UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In re: Cook Medical, Inc. Pelvic Repair System Products Liability Litigation	**)** **)**	**MDL No. 2440**

THIS DOCUMENT RELATES TO: ALL CASES

PRETRIAL ORDER # 13
(Direct Filing Order; Master Complaint, Short Form Complaint, Amended Short Form Complaint and Master Responsive Pleadings Due Date)

To eliminate the delays associated with the transfer of cases filed in or transferred from other federal district courts to this Court as part of MDL No. 2440, to promote efficiency and to accommodate plaintiffs who wish to bring claims against defendants in more than one pelvic repair system MDL, it is **ORDERED** as follows:

A. General.

(1) The attached Master Long Form Complaint and Jury Demand ("Master Complaint") against Cook Incorporated, Cook Medical Incorporated, and Cook Biotech Incorporated (sometimes collectively "Cook" or the "Cook Defendants") (Exhibit A), the Short Form Complaint for new cases against the Cook Defendants and others (Exhibit B), and the Amended Short Form Complaint for existing cases (Exhibit C), have been presented to the Court, and the Court **DIRECTS** that the Clerk file the same.

(2) The Cook Defendants shall file their Master Answers within 45 days of the entry of this Order.

(3) The Court refers the parties to Exhibit D, "Amended Filing Instructions for Short Form Complaints and Amended Short Form Complaints," which is appended to this Order.

(4) All factual allegations pled in the Master Complaint and all responses pled in the Cook Defendants' Master Answers are deemed pled in any previously filed Complaint and Responsive Pleading now pending in this MDL proceeding, and in any Short Form or Amended Short Form Complaint and Entry of Appearance hereafter filed; provided, however, the Master Complaint is applicable only as against Cook Medical Incorporated, Cook Incorporated, and Cook Biotech Incorporated.

B. Directly Filed Cases.[1]

(1) Subsequent to the filing of this Order, all actions initially filed directly in the Southern District of West Virginia in MDL 2440 against defendants named in the attached Master Complaint shall be filed by the Short Form Complaint. **If a Short Form Complaint is not utilized, the complaint will be struck from the docket; the plaintiff will have to file a Short Form Complaint and pay a second filing fee.**

(2) Subsequent to the filing of this Order, if a plaintiff filing a new case alleges she was implanted with pelvic repair system products manufactured or marketed by defendants in more than one MDL (i.e., plaintiff alleges that she was implanted with a Cook product and a product manufactured by a defendant named in a Master Long Form Complaint in MDL Nos. 2187, 2325, 2326, 2327, or 2387) and has claims against such defendants, then the plaintiff may choose in which MDL to initially file. However, such a plaintiff must check off each applicable defendant on the Short Form Complaint.

(3) For cases filed directly in MDL No. 2440 prior to the entry of this Order, each plaintiff shall file the attached Amended Short Form Complaint within ninety (90) days of entry of this Order, so long as the plaintiff names only defendants named in the Master Complaint in

[1] A "Directly Filed Case" is a case filed in the Southern District of West Virginia for inclusion in this MDL, but the Southern District of West Virginia does not necessarily have personal jurisdiction over the parties.

this MDL (and any defendants named in the Master Long Form Complaints in the other MDLs identified above).

(4) If a plaintiff filed directly in the Southern District of West Virginia in this MDL prior to the entry of this Order and named defendants other than those named in Master Complaints in this or the other five MDLs cited above, direct filing was inappropriate, and the plaintiff should either dismiss the inappropriately named defendants and file an **Amended** Short Form Complaint within 90 days of the entry of this Order or dismiss the direct filed case without prejudice and pursue her claims in her home district with subsequent transfer to this District through the MDL Panel. A plaintiff need not move to amend.

(5) This Court shall not be deemed to be the "transferor court" simply by virtue of the action having been directly filed in this District in this MDL. The direct filing of actions in MDL No. 2440 in the Southern District of West Virginia is solely for the purposes of consolidated discovery and related pretrial proceedings as provided by 28 U.S.C. § 1407; the parties submit to this Court's personal jurisdiction and venue in the Southern District for those purposes only. The defendants do not intend to waive their rights to transfer any case in this MDL to a court of proper venue under 28 U.S.C. § 1406(a) upon completion of all pretrial proceedings applicable to a case directly filed in the Southern District. At the conclusion of all pretrial proceedings, the Court, pursuant to 28 U.S.C. § 1404(a), will transfer each case filed directly in the Southern District to a federal district court of proper venue as defined in 28 U.S.C. § 1391, based on the recommendations of the parties to that case, or on its own determination after briefing from the parties if they cannot agree. In an effort to avoid serial objections to venue in a single action, plaintiff shall identify in response to a defendant's venue objection, proposed alternative venues

in order of preference, so that the Court can consider at the same time, any objections to plaintiff's alternative choices.

C. Cases Transferred by the Judicial Panel on Multidistrict Litigation ("MDL Panel").[2]

(1) For those cases transferred to MDL No. 2440 from another Federal District Court by the MDL Panel **after** the entry of this Order, those plaintiffs, who only named defendants named in Master Complaints in this or in one or more of the other five MDLs cited above (2187, 2325, 2326, 2327, 2387), shall file an **Amended** Short Form Complaint within 30 days of receipt of receipt of the member case number in MDL No. 2440.

For those cases transferred to MDL No. 2440 by the MDL Panel before or after the entry of this Order, wherein the plaintiff has named defendants named in Master Complaints in this or the other five MDLs noted above **AND** additional defendant(s) other than those named in Master Complaints, the plaintiff may not file an Amended Short Form Complaint, unless the plaintiff chooses to dismiss the additional defendants.

(2) Upon completion of the pretrial proceedings relating to a civil action as determined by this Court, civil actions in this MDL which were transferred to this Court by the MDL Panel shall be transferred for further proceedings to the District Court from which such action was transferred to this MDL.

D. All Cases.

(1) If a plaintiff in an existing case files an Amended Short Form Complaint in compliance with this Order that omits a defendant previously named in the prior complaint, the plaintiff is relieved of complying with Rule 41 of the Federal Rules of Civil Procedure in order

[2] A "Case Transferred by the MDL Panel" is a case filed in a district other than the Southern District of West Virginia and subsequently transferred to the Southern District by the MDL Panel.

to properly dismiss that defendant. Rather, where a plaintiff files an Amended Short Form Complaint, the Court instructs the Clerk, until further notice, to add defendants named in MDLs 2187, 2325, 2326, 2327, 2387, and 2440 as indicated on the Amended Short Form Complaints and to terminate any defendant not so indicated. If a plaintiff names an additional defendant listed on a Short Form Complaint but not named in the prior complaint, the plaintiff must comply with Rule 4 as to the new defendant.

(2) To the extent any change in parties on an Amended Short Form Complaint suggests that the case should be in a different MDL, an Amended Short Form Complaint should be accompanied by a motion to transfer MDLs. Attached hereto as Exhibit E is a PDF fillable form entitled "Motion to Transfer MDL," which also can be found on the Court's website. The Court strongly encourages use of this form.

(3) **Plaintiffs should not add parties to the Short Form or Amended Short Form Complaints or file versions of the Short Form or Amended Short Form Complaints that do not exactly match such complaints found on the Court's website. The Court will strike Short Form and Amended Short Form Complaints adding any party not named in a Master or Amended Master Complaint in MDLs 2187, 2325, 2326, 2327, 2387, or 2440. In the event a directly filed Short Form Complaint contains defendants not named in Master or Amended Master Complaints, the striking of such a pleading filed in a new case will require refiling and payment of a second filing fee.**

(4) **Plaintiffs must file the Amended Short Form Complaint in their member case, not in the main MDL case.**

(5) Each Short Form Complaint shall indicate those counts in the Master Complaint that are being asserted in the individual case and the specific consumer protection statute, if any, upon which the plaintiff relies.

(6) The Cook Defendants named in the Master Complaint, Cook Biotech Incorporated, Cook Incorporated, and Cook Medical Incorporated, are not required to file answers to Short Form or Amended Short Form Complaints. An Entry of Appearance (including an appearance entered prior to the filing of the Short Form Complaint) by an attorney representing such a defendant shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against any of the defendants named in the Master Complaint and an assertion of all defenses that are included in the Master Answers of the Cook Defendants once they are filed.

(7) If a defendant in MDL Nos. 2187, 2325, 2326, 2327, or 2387 is named in a case in this MDL, an Entry of Appearance (including an appearance entered prior to the filing of the Short Form or Amended Short Form Complaint) by an attorney representing such a defendant shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against any such defendant. In addition, the Master Responsive Pleading filed by that defendant in its designated MDL is deemed to be filed in that particular case.

(8) Upon agreement of the parties, given the large number of Complaints being filed, plaintiffs' counsel will meet and confer with defense counsel to advise the defendants before implementing any default procedures, and will provide the defendants ten business days in which to cure any alleged default.

(9) The Cook Defendants shall have thirty (30) days from the entry of this Order to file any motion asserting that the Master Complaint fails to state a claim upon which relief may

be granted, pursuant to Rule 12(b)(6), and plaintiffs shall have twenty (20) days thereafter to respond to the same.

The court **DIRECTS** the Clerk to file a copy of this order in 2:13-md-2440 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-28243. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: November 14, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In re: Cook Medical, Inc. Pelvic Repair System Products Liability Litigation	))	**MDL No. 2440**

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through counsel, bring this Master Long Form Complaint ("Master Complaint") as an administrative device to set forth potential claims individual plaintiffs may assert against defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any previously filed Complaint and any Short-Form Complaint hereinafter filed. Accordingly, plaintiffs allege as follows:

I. PARTIES

A. Plaintiffs

1. Plaintiffs include women who had one or more of defendants' pelvic mesh products (defined below) inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

2. Plaintiffs also include the spouses and intimate partners of the aforesaid women, as well as others with standing to file claims against defendants' products.

B. Defendants

3. Defendant, Cook Incorporated, is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, P. O. Box 489, Bloomington, Indiana 47402. Defendant Cook Incorporated alleges as follows: it is also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts. http://www.cookmedical.com/profile.do?id=profile_cookinc.

All acts and omissions of Cook Incorporated, 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. At all times material hereto, Cook Incorporated did business in all states of the United States of America.

4. Defendant, Cook Biotech, Inc., is a corporation organized under the laws of Indiana, with a principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906. Defendant, Cook Biotech alleges as follows: it was created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The company conducts research, development, and manufacturing operations in a state-of-the-art facility. Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials. In cooperation with university researchers, Cook Biotech has developed a line of products that can remodel native tissues using a biomaterial made from porcine small intestinal submucosa (SIS). Several FDA-cleared products using this technology to dress wounds or to surgically repair soft tissues are currently available from COOK and its distributors. Numerous potential medical applications for products made from SIS and other natural tissues are under development. http://www.cookmedical.com/profile.do?id=profile_biotech. All acts and omissions of Cook Biotech Inc. 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. At all times material hereto, Cook Biotech, Inc. did business in all states of the United States of America.

5. Cook Medical, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195.

Defendant Cook Medical Incorporated alleges as follows: it was established to offer a synchronized service for the efficient purchase and distribution of all Cook medical devices. With particular focus on lowering supply chain costs, the company coordinates price file access, purchase orders, ship points and accounts payable. http://www.cookmedical.com/profile.do?id=profile_cmi. All acts and omissions of Cook Medical, Inc. 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. At all times material hereto, Cook Medical, Inc. did business in all states of the United States of America.

6. Upon information and belief, the Cook defendants individually or collectively make, use, offer for sale, sell in the United States and/or import into the United States products used to treat pelvic organ prolapse and stress urinary incontinence including the Surgisis Biodesign system, the Stratasis TF Tension-Free Urethral Sling Kit, or line of pelvic products and related delivery devices.

7. All acts and omissions of each defendant 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.

8. Defendants share many of the same officers, directors, and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution, and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as “defendants”.

9. At all times relevant herein, defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training,

marketing, promoting, packaging, labeling, and/or selling such devices, and other pelvic mesh products unknown at the present (hereinafter collectively referred to as "pelvic mesh products" or the "products"). Defendants manufacture, market, advertise, promote and sell pelvic mesh products worldwide. As a result of the coordinated activities of all defendants named above, plaintiffs were implanted with defective pelvic floor repair products.

10. Defendants had a legal duty to insure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products. Furthermore, defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

II. DEFENDANTS' PELVIC MESH PRODUCTS

11. In or about 1999, defendants began to market and sell products for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

12. Specifically, Cook Biotech, Inc., sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of stress urinary incontinence: Surgisis Biodesign Urethral Sling on September 23, 1999; Surgisis Biodesign Tension-Free Urethral Sling on April 9, 2002; Stratasis Sling Kit on April 9, 2002; Stratasis Tension-Free Urethral Sling on September 1, 2002. Cook Biotech, Inc. sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of

pelvic floor repair; Surgisis Biodesign Anterior Pelvic Floor Graft; Surgisis Biodesign Posterior Pelvic Floor Graft; Surgisis Biodesign Vaginal Erosion Repair Graft on September 23, 1999; Stratasis TF Tension-Free Urethral Sling Kit on September 1, 2002.

13. Defendants' products were derived largely from hernia mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

14. Defendants' pelvic mesh products were designed, patented, manufactured, labeled, marketed, sold and distributed by the defendants, at all times relevant herein.

15. Defendants' make the following assertions regarding their products:

> Surgisis Biodesign is not a new graft or mesh, but a whole new category in the evolution of tissue repair. A breakthrough technology, it incorporates the best attributes of a biologic graft—**resistant to infection and complete remodeling**—with the added benefits of moderate price, ease of use and widespread availability. Surgisis Biodesign offers you a new level of assurance and, most important, contributes to an improved quality of life for your patient.
> http://www.cookmedical.com/bioNew/bio_overview.html.

16. Defendants' further assert the following about their Biodesign products: "And unlike synthetic mesh, **nothing is left permanently in the body to cause problems down the road**." http://www.cookbiodesign.com/for-patients/conditions/fistula/faqs.

17. On August 20, 2011, defendants issued a communication to the FDA in advance of the September 2011 Advisory Committee Hearings regarding the investigation into the risks associated with mesh for stress urinary incontinence and pelvic floor repair and/or pelvic floor prolapse. In its communication, defendants assert regarding its non-cross linked biologic matrix that: **"[a]ny inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain**."

18. Contrary to defendants assertions that its products are resistant to infection, result

in complete remodeling, are limited in inflammatory response to area where synthetic sutures are/were utilized during surgery and will not cause any problem down the road, the following non-inclusive literature suggests otherwise:

A. In November of 2005, results from a study were published in the International Journal of Obstetrics & Gynecology relating to the comparison of the host response, architectural integration and tensile strength of polypropylene to porcine small intestine submucosa-derived implants including defendants SIS products. Implants from the SIS group showed a short term increase in thickness in the first 14 days. **Formation of adhesions was significantly more extensive in the SIS group at 90 days. Tensile strength increased over time in both groups but was significantly lower in the SIS group. Implants in the SIS group showed inflammatory response**.

   Konstantinovic ML., Lagae P., Zheng F., Verbeken EK., De Ridder D., Deprest JA. (2005). Comparison of host response to polypropylene and non-cross-linked porcine small intestine serosal-derived collagen implants in a rat model. *BJOG: An International Journal of Ostetrics & Gynecology, 112(11), 1554-1560*.

   See also Dora CD, Dimarco DS, Zobitz ME, Elliott DS. Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: Implications for sling surgery. J Urol. 2004 May; 171(5):1970-3

   See also Krambeck AE, Dora CD, Sebo TJ, Rohlinger AL, DiMarco DS, Elliott DS. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. Urology. 2006 May; 67(5):1105-10

B. In October of 2008, results from a study were published in the Archives of Gastroenterology relating to the comparison of the repair of induced abdominal wall defects with defendants' Surgisis mesh and Covidien, Inc.'s Parietex. Both meshes induced skin erosions. There were peritoneal adhesions to the surface of both types of meshes after 30 and 60 days. **Meshes' shinking correspond to 1/3 of the original size and Parietex caused less inflammatory process at the histologic evaluation**.

   Baroncello JB., Czeczko NG., Malafaia O., Ribas-Filho JM., Nassif PA., Dietz AU. (2008). [The repair of abdominal defects in rabbits with Parietex and Surgisis meshes abdominal wall]. Arquivos de Gastroenterologia, 45(4), 323-9.

C. In November of 2008, results from a study were published in Urology relating to reports of intense local inflammatory reactions in patients undergoing pubovaginal sling or tape using a small intestinal submucosa graft. **After implantation of 16 standard pubovaginal sling or tension-free tape procedures for stress urinary incontinence, using the Cook 4-ply Stratasis or 8-ply Stratasis-TF system, 5 (31.3%) had intense suprapubic pain after surgery. One patient had induration of the mons pubis that required surgical drainage. One patient had vaginal inflammation, with expulsion of graft material. Other patients had intense rectus sheath inflammation, as confirmed on computed tomography. This study confirmed previous case reports of inflammatory complications of small intestinal submucosa leading to that institution's cessation of use of Defendants' products.**

> John TT., Aggarwal N., Singla AK., Santucci RA. (2008). Intense inflammatory reaction with porcine small intestine submucosa pubovaginal sling or tape for stress urinary incontinence. Urology, 72(5), 1036-9.

D. In January of 2009, results from a study were published in the Journal of Biomedical Materials Research Part B relating to the evaluation of Defendants' Surgisis Gold to other materials including C.R. Bard, Inc.'s Permacol; Ethicon's Prolene mesh and Life Cell's Alloderm in the context of human mesothelial cells. **The results of the study indicate that Surgisis Gold was inferior in aiding in the growth and fibrinolytic activity of human mesothelial cells than other products**.

> Wilshaw SP., Burke D., Fisher J., Ingham E. (2009). Investigation of the antiadhesive properties of human mesothelial cells cultured in vitro on implantable surgical materials. Journal of Biomedical Materials Research Part D: Applied Biomaterials, 88(1), 49-60.

E. In October of 2011, results from a study were published in the Archives of Gastroenterology relating to the comparison of different biologic materials regarding relative implant integration, shrinkage, and foreign body reaction. Relating to **Defendants' Surgisis, the integration of its product was insufficient and could detached easily from the underlying tissue; the penetration of fibroblasts and vessels was limited; foreign body reaction was pronounced, leading to persistent granulomatous inflammation; and shrinkage was excessive in comparison to all other products. Other products yielded sufficient anti-adhesion and elicited no foreign body reaction**.

> Petter-Puchner AH., Fortelny RH., Silic K, Brand J., Gruber-Blum S., Redl H. (2011). Biologic hernia implants in experimental intraperitoneal onlay mesh plasty repair: the impact of proprietary collagen processing methods and fibrin sealant application on tissue integration. Surg Endosc, 25(10), 3245-52.

F. In February of 2012, results from a study were published in Hernia relating to the comparison of different biologic meshes including Defendants' Surgisis Gold regarding the relative performance and efficacy as between two non-crosslinked meshes and two crosslinked prostheses. **Major complications seen with Defendants' product included: that it appeared to be wrinkled and folded by excessive shrinkage, eliciting severe adhesions and a pronounced local inflammation, characterized by foreign body giant cells. The multilayer design was preserved but disintegrated by transversal movement of layers against each other**.

> de Castro Brás LE., Shurey, S., Sibbons, PD. (2012). Evaluation of crosslinked and non-crosslinked biologic prostheses for abdominal hernia repair. Hernia, 16(1), 77-89.

G. In September of 2012, results from a study were published in Biomaterials relating to the clinical performance of biomaterials in the context of comparing leukocyte activation by commercially available biologic surgical materials and define the extent manufacturing variables influence down-stream response. The data demonstrated **Defendants' Surgisis Biodesign which was implanted in plaintiff showed excessive leukocyte activation and was significantly more pro-inflammatory as compared to the other products analyzed. High degrees of leukocyte activation lead to poor material/patient compliance, accelerated degeneration and graft rejection**.

> Bryan N., Ashwin H., Smart N., Bayon Y., Scarborough N., Hunt JA. (2012). The innate oxygen dependant immune pathway as a sensitive parameter to predict the performance of biological graft materials. Biomaterials, 33(27), 6380-92.

IV. FACTUAL BACKGROUND

19. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI. Today, defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also

tissue fixation anchors and insertion tools. The products manufactured by defendants are considered Class II medical devices.

20. Defendants' pelvic mesh products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are 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, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

21. Moreover, these pelvic mesh products contain biological mesh. Despite claims that this material is inert, the scientific evidence show that this mesh material is biologically reactive with human tissue and promotes an immune response in a large subset of the population receiving defendants' pelvic mesh products. This immune response promotes infection and rejection of the biological mesh, as well as damage to the surrounding pelvic tissue. This reaction will contribute to the formation of severe adverse reactions to the mesh and recurrence of pelvic organ prolapse and stress incontinence.

22. At various times, defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the pelvic mesh products under Section 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 pelvic mesh products and, thus, a formal review of the safety and efficacy of the pelvic mesh products was never conducted with regard to the products.

23. Defendants' pelvic mesh products have been and continue to be marketed to the

medical community and directly to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse 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.

24. The defendants have marketed and sold the pelvic mesh products 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. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the pelvic mesh products. Defendants' further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

25. At all times relevant to this action, defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the pelvic mesh products and advertised, promoted, marketed, sold and distributed the pelvic mesh products as a safe medical device when, in fact, defendants knew that the pelvic mesh products were not safe for their intended purposes and that the pelvic mesh products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries.

26. For example, defendants described in its patient brochures, instructions for use, and other marketing materials, that the known complications for its pelvic mesh products were

consistent with any surgical procedure of an implantable medical device and described such occurrences as “rare” and “small” when, in fact, defendants knew or should have known that the complications were not “rare” and “small” but common, permanent, and debilitating.

27. Contrary to defendants’ representations and marketing to the medical community and to the patients themselves, the defendants’ pelvic mesh products have high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the plaintiffs, making them defective under the law. The products’ defects include, but are not limited to:

a. the use of biologic material in the mesh itself and the immune reaction that results, causing chronic infections, adverse reactions and injuries;

b. the design of the pelvic mesh products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. the procedure itself, which is a part of the pelvic mesh products, requires to the physician to insert the device “blindly,” resulting in nerve damage and damage to other organs;

d. biomechanical issues with the design of the mesh that create an increased reaction between the native tissue and the foreign body of the product, leading to injuries and complications;

e. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in increased inflammatory response, excessive scarring, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

f. the use and design of anchors in the pelvic mesh products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

g. the intended design of the product in dissolving and degrading in the tissue over some desired and hopeful time period does not allow for appropriate long-term successful results and, in fact, causes an increased immune

reaction and a resultant cascade of inflammatory events leading to excessive scarring and chronic pelvic pain;

h. the design of trocars, as devices to insert the pelvic mesh products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing chronic pelvic pain and other injuries;

i. the mesh does not maintain its integrity over time, leading to loss of function for its intended purpose of providing support to the tissues in which it is implanted;

j. folding of the product inside the body leading to increased inflammatory reaction and recurrence; and,

k. the creation of a non-anatomic condition in the pelvic tissues leading to an increased foreign body reaction and an enhanced and chronic inflammatory response further leading to chronic pain, recurrence, erosion, excessive scarring and functional disabilities when the mesh is implanted according to the manufacturer's instructions

28. Upon information and belief, the defendants have consistently under-reported and withheld information about the propensity of the defendants' pelvic mesh products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the pelvic mesh products through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

29. Defendants have further deliberately chosen to forego the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

30. Despite the chronic under-reporting of adverse events associated with the defendants' pelvic mesh products, the under-reporting of events associated with similarly designed competitor products, and defendants' deliberately avoiding the conduct of studies and registries to avoid the reporting of adverse events, eventually enough complaints were recorded

for the FDA to issue a public health notification regarding the dangers of these devices.

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

32. On July 13, 2011, the FDA issued a Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse, were "not rare". These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

33. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of pelvic organ prolapse with mesh or repair of stress urinary incontinence with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." The

FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

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

35. In fact, 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.

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 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.

37. 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.

38. Defendants also knew or should have known that: (1) some of the predicate products for the pelvic mesh products had high failure and complication rates, resulting in the

recall of some of those predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the defendants' pelvic mesh products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the pelvic mesh products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the pelvic mesh products were and are causing numerous patients severe injuries and complications.

39. The defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, the defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the pelvic mesh products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the pelvic mesh products into plaintiff.

40. Defendants' pelvic mesh products are also defective due to defendants' failure to adequately warn or instruct the female plaintiffs named in the Short Form Complaint and/or her health care providers of risks and complications 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 implant versus host interaction with the pelvic floor and vaginal region;

d. the products lack of porosity in preventing proper mating with the pelvic floor and vaginal region;

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

f. the risk of chronic inflammation resulting from the products;

g. the risk of chronic infections resulting from the products;

h. the risk of chronic foreign body reaction due to the presence of the product.

i. the risk of permanent vaginal or pelvic scarring as a result of the products;

j. the risk of permanent vaginal shorting as a result of the products;

k. the risk of recurrent, intractable pelvic pain and other pain resulting from the products;

l. the need for corrective or revision surgery to adjust or remove the products;

m. the severity of complications that could arise as a result of implantation of the products;

n. the hazards associated with the products;

o. the products' defects described herein;

p. folding of the product inside the body;

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

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

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

t. use of the products puts the patients at greater risk of requiring additional surgery than feasible available alternatives;

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

v. complete removal of the products is most likely not possible and may not result in complete resolution of the complications, including pain and recurrent urinary leakage and pelvic organ prolapse.

w. the fact that neither pelvic organ prolapse, nor stress urinary incontinence, are life threatening conditions, and that other options, including non-surgical options, were available and superior alternatives to the use of the products.

51. 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 pelvic mesh products.

52. Defendants failed to design and establish a safe, effective procedure for removal of the pelvic mesh products. Therefore, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the pelvic mesh products.

53. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the defendants' pelvic mesh products.

54. The pelvic mesh products were at all times utilized and implanted in a manner foreseeable to the defendants, as defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

55. Furthermore, the defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the pelvic mesh products, and thus increase the sales of the pelvic mesh products, and also leading to the dissemination of inadequate and misleading information to patients, including plaintiff.

56. The pelvic mesh products implanted into the plaintiffs were in the same or substantially similar condition as they were when they left the possession of defendants, and in the condition directed by and expected by the defendants.

57. Plaintiffs and plaintiffs' physicians foreseeably used and implanted the pelvic mesh products, and did not misuse or alter the pelvic mesh product in an unforeseeable manner.

58. The injuries, conditions, and complications suffered by women who have been implanted with defendants' pelvic mesh products include but are not limited to, mesh erosion, mesh contraction, mesh vaginal exposure mesh folding, mesh degradation, chronic foreign body reaction, chronic immune response, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical and surgical treatment, including, but not limited to, operations to locate and remove the mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control, intensive physical therapy, and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

59. The medical and scientific literature studying the effects of biologic pelvic mesh, like defendants' pelvic mesh products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

60. Defendants misrepresented to the medical and healthcare community, plaintiffs, the FDA, and the public that the pelvic mesh products had been tested and were found to be safe and effective for the purpose of treating incontinence and/or prolapse.

61. These representations were made by defendants with the intent of inducing the medical community, plaintiff, and the public, to recommend, prescribe, dispense, and purchase the pelvic mesh products for use as a means of treatment for stress urinary incontinence and/or

prolapse, all of which evinced an indifference to the health, safety, and welfare of plaintiff.

62. Defendants failed to undertake their duties to properly know the qualities of their pelvic mesh products and in representations to plaintiffs and/or to plaintiffs' healthcare providers, and concealed and intentionally omitted the following material information:

a. That the pelvic mesh products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the pelvic mesh products were not as effective as other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the pelvic mesh products was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. That the risk of adverse events with the pelvic mesh products were not adequately testing and were known by defendants;

e. That the limited clinical testing revealed the pelvic mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

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

g. That defendants were aware of dangers in the pelvic mesh products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. That the pelvic mesh products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. That patients needed to be monitored more regularly than usual while using the pelvic mesh products and that in the event the pelvic mesh products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

j. That the pelvic mesh products were manufactured negligently;

k. That the pelvic mesh products were manufactured defectively; and

l. That the pelvic mesh products were designed negligently, and designed defectively.

63. Defendants were under a duty to disclose to plaintiffs and plaintiffs' physicians, the defective nature of the pelvic mesh products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

64. Defendants had sole access to material facts concerning the defective nature of the pelvic mesh products and their propensity to cause serious and dangerous side effects and hence cause dangerous injuries and damage to persons who used the pelvic mesh products;

65. Defendants' concealment and omissions of material fact concerning the safety of the pelvic mesh products were made to cause the plaintiffs, the plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the pelvic mesh products; and/or to mislead plaintiffs and plaintiffs' physicians into reliance and cause plaintiffs to have the pelvic mesh products implanted into their bodies.

66. At the time these representations were made by defendants, and at the time plaintiffs used the pelvic mesh products, plaintiffs were unaware of the falsehood of these representations and reasonably believed them to be true.

67. Defendant knew or had reason to know that the pelvic mesh products could and would cause severe and grievous personal injury to the users of the pelvic mesh products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

68. In reliance upon these false representations, plaintiffs were induced to, and did use the pelvic mesh products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that plaintiffs and plaintiffs' physicians and

other healthcare providers had no way to determine the truth behind defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the pelvic mesh products, as described in detail herein.

69. As a result of defendants' research and testing or lack thereof, defendants distributed false information, including but not limited to assuring plaintiffs, the public, and plaintiffs' healthcare providers and physicians, that the pelvic mesh products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. Further, defendants misrepresented to the plaintiffs and to plaintiffs' physicians that the pelvic mesh products were more effective than other means of treatment for these conditions for which they were implanted. As a result of defendants' research and testing, or lack thereof, defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, plaintiffs, and the public at large.

70. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, plaintiffs, plaintiffs' healthcare providers, and the FDA.

71. The information distributed to the public, the medical community, the FDA, and plaintiffs by defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the pelvic mesh products.

72. Defendants intentionally made material representations to the medical community and public, including plaintiffs, regarding the safety of the pelvic mesh products, specifically,

that the pelvic mesh products did not have dangerous and/or serious adverse health safety concerns, and that the pelvic mesh products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

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

74. Defendants chose to over-promote the safety, efficacy and benefits of the pelvic mesh products instead.

75. Defendants' intent and purpose in making these representations was to deceive the public, the medical community, and plaintiffs; to gain the confidence of the public, the medical community, and plaintiffs; to falsely assure them of the quality and fitness for use of the pelvic mesh products; and induce plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the pelvic mesh products;

76. Upon information and belief, defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the pelvic mesh products did not present serious health risks.

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

78. These representations, and others made by defendants, were made with the intention of deceiving plaintiffs, plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce plaintiffs, and plaintiffs' healthcare professionals, to rely on misrepresentations, and caused plaintiffs to purchase, rely, use, and

request the pelvic mesh products, and caused her healthcare professionals to dispense, recommend, or prescribe the pelvic mesh products.

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

80. At the time the representations were made, plaintiffs and plaintiffs' healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the pelvic mesh products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did plaintiffs discovery the false representations of defendants, nor would plaintiffs with reasonable diligence have discovered the true facts or defendants' misrepresentations.

81. Had plaintiffs known the true facts about the dangers and serious health and/or safety risks of the pelvic mesh products, plaintiffs would not have purchased, used, or relied on defendants' pelvic mesh products.

82. At all times relevant herein, the pelvic mesh products were widely advertised and promoted by the defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks poses to rectocele and vaginal prolapse patients with implantation of the pelvic mesh products.

83. At all times relevant to this action, defendants knew that the pelvic mesh products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous

manner causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic foreign body invasion, mesh folding, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

84. 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.

85. At all relevant times herein, defendants continued to promote pelvic mesh products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

86. In doing so the defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the pelvic mesh products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

87. At all relevant times herein, defendants failed to provide sufficient warnings and instructions that would have put plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the pelvic mesh products system including, but not limited to, mesh erosion, mesh folding, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

88. The pelvic mesh products as designed, manufactured, distributed, sold and/or supplied by defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of defendants' knowledge of lack of pelvic

health safety.

89. At all times herein mentioned, the employees, agents, officers, and/or directors of the defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned pelvic mesh products when they knew of the hazards and dangerous propensities of said pelvic mesh products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by plaintiffs.

V. FRAUDULENT CONCEALMENT

90. Defendant's failure to document or follow up on the known defects in its products, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

91. Defendants are estopped from relying on the statute of limitations defense because defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, defendants continued to represent its pelvic mesh products as safe for their intended use.

92. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their pelvic mesh products. Because of defendants' concealment of the true character, quality, and nature of their pelvic mesh products, defendants are estopped from relying on any statute of limitations defense.

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

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

95. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of plaintiffs.

96. Defendants' conduct as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of plaintiffs' Complaint.

VI. CAUSES OF ACTION

COUNT I

NEGLIGENCE

97. Paragraphs 1-96 of the Master Complaint are hereby incorporated by reference as if fully set forth herein.

98. Defendants had a duty to individuals, including plaintiffs, to exercise reasonable and ordinary care in the manufacture design, labeling, packaging, testing, instruction, warning, selling, marketing, distribution, and training related to its pelvic mesh products.

99. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the pelvic mesh products in one or more of the following respects:

a. Failing to design the products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including plaintiffs

b. Failing to manufacture the products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including plaintiffs;

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 plaintiffs;

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 plaintiffs;

e. Failing to use reasonable care in training its employees and health care providers related to the use of the products so as to avoid unreasonable risk of harm to women in whom the products were implanted, including plaintiffs;

f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public as set forth herein of risks associated with the products, so as to avoid unreasonable risk of harm to women in whom the products were implanted, including plaintiffs;

g. Failing to use reasonable care in marketing and promoting the products so as to avoid unreasonable risk of harm to women in whom the products were implanted, including plaintiffs;

h. In negligently and carelessly promoting the use of the pelvic mesh products to physicians who had not received sufficient training to master the techniques necessary for implantation of the device into the plaintiffs;

i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling, studying, testing, or selling the pelvic mesh products, and;

j. In failing to use reasonable care in seeking and obtaining FDA clearance prior to marketing the selling the devices for implantation into the human body.

100. Failed to conduct post-marketing vigilance, or surveillance, by:

a. Monitoring or acting on findings in the scientific and medical literature; and

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for defendants' pelvic mesh products.

101. Failed to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

a. Failed to report MDRs (Medical Device [adverse event] Reports); and

b. Failed to investigate reports of serious adverse events.

102. As a direct and proximate result of defendants' negligence, plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or 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 II

STRICT LIABILITY – MANUFACTURING DEFECT

103. Paragraphs 1 through 102 of the Master Complaint are hereby incorporated by reference as if fully set forth herein.

104. The pelvic mesh products implanted in plaintiffs were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posted an unreasonable risk of harm to plaintiffs in whom the pelvic mesh products were implanted.

105. The defendants' pelvic mesh products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

106. The pelvic mesh products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the pelvic mesh products.

107. Defendants have intentionally and recklessly manufactured the pelvic mesh products with wanton and willful disregard for the rights and health of the plaintiffs and others, and with malice, placing their economic interests above and health and safety of the plaintiffs and others.

108. As a direct and proximate result of the defendants' defective manufacture of the pelvic mesh products, plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

109. The defendants are strictly liable in tort to the plaintiffs for their wrongful conduct.

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 – FAILURE TO WARN

110. Paragraphs 1 through 109 of the Master Complaint are hereby incorporated by reference as if fully set forth herein.

111. The defendants failed to properly and adequately warn and instruct the plaintiffs and their health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the defendants' pelvic mesh products.

112. The defendants failed to properly and adequately warn and instruct the plaintiffs and their health care providers as to the risks and benefits of the defendants' pelvic mesh products, given the plaintiffs' conditions and need for information.

113. The defendants failed to properly and adequately warn and instruct the plaintiffs and their health care providers with regard to the inadequate research and testing of the pelvic mesh products, and the complete lack of a safe, effective procedure for removal of the pelvic mesh products.

114. In addition, the pelvic mesh products were defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

a. the use of biologic material in the mesh itself and the immune reaction that results, causing chronic infections, adverse reactions and injuries;

b. the design of the pelvic mesh products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. the procedure itself, which is a part of the pelvic mesh products, requires to the physician to insert the device "blindly," resulting in nerve damage and damage to other organs;

d. biomechanical issues with the design of the mesh that create an increased reaction between the native tissue and the foreign body of the product, leading to injuries and complications;

e. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in increased inflammatory response, excessive scarring, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

f. the use and design of anchors in the pelvic mesh products which when placed

correctly are likely to pass through and injure major nerve routes in the pelvic region;

g. the intended design of the product in dissolving and degrading in the tissue over some desired and hopeful time period does not allow for appropriate long-term successful results and, in fact, causes an increased immune reaction and a resultant cascade of inflammatory events leading to excessive scarring and chronic pelvic pain;

h. the design of trocars, as devices to insert the pelvic mesh products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing chronic pelvic pain and other injuries;

i. the mesh does not maintain its integrity over time, leading to loss of function for its intended purpose of providing support to the tissues in which it is implanted;

j. folding of the product inside the body leading to increased inflammatory reaction and recurrence; and,

k. the creation of a non-anatomic condition in the pelvic tissues leading to an increased foreign body reaction and an enhanced and chronic inflammatory response further leading to chronic pain, recurrence, erosion, excessive scarring and functional disabilities when the mesh is implanted according to the manufacturer's instructions

115. The defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the defendants' pelvic mesh products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the plaintiffs.

116. As a direct and proximate result of the pelvic mesh products' aforementioned defects, plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

117. The defendants are strictly liable in tort to the plaintiffs for their wrongful

conduct.

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 – DEFECTIVE PRODUCT

118. Paragraphs 1 through 117 of the Master Complaint are hereby incorporated by reference as if fully set forth herein. At the time of the plaintiffs' injuries, the defendants' pelvic mesh products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including plaintiffs, and the warning labels, and instructions were deficient.

119. The defendants' pelvic mesh products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

120. Plaintiffs from Alaska, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, Minnesota, 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.

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

122. 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 V

STRICT LIABILITY – DESIGN DEFECT

123. Plaintiffs incorporate by reference paragraphs 1 through 122 of this Master Complaint as if fully set forth herein.

124. The pelvic mesh products implanted in plaintiffs were not reasonably safe for their intended use and were defective as described herein with respect to their design. As previously stated, the products' design defects included, but are not limited to:

a. the use of biologic material in the mesh itself and the immune reaction that results, causing chronic infections, adverse reactions and injuries;

b. the design of the pelvic mesh products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. the procedure itself, which is a part of the pelvic mesh products, requires to the physician to insert the device "blindly," resulting in nerve damage and damage to other organs;

d. biomechanical issues with the design of the mesh that create an increased reaction between the native tissue and the foreign body of the product, leading to injuries and complications;

e. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in increased inflammatory response, excessive scarring, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

f. the use and design of anchors in the pelvic mesh products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

g. the intended design of the product in dissolving and degrading in the tissue over some desired and hopeful time period does not allow for appropriate long-term successful results and, in fact, causes an increased immune reaction and a resultant cascade of inflammatory events leading to excessive scarring and chronic pelvic pain;

h. the design of trocars, as devices to insert the pelvic mesh products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing chronic pelvic pain and other injuries;

i. the mesh does not maintain its integrity over time, leading to loss of function for its intended purpose of providing support to the tissues in which it is implanted;

j. folding of the product inside the body leading to increased inflammatory reaction and recurrence; and,

k. the creation of a non-anatomic condition in the pelvic tissues leading to an increased foreign body reaction and an enhanced and chronic inflammatory response further leading to chronic pain, recurrence, erosion, excessive scarring and functional disabilities when the mesh is implanted according to the manufacturer's instructions

125. As a direct and proximate result of the products' aforementioned defects as described herein, plaintiffs experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, other damages, and death.

126. Defendants are strictly liable to plaintiffs for designing a defective product.

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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

COMMON LAW FRAUD

127. Plaintiffs incorporate by reference paragraphs 1 through 126 of the Master Complaint as if fully set forth herein.

128. Defendants falsely and fraudulently represented and continue to represent to the medical and healthcare community, plaintiffs, and the public that the pelvic mesh products had been tested and were found to be safe and effective.

129. The representations made by defendants were, in fact, false. When defendants made their representations, defendants knew and/or had reason to know that those representations were false, and defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the pelvic mesh products.

130. These representations were made by defendants with the intent of defrauding and deceiving the medical community, plaintiffs, and the public, and also inducing the medical community, plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the pelvic mesh products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of plaintiffs.

131. In representations to plaintiffs and/or to plaintiffs' healthcare providers, defendants fraudulently concealed and intentionally or recklessly omitted the following material

information:

a. That the defendants' pelvic mesh products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the defendants' pelvic mesh products were not more effective than other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the defendants' pelvic mesh products was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. The defendants' pelvic mesh products were not adequately tested;

e. That the limited clinical testing revealed the defendants' pelvic mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f. That defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

g. That defendants deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to the plaintiff, the medical community, or the regulatory authorities;

h. That defendants were aware of dangers in the defendants' pelvic mesh products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

i. That the defendants' pelvic mesh products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

j. That patients needed to be monitored more regularly than usual while using the defendants' pelvic mesh products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

k. That the defendants' pelvic mesh products were manufactured negligently;

l. That the defendants' pelvic mesh products were manufactured defectively;

m. That the defendants' pelvic mesh products were designed negligently and designed defectively; and

132. Defendants were under a duty to disclose to plaintiffs and their physicians, the defective nature of the defendants' pelvic mesh products, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

133. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the defendants' pelvic mesh products.

134. Defendants' concealment and omissions of material fact concerning the safety of the products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the pelvic mesh products, and/or to mislead plaintiffs into reliance and cause plaintiffs to use the defendants' pelvic mesh products.

135. That the time these representations were made by defendants, and at the time plaintiffs used the pelvic mesh products, plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

136. Defendants knew and had reason to know that the defendants' pelvic mesh products could and would cause severe and grievous personal injury to the users of the defendants' pelvic mesh products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

137. In reliance upon these false representations, plaintiffs were induced to, and did use the pelvic mesh products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind defendants' concealment and

omissions, and that these included material omissions of facts surrounding the use of defendants' pelvic mesh products, as described in detail herein.

138. Plaintiffs reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the defendants' pelvic mesh products.

139. Having knowledge based upon defendants' research and testing, or lack thereof, defendants blatantly and intentionally distributed false information, including but not limited to assuring plaintiffs, the public, and plaintiff's healthcare providers and physicians, that the defendants' pelvic mesh products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of defendants' research and testing, or lack thereof, defendants intentionally omitted, concealed, and suppressed certain results of testing and research to healthcare professionals, plaintiffs, and the public at large.

140. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public. Plaintiffs, plaintiffs' healthcare providers, and the United States Food and Drug Administration ("FDA").

141. The information distributed to the public, the medical community, the FDA, and plaintiffs, by defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the defendants' pelvic mesh products.

142. Defendants intentionally made material misrepresentations to the medical community and public, including plaintiffs, regarding the safety of the defendants' pelvic mesh products specifically that the products did not have dangerous and/or serious adverse health safety concerns, and that the defendants' pelvic mesh products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

143. Defendants intentionally failed to inform the public, including plaintiffs, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and risk of permanent injury.

144. Defendants chose to over-promote the purported safety, efficacy, and benefits of the defendants' pelvic mesh products instead.

145. Defendants' intent and purpose in making these representations was to deceive and defraud the public, the medical community, and plaintiffs; to gain the confidence of the public, the medical community, and plaintiffs; to falsely assure them of the quality and fitness for use of the products; and induce plaintiffs, the public, and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the defendants' pelvic mesh products.

146. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the defendants' pelvic mesh product had innovative beneficial properties and did not present serious health risks.

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

148. These representations, and others made by defendants, were made with the intention of deceiving and defrauding plaintiffs, plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce plaintiffs, and their respective healthcare professionals, to rely on misrepresentations, and caused plaintiffs to purchase, rely, use, and request the defendants' pelvic mesh products and their healthcare professionals to dispense, recommend, or prescribe the defendants' pelvic mesh products.

149. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the defendants' pelvic mesh products to the public at large, for the purpose of influencing the sales of the products known to be dangerous and defective, and/or not as safe as other alternatives.

150. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling plaintiffs, as well as their healthcare professionals, into a false sense of security, so that plaintiffs and their healthcare providers would rely on defendants' representations, and plaintiffs would request and purchase the defendants' pelvic mesh products, and that their healthcare providers would dispense, prescribe, and recommend the defendants' pelvic mesh products.

151. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the defendants' pelvic mesh products.

152. At the time the representations were made, plaintiffs and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the defendants' pelvic mesh products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did plaintiffs discover the false representations of defendants, nor would plaintiffs with reasonable diligence have discovered the

true facts of defendants' misrepresentations.

153. Had plaintiffs known the true facts about the dangers and serious health and/or safety risks of the defendants' pelvic mesh products, plaintiffs would not have purchased, used, or relied on defendants' pelvic mesh products.

154. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on plaintiffs.

155. As a direct and proximate result of defendants' conduct, plaintiffs experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, other 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 VII

FRAUDULENT CONCEALMENT

156. Plaintiffs incorporate by reference paragraphs 1 through 155 of this Master Complaint as if fully set forth herein.

157. Plaintiffs from Alabama, Arizona, California, Colorado, Delaware, Georgia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin and any other states that recognize such a cause of action bring

this fraudulent concealment claim under the common law.

158. Throughout the relevant time period, defendants knew that their pelvic mesh products were defective and unreasonably unsafe for their intended purpose.

159. Defendants fraudulently concealed from and/or failed to disclose to or warn plaintiffs, their physicians, and the medical community that their pelvic mesh products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

160. 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.

161. 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.

162. 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.

163. Defendants, by concealment or other action, intentionally prevented plaintiffs and plaintiffs' physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the defendants' pelvic mesh products and are subject to the same liability to plaintiffs for plaintiffs' pecuniary losses, as though defendants had state the non-existence of such material information regarding the defendants' pelvic mesh products' lack of safety and effectiveness and dangers and defects, and as though defendants had affirmatively state the non-existence of such matters that plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia, Restatement (Second) of Torts* §550 (1977).

164. As a proximate result of 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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII

CONSTRUCTIVE FRAUD

165. Plaintiffs incorporate by reference paragraphs 1 through 164 of this Master Complaint as if fully set forth herein.

166. 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.

167. 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.

168. 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.

169. 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.

170. 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.

171. 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.

172. As a proximate result of the defendants' conduct, plaintiffs have been injured and have 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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX

NEGLIGENT MISREPRESENTATION

173. Plaintiffs incorporate by reference paragraphs 1 through 172 of this Master Complaint as if fully set forth herein.

174. 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.

175. 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.

176. 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.

177. 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.

178. 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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X

BREACH OF EXPRESS WARRANTY

179. Plaintiffs incorporate by reference paragraphs 1 through 182 of this Master Complaint as if fully set forth herein.

180. At all relevant and material times, defendants manufactured, distributed, advertised, promoted, and sold the defendants' pelvic mesh products.

181. At all relevant times, defendants intended that the defendants' pelvic mesh products be used in the manner that plaintiffs in fact used them and defendants expressly warranted that each product was safe and fit for use by consumers, that each product was of merchantable quality, that their side effects were minimal and comparable to other pelvic mesh products, and that they were adequately tested and fit for their intended use.

182. At all relevant times, defendants were aware that consumers, including plaintiffs, would use the pelvic mesh products; which is to say that plaintiffs were foreseeable users of the defendants' pelvic mesh products.

183. Plaintiffs and/or their implanting physicians were at all relevant times in privity with defendants.

184. The defendants' pelvic mesh products were expected to reach and did, in fact, reach consumers, including plaintiffs and their implanting physicians, without substantial change in the condition in which it was manufactured and sold by defendants.

185. Defendants breached various express warranties with respect to the pelvic mesh products including the following particulars:

a) Defendants represented to plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the defendants' pelvic mesh products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the pelvic mesh products;

b) Defendants represented to plaintiffs and their physicians and healthcare providers that the defendants' pelvic mesh products were as safe, and/or safer than other alternative procedures and devices, that complications are rare, and fraudulently concealed information, which demonstrated that the products were not safer than alternatives available on the market and that complications were not, in fact rare; and

c) Defendants represented to plaintiffs and their physicians and healthcare providers that the defendants' pelvic mesh products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

190. In reliance upon defendants' express warranties, plaintiffs were implanted with the defendants' pelvic mesh products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by defendants.

191. At the time of making such express warranties, defendants knew or should have

known that the defendants' pelvic mesh products do not conform to these express representations because the defendants' pelvic mesh products were not safe and had numerous serious side effects, many of which are common and defendants did not accurately warn about, thus making the defendants' pelvic mesh products unreasonably unsafe for their intended purpose.

192. Members of the medical community, including physicians and other healthcare professionals, as well as plaintiffs and the public relied upon the representations and warranties of defendants in connection with the use recommendation, description, and/or dispensing of the defendants' pelvic mesh products.

193. Defendants breached their express warranties to plaintiffs in that the defendants' pelvic mesh products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

194. Defendants' breaches constitute violations of common law principles and the statutory provisions of the plaintiffs' respective states.

195. 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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI

BREACH OF IMPLIED WARRANTY

196. Plaintiffs incorporate by reference paragraphs 1 through 195 of this Master

Complaint as if fully set forth herein.

197. At all relevant and material times, defendants manufactured, distributed, advertised, promoted, and sold the defendants' pelvic mesh products.

198. At all relevant times, defendants intended that the defendants pelvic mesh products be implanted for the purposes and in the manner those plaintiffs or plaintiffs' implanting physicians in fact used them and defendants impliedly warranted each product to be of merchantable quality, safe, and fit for such use, even though they were not adequately tested.

199. Defendants were aware that consumers, including plaintiffs or plaintiffs' physicians, would implant the defendants' pelvic mesh products in the manner directed by the instructions for use; which is to say that plaintiffs or plaintiffs' decedents were foreseeable users of the defendants' pelvic mesh products.

200. Plaintiffs and/or their physicians were at all relevant times in privity with defendants.

201. The defendants' pelvic mesh products were expected to reach and did, in fact, reach consumers, including plaintiffs or plaintiffs' physicians, without substantial change in the condition in which they were manufactured and sold by defendants.

202. Defendants breached various implied warranties with respect to the defendants' pelvic mesh products, including, but not limited to, the following particulars:

a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the defendants' pelvic mesh products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the pelvic mesh products;

b) Defendants represented that the defendants' pelvic mesh products were safe, and/or safer than other alternative devices or procedures and that complications were rare, and fraudulently concealed information, which demonstrated that the defendants' pelvic mesh products were not as safe or safer than alternatives

available on the market; and

c) Defendants represented that the defendants' pelvic mesh products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the defendants' pelvic mesh products.

203. In reliance upon defendants' implied warranty, plaintiffs used the pelvic mesh products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by defendants.

204. Defendants breached their implied warranty to plaintiffs in that the defendants' pelvic mesh products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles and the statutory provisions of the plaintiffs' respective states.

205. 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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII

VIOLATION OF CONSUMER PROTECTION LAWS

206. Plaintiffs incorporate by reference paragraphs 1 through 205 of the Master Complaint as if fully set forth herein.

207. 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.

208. 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.

209. 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.

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

a) Representing that goods or serves 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.

211. 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.

212. 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.

213. 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.

214. 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.

215. 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.

216. 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.

217. 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, advertiser, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

218. 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.

219. 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.

220. 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.

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

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

223. 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.

224. 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 compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII

GROSS NEGLIGENCE

225. Plaintiffs incorporate by reference paragraphs 1 through 224 of this Master Complaint as if fully set forth herein.

226. 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.

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

228. 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.

229. 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 will 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,

punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIV

UNJUST ENRICHMENT

230. Plaintiffs incorporate by reference paragraphs 1 through 229 of this Master Complaint as if fully set forth herein.

231. Defendants are and at all times relevant were the manufacturers, sellers, and/or suppliers of the defendants' pelvic mesh products.

232. 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.

233. Defendants have accepted payment by plaintiffs and others on plaintiffs' behalf for the purchase of the defendants' pelvic mesh products.

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

235. 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, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV

LOSS OF CONSORTIUM

236. Plaintiffs incorporate by reference paragraphs 1 through 235 of this Master

Complaint as if fully set forth herein.

237. At all relevant times hereto, plaintiffs had spouses (hereafter referred to as "spouse plaintiffs") and/or family members (hereinafter referred to as "family member plaintiffs") who have suffered injuries and losses as a result of the pelvic mesh products and plaintiffs' injuries.

238. For the reasons set forth herein, spouse plaintiffs and/or family member plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of defendants' misconduct.

239. For the reasons set forth herein, spouse plaintiffs and /or family member plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

240. For all spouse plaintiffs, plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

241. Spouse plaintiffs and/or family member plaintiffs have suffered great emotional pain and mental anguish.

242. As a direct and proximate result of defendants' wrongful conduct, spouse plaintiffs, family member plaintiffs, and/or intimate partners of the aforesaid women, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to spouse plaintiffs, family member plaintiffs, and intimate partners jointly and severally for all

general, special, and equitable relief to which spouse plaintiffs, family member plaintiffs, and intimate partners are entitled by law.

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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI

PUNITIVE DAMAGES

243. Plaintiffs incorporate by reference paragraphs 1 through 242 of this Master Complaint as if fully set forth herein.

244. Defendants sold their products to plaintiffs' healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the products were reasonably safe for implantation in the female pelvic area.

245. Defendants sold the products to plaintiffs' healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the products were reasonably safe for implantation in the female pelvic area.

246. Defendants sold the products to plaintiffs' healthcare providers and other healthcare providers throughout the United States in spite of their knowledge that their products can shrink disintegrate, and/or degrade inside the body, and caused the other problems heretofore set forth in this First Master Complaint, thereby causing severe and debilitating injuries suffered by the plaintiffs.

247. At all times relevant hereto, defendants knew or should have known that the defendants' pelvic mesh products were inherently dangerous with respect to the risks of erosion,

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 product, as well as other severe and personal injuries which are permanent and lasting in nature.

248. At all times material hereto, defendants attempted to misrepresent and did misrepresent facts concerning the safety of the defendants' pelvic mesh products.

249. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including plaintiffs concerning the safety and efficacy of the defendants' pelvic mesh products.

250. At all times material hereto, defendants knew and intentionally and/or recklessly disregarded the fact that the defendants' pelvic mesh products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

251. At all times material hereto, defendants knew and intentionally and/or recklessly disregarded the fact that the defendants' pelvic mesh products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise healthcare providers, the public, and the FDA of same.

252. At all times material hereto, defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the defendants' pelvic mesh products.

253. Notwithstanding the foregoing, defendants continue to aggressively market the defendants' pelvic mesh products to consumers, without disclosing the true risk of side effects and complications.

254. Defendants knew or the defendants' pelvic mesh products defective and

unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the defendants' pelvic mesh products so as to maximize sales and profits at the expense of the health and safety of the public, including plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by the defendants' pelvic mesh products.

255. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including plaintiffs, the serious side effects of the defendants' pelvic mesh products in order to ensure continued and increased sales.

256. Defendants' intentionally, reckless and /or grossly negligent failure to disclose information deprived plaintiffs of necessary information to enable them to weigh the true risks of using the defendants' pelvic mesh products against their benefits.

257. As a direct and proximate result of the foregoing acts and omissions, plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

258. Defendants have engaged in conduct entitling plaintiffs to an award of punitive damages pursuant to Common Law principles and the statutory provisions of the plaintiffs' respective states.

259. 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.

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, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVII

DISCOVERY RULE AND TOLLING

260. Plaintiffs incorporate by reference paragraphs 1 through 259 of this Master Complaint as if fully set forth herein.

261. 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.

262. 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.

263. Despite diligent investigation by plaintiffs 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.

264. 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).

V. 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 cost of these proceedings;
5. All ascertainable economic damages;
6. Medical monitoring damages;
7. Punitive damages;
8. Survival damages (if applicable);
9. Wrongful death damages (if applicable); and
10. Such other and further relief as this Court deems just and proper.

Dated: October 15, 2013

Respectfully submitted,

/s/ Martin D. Crump_____

Martin D. Crump
Davis & Crump, P.C.
1712 15th Street, 3rd Floor
Gulfport, MS 39501
228-863-6000 (phone)
228-864-0907 (fax)
martin.crump@daviscrump.com

/s/ Benjamin H. Anderson_____

Benjamin H. Anderson
Anderson Law Offices, LLC
1360 W. 9th Street, Suite 215
Cleveland, OH 44113
ben@andersonlawoffices.net

DEMAND FOR JURY TRIAL

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

Dated: October 15, 2013

Respectfully submitted,

/s/ Martin D. Crump

Martin D. Crump
Davis & Crump, P.C.
1712 15th Street, 3rd Floor
Gulfport, MS 39501
228-863-6000 (phone)
228-864-0907 (fax)
martin.crump@daviscrump.com

/s/ Benjamin H. Anderson

Benjamin H. Anderson
Anderson Law Offices, LLC
1360 W. 9th Street, Suite 215
Cleveland, OH 44113
ben@andersonlawoffices.net

Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In Re: Cook Medical, Inc.,
Pelvic Repair System Products Liability Litigation
MDL No. 2440
Civil Action No. _____

SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate the Master Complaint in MDL No. 2440 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

   _____

2. Plaintiff Spouse (if applicable)

   _____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator)

   _____

4. State of Residence

   _____

5. District Court and Division in which venue would be proper absent direct filing

   _____

   _____

6. Defendants (Check Defendants against whom Complaint is made):

   ☐ A. Cook Incorporated

☐ B. Cook Biotech, Inc.

☐ C. Cook Medical, Inc.

☐ D. American Medical Systems, Inc. (“AMS”)

☐ E. Ethicon, Inc.

☐ F. Ethicon, LLC

☐ G. Johnson & Johnson

☐ H. Boston Scientific Corporation

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

☐ K. Tissue Science Laboratories Limited (“TSL”)

☐ L. Mentor Worldwide LLC

☐ M. Coloplast Corp.

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other: _____

A. Paragraphs in Master Complaint upon which venue and jurisdiction lie:

_____

_____

_____

B. Other allegations of jurisdiction and venue

_____

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff)

- ☐ A. Biodesign® or Surgisis® Tension-Free Urethral Sling;
- ☐ B. Biodesign® or Surgisis® Urethral Sling;
- ☐ C. Stratasis™ Urethral Sling;
- ☐ D. Biodesign® or Surgisis® Anterior Pelvic Floor Graft;
- ☐ E. Biodesign® or Surgisis® Posterior Pelvic Floor Graft;
- ☐ F. Biodesign® or Surgisis® 4-Layer Tissue Graft;
- ☐ G. Biodesign® or Surgisis® 1-Layer Tissue Graft;
- ☐ H. Biodesign® or Surgisis® 8-Layer Tissue Graft;
- ☐ I. Biodesign® or Surgisis® Vaginal Erosion Repair Graft;
- ☐ J. Biodesign® or Surgisis® Peyronie's Repair Graft;
- ☐ L. Cook Pelvic Repair Product(s), specific product name(s) unknown at present;
- ☐ M. Non-Cook Pelvic Repair Product(s) known as _____; and/or
- ☐ N. Other: _____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products)

- ☐ A. Biodesign® or Surgisis® Tension-Free Urethral Sling;
- ☐ B. Biodesign® or Surgisis® Urethral Sling;
- ☐ C. Stratasis™ Urethral Sling;
- ☐ D. Biodesign® or Surgisis® Anterior Pelvic Floor Graft;
- ☐ E. Biodesign® or Surgisis® Posterior Pelvic Floor Graft;
- ☐ F. Biodesign® or Surgisis® 4-Layer Tissue Graft;
- ☐ G. Biodesign® or Surgisis® 1-Layer Tissue Graft;
- ☐ H. Biodesign® or Surgisis® 8-Layer Tissue Graft;

☐ I. Biodesign® or Surgisis® Vaginal Erosion Repair Graft;

☐ J. Biodesign® or Surgisis® Peyronie's Repair Graft;

☐ L. Cook Pelvic Repair Product(s), specific product name(s) unknown at present;

☐ M. Non-Cook Pelvic Repair Product(s) known as _____; and/or

☐ N. Other: _____

_____

10. Date of Implantation as to Each Product

_____

_____

_____

11. Hospital(s) where Plaintiff was implanted (including City and State)

_____

_____

12. Implanting Surgeon(s)

_____

_____

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I - Negligence

☐ Count II - Strict Liability – Manufacturing Defect

☐ Count III - Strict Liability – Failure to Warn

☐ Count IV - Strict Liability – Defective Product

☐ Count V - Strict Liability – Design Defect

☐ Count VI – Common Law Fraud

☐ Count VII - Fraudulent Concealment

☐ Count VIII - Constructive Fraud

☐ Count IX - Negligent Misrepresentation

☐ Count X - Breach of Express Warranty

☐ Count XI - Breach of Implied Warranty

☐ Count XII - Violation of Consumer Protection Laws

☐ Count XIII - Gross Negligence

☐ Count XIV - Unjust Enrichment

☐ Count XV - (By the Spouse) – Loss of Consortium

☐ Count XVI - Punitive Damages

☐ Count XVII - Discovery Rule and Tolling

☐ Other _____ (please state the facts supporting this Count in the space, immediately below)

_____
_____
_____
_____
_____
_____
_____
_____
_____

s/ _____
Attorney(s) for Plaintiff

Address, phone number, email address and bar information:

Exhibit C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In Re: Cook Medical, Inc.,
Pelvic Repair System Products Liability Litigation
MDL No. 2440
Civil Action No. _____

AMENDED SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate the Master Complaint in MDL No. 2440 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

   _____

2. Plaintiff Spouse (if applicable)

   _____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator)

   _____

4. State of Residence

   _____

5. District Court and Division in which venue would be proper absent direct filing

   _____

   _____

6. Defendants (Check Defendants against whom Complaint is made):

   ☐ A. Cook Incorporated

☐ B. Cook Biotech, Inc.

☐ C. Cook Medical, Inc.

☐ D. American Medical Systems, Inc. (“AMS”)

☐ E. Ethicon, Inc.

☐ F. Ethicon, LLC

☐ G. Johnson & Johnson

☐ H. Boston Scientific Corporation

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

☐ K. Tissue Science Laboratories Limited (“TSL”)

☐ L. Mentor Worldwide LLC

☐ M. Coloplast Corp.

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other: _____

A. Paragraphs in Master Complaint upon which venue and jurisdiction lie:

_____

_____

_____

B. Other allegations of jurisdiction and venue

_____

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff)

- ☐ A. Biodesign® or Surgisis® Tension-Free Urethral Sling;
- ☐ B. Biodesign® or Surgisis® Urethral Sling;
- ☐ C. Stratasis™ Urethral Sling;
- ☐ D. Biodesign® or Surgisis® Anterior Pelvic Floor Graft;
- ☐ E. Biodesign® or Surgisis® Posterior Pelvic Floor Graft;
- ☐ F. Biodesign® or Surgisis® 4-Layer Tissue Graft;
- ☐ G. Biodesign® or Surgisis® 1-Layer Tissue Graft;
- ☐ H. Biodesign® or Surgisis® 8-Layer Tissue Graft;
- ☐ I. Biodesign® or Surgisis® Vaginal Erosion Repair Graft;
- ☐ J. Biodesign® or Surgisis® Peyronie's Repair Graft;
- ☐ L. Cook Pelvic Repair Product(s), specific product name(s) unknown at present;
- ☐ M. Non-Cook Pelvic Repair Product(s) known as _____; and/or
- ☐ N. Other: _____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products)

- ☐ A. Biodesign® or Surgisis® Tension-Free Urethral Sling;
- ☐ B. Biodesign® or Surgisis® Urethral Sling;
- ☐ C. Stratasis™ Urethral Sling;
- ☐ D. Biodesign® or Surgisis® Anterior Pelvic Floor Graft;
- ☐ E. Biodesign® or Surgisis® Posterior Pelvic Floor Graft;
- ☐ F. Biodesign® or Surgisis® 4-Layer Tissue Graft;
- ☐ G. Biodesign® or Surgisis® 1-Layer Tissue Graft;
- ☐ H. Biodesign® or Surgisis® 8-Layer Tissue Graft;

☐ I. Biodesign® or Surgisis® Vaginal Erosion Repair Graft;

☐ J. Biodesign® or Surgisis® Peyronie's Repair Graft;

☐ L. Cook Pelvic Repair Product(s), specific product name(s) unknown at present;

☐ M. Non-Cook Pelvic Repair Product(s) known as _____; and/or

☐ N. Other: _____

_____

10. Date of Implantation as to Each Product

_____

_____

_____

11. Hospital(s) where Plaintiff was implanted (including City and State)

_____

_____

12. Implanting Surgeon(s)

_____

_____

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I - Negligence

☐ Count II - Strict Liability – Manufacturing Defect

☐ Count III - Strict Liability – Failure to Warn

☐ Count IV - Strict Liability – Defective Product

☐ Count V - Strict Liability – Design Defect

☐ Count VI – Common Law Fraud

☐ Count VII - Fraudulent Concealment

☐ Count VIII - Constructive Fraud

☐ Count IX - Negligent Misrepresentation

☐ Count X - Breach of Express Warranty

☐ Count XI - Breach of Implied Warranty

☐ Count XII - Violation of Consumer Protection Laws

☐ Count XIII - Gross Negligence

☐ Count XIV - Unjust Enrichment

☐ Count XV - (By the Spouse) – Loss of Consortium

☐ Count XVI - Punitive Damages

☐ Count XVII - Discovery Rule and Tolling

☐ Other _____ (please state the facts supporting this Count in the space, immediately below)

_____
_____
_____
_____
_____
_____
_____
_____
_____

s/ _____
Attorney(s) for Plaintiff

Address, phone number, email address and bar information:

Exhibit D

AMENDED FILING INSTRUCTIONS FOR
SHORT FORM COMPLAINTS AND AMENDED SHORT FORM COMPLAINTS
and
FILING INSTRUCTIONS FOR MOVING TO TRANSFER MDL

TO FILE AN AMENDED SHORT FORM COMPLAINT IN AN EXISTING MEMBER CASE

Abbreviated instructions to file an **Amended Short Form Complaint**, in an existing MDL member case, whether transferred to the Southern District by the MDL Panel or directly filed here, include:

- From the *CM/ECF Civil Menu*, go to *Other Documents;*
- Select one of the following events:
  C. R. BARD, INC. – Amended Short Form Complaint – C. R. BARD, INC. CASE ONLY
  AMERICAN MEDICAL – Amended Short Form Complaint – AMERICAN MEDICAL CASE ONLY
  BOSTON SCIENTIFIC – Amended Short Form Complaint – BOSTON SCIENTIFIC CASE ONLY
  ETHICON – Amended Short Form Complaint – ETHICON CASE ONLY
  COLOPLAST – Amended Short Form Complaint - COLOPLAST CASE ONLY
  COOK – Amended Short Form Complaint – COOK CASE ONLY
- Enter the civil action number for the member MDL case; **DO NOT USE THESE EVENTS IN THE MAIN CASE OR WHEN FILING A NEW CIVIL ACTION**;
- Select the party(s) filing the Amended Short Form Complaint;
- The filed date for the Amended Short Form Complaint automatically defaults to the current date at this screen; browse in the image;
- Read the cautionary notices;
- Select EACH defendant on the Amended Short Form Complaint that you wish to name; do not add defendants not listed; and
- Review the final text; if correct, press NEXT to commit the transaction.

Any changes to the style of the case will be made by designated Clerk's Office staff during the Quality Control (QC) process. As stated in the PTO at paragraph D(2), to the extent any change in parties on an Amended Short Form Complaint suggests that the case should be in a different MDL, plaintiff(s) must submit a motion entitled **Motion to Transfer MDL.** Parties are directed to use the **Motion to Transfer MDL** PDF fillable form located on the Court's website for the appropriate MDL**.**

Abbreviated instructions to file a completed **Motion to Transfer MDL**, in an existing MDL member case, whether transferred to the Southern District by the MDL Panel or directly filed here, include:

- From the *CM/ECF Civil Menu*, go to *Motions and Related Filings > Motions/Applications/Petitions;*
- Select **Motion**;
- Select *Transfer between MDL Cases ***MDL Cases Only***;
- Enter the civil action number for the member MDL case -- **DO NOT USE THESE EVENTS IN THE MAIN CASE;**
- Select the party(s) filing the Motion to Transfer MDL;
- Browse in the image;
- Select the MDL case to transfer the member case FROM ;
- Select the MDL case to transfer the member case TO; and
- Review the final text; if correct, press NEXT to commit the transaction.

TO FILE A SHORT FORM COMPLAINT AS THE INITIATING DOCUMENT IN A NEW CIVIL ACTION:

To file a new civil action via the CM/ECF system using a **Short Form Complaint** follow the instructions located on the Court's website at **CM/ECF Information > Filing New Civil Actions Electronically > Filing a Complaint**. Simply substitute a **Short Form Complaint** for a regular complaint. No special procedures are required.

CAUTION: Both the Pay.gov payment transaction and the CM/ECF filing transaction must be completed to finalize the filing.

PRINT FORM RESET FORM

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Exhibit E

IN RE COOK MEDICAL, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2440
Honorable Joseph R. Goodwin

Plaintiff(s),

v.

CASE NO.

Defendant(s).

MOTION TO TRANSFER MDL

COME NOW the plaintiff(s), by and through the undersigned counsel, and move the court to transfer this member case from MDL 2440, In re: Cook Medical, Inc., Pelvic Repair System Products Liability Litigation, to:

MDL Select One:

Plaintiff(s) herein filed a Complaint or Short Form Complaint in MDL 2440 against Cook Medical, Inc., and others. Plaintiff(s) later filed an Amended Short Form Complaint that no longer included Cook Medical, Inc. or another named defendant in that litigation; included instead, among others, were the following parties from MDL :

Because Cook Medical, Inc. or another defendant named in the Master Complaint, is no longer a named defendant in this member case, Plaintiff(s) respectfully request that the Court: 1) **GRANT** the Plaintiff(s) motion to transfer this civil action from MDL 2440 to ; and 2) direct the Clerk to disassociate this civil action as a member case in MDL 2440 and re-associate it with MDL .

CERTIFICATE OF SERVICE

I hereby certify that on , I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this member case.