**Exhibit A**
**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

*MDL No. 2325*
*In Re American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation*

**FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND**

Plaintiffs, by and through their counsel, bring this First Amended Master Long Form Complaint as an administrative device to set forth potential claims individual plaintiffs may assert against Defendant in this litigation. By operation of Case Management Order No. 2, all allegations pled herein are deemed pled in any previously filed Complaint and in any First Amended Short Form Complaint hereafter filed.

**PARTIES, JURISDICTION & VENUE**

**PLAINTIFFS**

1.

Plaintiffs include women who had one or more of Defendants' pelvic mesh products listed in Paragraph 10 of this First Amended Master Complaint inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. Plaintiffs also include the spouses of some of said women, as well as others with standing to file claims arising from the Products.

**DEFENDANTS**

2.

American Medical Systems, Inc. ("AMS") is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc., Defendant AMS is a wholly owned subsidiary of defendant Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings Inc. and Endo Health

Solutions Inc. and is a Delaware corporation and may be served pursuant to 10 Del. C. § 3111 by serving its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

3.

Defendant American Medical Systems, Holdings Inc., ("AMS HOLDINGS") is a Delaware corporation and may be served pursuant to 10 Del. C. § 3111 by serving its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801 and is the parent of wholly-owned subsidiary AMS.

4.

Defendant Endo Pharmaceuticals, Inc. (ENDO) is a Pennsylvania corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania. 19317.

5.

Defendant Endo Pharmaceuticals Holdings, Inc. (ENDO HOLDINGS) was a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. ENDO HOLDINGS was the parent of wholly-owned subsidiary, ENDO. On May 23, 2012, ENDO HOLDINGS changed its name to Endo Health Solutions, Inc.

6.

Defendant Endo Health Solutions Inc. (ENDO HEALTH SOLUTIONS) is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. and is the parent of AMS and AMS HOLDINGS.

7.

Defendant ENDO HEALTH SOLUTIONS has aggregated four operating businesses into one enterprise including AMS and AMS HOLDINGS.

8.

At all relevant times, defendant ENDO merged with AMS and as part of that acquisition, purchased and assumed all liability relating to legal claims arising from the implantation of defective synthetic pelvic mesh systems. ENDO and AMS shall be referred to hereinafter collectively as "Defendants."

9.

At all times material to this action, Defendants have designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products was cleared for sale in the U.S. 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.

10.

The products known as Apogee, Perigee, Mini-Arc Sling, Monarc Subfascial Hammock, Sparc, Bio-Arc, In-Fast Ultra, Influence In-Fast, and Elevate as well as any variations of these products and any unnamed AMS pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as "Defendants' Pelvic Mesh Products" or "the Products".

**VENUE**

11.

Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. §

1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

12.

Defendants have significant contacts with the federal judicial district identified in the First Amended Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

13.

A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the First Amended Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

## FACTUAL BACKGROUND

14.

Defendants' Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth in the First Amended Short Form Complaint is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' 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 tissue. Animal collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

15.

Defendants sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices 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 with regard to the Products.

16.

On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "**rare**."

17.

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).

18.

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).

19.

The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

20.

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 expose 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."

25.

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."

26.

At the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication,

27.

The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions of use or labeling.

28.

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.

29.

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."

30.

The injuries of the female Plaintiff as will be more fully set forth in the Plaintiff's Fact Sheet to be served in this civil action are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

31.

Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

32.

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

33.

The scientific evidence shows that the material from which Defendants' Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including the female Plaintiff named in the First Amended Short Form Complaint.

34.

This 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 female Plaintiff named in the First Amended Short Form Complaint.

35.

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 device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

36.

The Products were unreasonably susceptible to shrinkage and contraction inside the body.

37.

The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

38.

The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, 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.

39.

Defendants omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including the female Plaintiff named in the First Amended Short Form Complaint, catastrophic injuries.

40.

Contrary to Defendants' 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 female Plaintiff named in the First Amended Short Form Complaint, making them defective under the law.

41.

The specific nature of the Products' defects includes, but is not limited to, the following:

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

b. the design of the Products to be inserted transvaginally, 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 Products, 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 Products, 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 Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them 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); and

g. the propensity of the Products 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;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product 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;

m. the procedure itself, which is part of Defendants' Pelvic Mesh Products, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs;

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

42.

The Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff named in the First Amended Short Form Complaint and/or her health care providers of subjects including, but not limited to, the following:

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

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

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

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

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

h. the risk of permanent vaginal shortening resulting from the Products;

i. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

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

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

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

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

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

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

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

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

43.

Defendants have underreported information about the propensity of the Products 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. Defendants have also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their pelvic meshes.

44.

Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

45.

Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

46.

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

47.

The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation, and provided training for the implanting physician.

48.

Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

49.

The Product or products implanted in the female Plaintiff named in the First Amended Short Form Complaint were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

50.

The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, 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, chronic pelvic pain and other debilitating complications.

51.

In many cases, including the female Plaintiff named in the First Amended Short Form Complaint, the 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.

52.

The medical and scientific literature studying the effects of Defendants' mesh products, like that of the product(s) implanted in the relevant female Plaintiff named in the First Amended

Short Form Complaint, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

53.

Removal of 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.

54.

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

55.

In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

56.

At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the female Plaintiff named in the First Amended Short Form

Complaint and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

57.

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

58.

As a result of having the Products implanted in her, the female Plaintiff named in the First Amended Short Form 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, and/or lost income, and other damages.

## CAUSES OF ACTION

## COUNT I: NEGLIGENCE

59.

Paragraphs 1-58 of this First Amended Master Complaint are hereby incorporated by reference as if fully set forth herein.

60.

Defendants had a duty to individuals, including the female Plaintiff named in the First Amended Short Form Complaint, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

61.

Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the First Amended Short Form Complaint;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the First Amended Short Form Complaint;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the First Amended Short Form Complaint;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the First Amended Short Form Complaint;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

62.

The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

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

b. the design of the Products 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 Products, 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 Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

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

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing

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

g. the propensity of the Products 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;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product 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 implanting according to the manufacturers' instructions.

63.

Defendant also negligently failed to warn or instruct the female Plaintiff named in the First Amended Short Form Complaint and/or her health care providers of subjects including, but not limited to, the following:

a. the Products’ propensities to contract, retract, and/or shrink inside the body;

b. the Products’ propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

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

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

f. the risk of chronic infections resulting from the Products;

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

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

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

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

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

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

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

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

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

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

64.

As a direct and proximate result of Defendants' negligence, the female Plaintiff named in the First Amended Short Form Complaint 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.

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

## COUNT II: STRICT LIABILITY – DESIGN DEFECT

65.

Plaintiffs incorporate by reference paragraphs 1-64 of this First Amended Master Complaint as if fully set forth herein.

66.

The Products implanted in the female Plaintiff named in the First Amended Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

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

b. the design of the Products 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 Products, 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 Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

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

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

g. the propensity of the Products 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;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product 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 implanting according to the manufacturers' instructions.

67.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the First Amended Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future 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.

68.

Defendants are strictly liable to the female Plaintiff named in the First Amended Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

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

**COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT**

69.

Plaintiffs incorporate by reference paragraphs 1-68 of this First Amended Master Complaint as if fully set forth herein.

70.

The Product(s) implanted in the female Plaintiff named in the First Amended Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the female Plaintiff named in the First Amended Short Form Complaint.

71.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the First Amended Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

72.

Defendant is strictly liable to the female Plaintiff named in the First Amended Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

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

## COUNT IV: STRICT LIABILITY – FAILURE TO WARN

73.

Plaintiffs incorporate by reference paragraphs 1-72 of this First Amended Master Complaint as if fully set forth herein.

74.

The Product(s) implanted in the female Plaintiff named in the First Amended Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

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

b. the Products' propensities for degradation, fragmentation, disintegration and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

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

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

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

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

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

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

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

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

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

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

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

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

75.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the First Amended Short Form Complaint 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, and/or lost income, and other damages.

76.

Defendant is strictly liable to the female Plaintiff named in the First Amended Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

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

## COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

77.

Plaintiffs incorporate by reference paragraphs 1-76 of this First Amended Master Complaint as if fully set forth herein.

78.

At the time of Plaintiffs' injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiffs, and the warnings labels, and instructions were deficient.

79.

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

80.

Plaintiffs from Alaska, Arizona, California, Florida, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Washington, D.C., West Virginia, Wisconsin, Wyoming and such other states where the common law, the Restatement of Torts (Second) and/or the Restatement of Torts (Third) are adopted, bring strict product liability

claims under the common law, Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third)) against Defendants.

81.

Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert each of these claims against Defendants.

82.

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

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

## COUNT VI: BREACH OF EXPRESS WARRANTY

83.

Plaintiffs incorporate by reference paragraphs 1-82 of this First Amended Master Complaint as if fully set forth herein.

84.

Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

85.

The female Plaintiff named in the First Amended Short Form Complaint and/or her healthcare provider chose the Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

86.

The female Plaintiff named in the First Amended Short Form Complaint, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

87.

Defendants breached these express warranties because the Product(s) implanted in the female Plaintiff named in the First Amended Short Form Complaint were unreasonably dangerous and defective as described herein and not as Defendants had represented.

88.

Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product(s) in the body of the female Plaintiff named in the First Amended Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

89.

As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the female Plaintiff named in the First Amended Short Form Complaint 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, and/or lost income, and other damages.

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

## COUNT VII: BREACH OF IMPLIED WARRANTY

90.

Plaintiffs incorporate by reference paragraphs 1-89 of this First Amended Master Complaint as if fully set forth herein.

91.

Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

92.

When the Products were implanted in the female Plaintiff named in the First Amended Short Form Complaint to treat her pelvic organ prolapse and/or stress urinary incontinence, the Products were being used for the ordinary purposes for which they were intended.

93.

The female Plaintiff named in the First Amended Short Form Complaint, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

94.

Defendants breached these implied warranties of merchantability because the Product(s) implanted in the female Plaintiff named in the First Amended Short Form Complaint were neither merchantable nor suited for their intended uses as warranted.

95.

Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of the female Plaintiff named in the First Amended Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

96.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the female Plaintiff named in the First Amended Short Form Complaint 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, and/or lost income, and other damages.

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

## COUNT VIII: FRAUDULENT CONCEALMENT

97.

Plaintiffs incorporate by reference paragraphs 1-96 of this First Amended Master Complaint as if fully set forth herein.

98.

On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

99.

The FDA further stated that "specific characteristics of patients at increased risk for complications have not been determined." As a result, the FDA recommended, among other things, Doctors "[o]btain specialized training for each mesh placement technique, and be aware of its risks."

100.

Despite the FDA's statement that complications caused by the mesh were "rare", the Defendant(s) knew at all times material to these actions that complications were, in fact not rare. Furthermore, the Defendant(s) knew at all relevant times that the FDA's focus on training and surgical technique of the implanting physicians was misguided.

101.

At all times prior to the October 20, 2008 Public Health Notification to the present, it was known or knowable to Defendant(s) that their pelvic mesh products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendant(s) that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendant(s) that the safety and efficacy of its pelvic mesh products 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 Defendant(s) that there was not evidence that its pelvic mesh products were safe and effective and, in fact the evidence that was known or knowable to Defendant(s) was that its pelvic mesh products were not safe and effective. Defendant continued to represent that its pelvic mesh products were safe and effective.

102.

Despite what was known or knowable to Defendant(s) about the lack of safety and efficacy of its pelvic mesh products prior to 2008, Defendant(s) failed to disclose this information to the plaintiffs, to their physicians or to the public at large.

103.

Despite this knowledge, Defendant(s) continued to market and sell their pelvic mesh products and procedures as being safe and efficacious with evidence to the contrary. Additionally, Defendant(s) wrongfully and intentionally, through their physician training program, provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

104.

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 products, that is, that said products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendant concealed these material facts prior to the time that plaintiffs were implanted with Defendants' pelvic mesh products.

105.

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

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

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

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

106.

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

107.

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

108.

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

109.

At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they

did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the AMS' pelvic mesh products for treatment of stress urinary incontinence and pelvic organ prolapse. Defendants' failure to disclose this information was a substantial factor in Plaintiffs' physicians selecting defendant(s) pelvic mesh products and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the plaintiff-patients.

110.

As a direct and proximate result of this conduct, Plaintiffs were injured.

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

**COUNT IX: CONSTRUCTIVE FRAUD**

111.

Plaintiffs incorporate by reference paragraphs 1-110 of this First Amended Master Complaint as if fully set forth herein.

112.

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

113.

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

114.

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

115.

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

116.

Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Defendants' Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Defendants' representations.

117.

Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud in their

relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

118.

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

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

**COUNT X: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT**

119.

Plaintiffs incorporate by reference paragraphs 1-118 of this First Amended Master Complaint as if fully set forth herein.

120.

Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

121.

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.

122.

Despite diligent investigation by Plaintiffs, including the female Plaintiff named in Plaintiffs' First Amended Short-Form Complaint, into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the Products was 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.

123.

The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

## COUNT XI: NEGLIGENT MISREPRESENTATION

124.

Plaintiffs incorporate by reference paragraphs 1-123 of this First Amended Master Complaint as if fully set forth herein.

125.

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

126.

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

127.

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

128.

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

129.

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

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

**COUNT XII : NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

130.

Plaintiffs incorporate by reference paragraphs 1-129 of this First Amended Master Complaint as if fully set forth herein.

131.

Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from

Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

132.

Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of being implanted with the Pelvic Mesh Products sold and distributed by Defendants and/or because of thee nature of their relationship to the individual implanted with the Pelvic Mesh Products

133.

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

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

**COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS**

134.

Plaintiffs incorporate by reference paragraphs 1-133 of this First Amended Master Complaint as if fully set forth herein.

135.

Plaintiffs purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

136.

Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

137.

Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

138.

Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and,

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

139.

Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was

to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

140.

Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

141.

Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

142.

Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

143.

Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

144.

Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statutory provisions of the Plaintiffs' respective states.

145.

Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

146.

Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

147.

The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

148.

Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

149.

Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

150.

Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

151.

By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

152.

As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

## COUNT XIV: GROSS NEGLIGENCE

153.

Plaintiffs incorporate by reference paragraphs 1-152 of this First Amended Master Complaint as if fully set forth herein

154.

The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

155.

Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

156.

Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

157.

Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

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

**COUNT XV: UNJUST ENRICHMENT**

158.

Plaintiffs incorporate by reference paragraphs 1-157 of this First Amended Master Complaint as if fully set forth herein Defendants are and at all times relevant were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

159.

Plaintiffs paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

160.

Defendants have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Defendants' Pelvic Mesh Products.

161.

Plaintiffs have not received the safe and effective medical devices for which they paid.

162.

It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device as represented by Defendants.

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

## COUNT XVI: LOSS OF CONSORTIUM

163.

Plaintiffs incorporate by reference paragraphs 1-162 of this First Amended Master Complaint as if fully set forth herein.

164.

As a direct and proximate result of the above-described injuries sustained by the female Plaintiff named in the First Amended Short Form Complaint, where applicable, her spouse named in the First Amended Short Form Complaint has suffered a loss of spousal consortium, companionship, society, affection, services and support.

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

## COUNT XVII: PUNITIVE DAMAGES

165.

Plaintiffs incorporate by reference paragraphs 1-164 of this First Amended Master Complaint as if fully set forth herein.

166.

Defendants sold their Products to the Healthcare providers of the Plaintiff named in the First Amended Short Form Complaint and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

167.

Defendants sold the Products to the female Plaintiff named in the First Amended Short Form Complaint's health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this First Amended Master Complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff named in the First Amended Short Form Complaint and numerous other women.

168.

Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff named in the First Amended Short Form

Complaint and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Products as safe and effective.

169.

Defendants knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

170.

Defendants withheld material information from the medical community and the public in general, including the female Plaintiff named in the First Amended Short Form Complaint, regarding the safety and efficacy of the Products.

171.

Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

172.

Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

173.

Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

174.

Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including the female Plaintiff named in the First Amended Short Form Complaint.

175.

Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff named in the First Amended Short Form Complaint, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

176.

Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

**PRAYER FOR RELIEF**

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

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

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits;

3. Reasonable attorneys' fees;

4. The costs of these proceedings;

5. All ascertainable economic damages;

6. Punitive damages;

7. Survival damages (if applicable);

8. Wrongful death damages (if applicable); and

9. Such other and further relief as this Court deems just and proper.

Dated: August 24, 2012

Respectfully submitted,

/s/ Amy Eskin

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**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: August 24, 2012

Respectfully submitted,

/s/ Amy Eskin

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