasonable probability, Plaintiff Joe Mike Stepp will sustain in the future.

COUNT V:
VICARIOUS LIABILITY

139. Whenever in this Complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, or representatives.

140. As a direct and proximate result of Defendants' improper acts and/or omissions

described herein, Plaintiffs were caused to suffer severe injuries and damages, including the following:

a. Physical pain and mental anguish sustained in the past;

b. Physical pain and mental anguish that, in reasonable probability, Plaintiffs will sustain in the future;

c. Disfigurement sustained in the past;

d. Disfigurement that, in reasonable probability, Plaintiffs will sustain in the future;

e. Loss of earning capacity sustained in the past;

f. Loss of earning capacity that, in reasonable probability, Plaintiffs will sustain in the future;

g. Physical impairment sustained in the past;

h. Physical impairment that, in reasonable probability, Plaintiffs will sustain in the future;

i. Medical care expenses incurred in the past; and

j. Medical care expenses that, in reasonable probability, Plaintiffs will incur in the future.

COUNT VI:
PUNITIVE DAMAGES

141. Plaintiffs hereby incorporate by reference as if fully set forth herein, each and every allegation of fact contained in each and every paragraph above, and further allege as follows:

142. At all times relevant hereto, Defendants Ethicon, Inc. and Johnson & Johnson knew or should have known that the Prosima was inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, remedial surgeries and treatments in an effort to cure the

conditions proximately related to the use of the product as well as other severe and personal injuries dangerous which are permanent and lasting in nature.

143. At all times material here too, Defendants Ethicon, Inc. and Johnson & Johnson attempted to misrepresent and did misrepresent facts concerning the safety of the Prosima.

144. Defendants Ethicon, Inc. and Johnson & Johnson's misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff and her physician, concerning the safety and efficacy of the Prosima.

145. At all times material hereto, Defendants Ethicon, Inc. and Johnson & Johnson knew and recklessly disregarded the fact that the Prosima causes debilitating and potentially catastrophic side effects with greater frequency than safer alternative methods, products, and/or procedures, and/or treatments.

146. At all times material hereto Defendants Ethicon, Inc. and Johnson & Johnson intentionally misstated and misrepresented data and continued to misrepresent data so as to minimize the risk of injuries caused by the Prosima.

147. Notwithstanding the foregoing, Defendants Ethicon, Inc. and Johnson & Johnson continued to aggressively market the Prosima to consumers, including Plaintiff's physician, without disclosing the true risk of side effects when there were safer alternatives.

148. Defendants Ethicon, Inc. and Johnson & Johnson knew of the Prosima's defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Prosima so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Prosima.

149. Defendants Ethicon, Inc. and Johnson & Johnson continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of its polypropylene mesh devices.

150. Defendants Ethicon, Inc. and Johnson & Johnson's intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Prosima against her benefit.

151. As a direct and proximate result of foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that she will in the future be required to obtain further medical care and/or hospital care and medical services.

152. Defendants Ethicon, Inc. and Johnson & Johnson have engaged in conduct entitling Plaintiffs to an award of punitive damages pursuant to common law principles.

WHEREFORE, Plaintiffs demand judgment against Defendants Ethicon, Inc. and Johnson & Johnson and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants Ethicon, Inc. and Johnson & Johnson, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, punitive damages, and all such other relief as the Court deems just and proper as well as:

A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiffs for all injuries and damages, both past and present;

B. All special and economic damages, in excess of the amount required for federal diversity to restriction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, pain and suffering;

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

D. Double or triple damages as allowed by law;

E. Punitive and/or exemplary damages;

F. Pre-judgment and post-judgment interest in the maximum amount allowed by land; and

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

DEMAND FOR JURY TRIAL

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

Respectfully Submitted,

/s/ Sheila M. Bossier
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