IN THE CIRCUIT COURT OF MONONGALIA COUNTY, WEST VIRGINIA

STATE OF WEST VIRGINIA *ex rel.*
PATRICK MORRISEY,
Attorney General,

Plaintiff,

v.

CIVIL ACTION NO. _____
JUDGE _____

JOHNSON & JOHNSON,
a New Jersey Corporation;
ETHICON, INC., a subsidiary of
Johnson & Johnson; and
ETHICON US, LLC,
a subsidiary of Johnson & Johnson,

Defendants.

COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, brings this action against Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC ("Defendants") for their unlawful, unfair and deceptive marketing of polypropylene mesh products ("PMP" or "surgical mesh") in the trade and commerce of West Virginia, violations of the West Virginia Consumer Credit and Protection Act ("WVCCPA"), W. Va. §§ 46A-1-101, *et seq*.

I. PARTIES

1. The State of West Virginia *ex rel.* Patrick Morrisey, Attorney General, ("Attorney General") is charged with enforcing the WVCCPA. Pursuant to W. Va. Code § 46A-7-108, the Attorney General is authorized to bring a civil action for violations of the WVCCPA and for other appropriate relief. The Attorney General has all common law powers except as restricted by statute

or court decision. *Syl. pt. 3, State ex rel. Discover Financial Services, Inc., et al. v. Nibert*, 744 S.E.2d 625, 231 W. Va. 227 (2013).

2. Johnson & Johnson ("J&J") is a publicly-held multinational corporation organized and existing under the laws of New Jersey. Its principal place of business is located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. According to its website, J&J is engaged in the manufacture and sale of medical devices, pharmaceuticals, and consumer goods, the "world's most comprehensive medical devices business" with 265 operating companies in more than sixty countries, including the United States. J&J was founded in 1886, by the Johnson brothers to improve sanitation practices and create a line of ready-to-use surgical dressings. The company focuses on three main areas: consumer healthcare, medical devices and diagnostics, and pharmaceuticals. In 2018, J&J sales figures were reported to be: $13.9B consumer sales; $40.7B pharmaceutical sales; and $27B medical devices sales.

3. At all relevant times, J&J has transacted and continues to transact business throughout the State of West Virginia, including Monongalia County.

4. Ethicon, Inc. is a subsidiary of J&J, incorporated in 1949, and is a manufacturer of surgical sutures and wound closure devices. Ethicon, Inc. is a New Jersey corporation headquartered in Somerville, New Jersey. At all relevant times, Ethicon, Inc. has transacted and continues to transact business throughout the State of West Virginia, including Monongalia County.

5. Ethicon US, LLC, is a subsidiary of Johnson & Johnson, organized under the laws of Texas. At all relevant times, Ethicon US, LLC has transacted and continues to transact business in the State of West Virginia, including Monongalia County.

6. Ethicon, Inc. and Ethicon US, LLC are wholly owned subsidiaries of Johnson & Johnson. Their websites proclaim them to be "Part of the Johnson & Johnson Family of

Companies." The "Ethicon Franchise" is a business unit in J&J's medical devices sector. All defendants may be collectively referred to hereinafter as "Defendants."

7. At all relevant times, each Defendant acted individually or jointly with one another when committing all acts alleged in this Complaint.

8. At all relevant times, each Defendant acted: (a) as principal; (b) under express or implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this Complaint on behalf of every other named Defendant.

9. At all relevant times, one or all of the Defendants acted as the agent of the others, and all Defendants acted within the scope of their agency as if acting as the agent of the other.

10. At all relevant times, each Defendant and its employees had awareness of the others' conduct relating to the matters alleged within the Complaint.

II. JURISDICTION AND VENUE

11. As a court of general jurisdiction, based on the WVCCPA, nuisance claims, the amount at issue, and the relief sought, the Attorney General is authorized to bring suit, and the circuit court is authorized to hear this matter.

12. This court has personal jurisdiction over Defendants because Defendants have transacted substantial business in this State; their products were surgically implanted in, and have been surgically removed from, West Virginia consumers; the acts alleged herein have been committed in this State; Defendants derived substantial profits from West Virginia consumers, hospitals, clinics, and health care providers from the sale and application of their surgical mesh products; and Defendants promoted, marketed and sold their surgical mesh products in the State of West Virginia and throughout Monongalia County. Further, Defendants intentionally availed themselves of the West Virginia market so as to render the exercise of jurisdiction over Defendants.

13. Upon information and belief, Defendants sold their surgical mesh products in the State of West Virginia between 1998 and the present time (the "relevant period of time").

14. Upon information and belief, Defendants had sales and marketing contacts to promote their surgical mesh products in the State of West Virginia and in Monongalia County, including but not limited to: Defendants' sales representatives and other employees who had contacts with doctors; offered medical and other training to West Virginia licensed doctors; poster presentations received by doctors; paid consultants who promoted Defendants' surgical mesh products to doctors; Defendants and their agents provided written communications and training videos; and Defendants engaged in direct-to-consumer marketing through brochures, radio advertisements, television advertisements, internet advertisements, phone scripts, websites, and other materials.

15. The violations alleged in this Complaint occurred in Monongalia County and elsewhere in West Virginia. Venue is proper in Monongalia County pursuant to W. Va. Code § 46A-7-114 because Defendants' marketing and sales activities included Monongalia County and therefore Defendants' liability arises in Monongalia County.

16. In sum, this action arises from Defendants' purposeful contacts with the State. Therefore, exercise of personal jurisdiction over Defendants comports with traditional notions of fair play and substantial justice, and jurisdiction is consistent with the United States Constitution and the West Virginia State Constitution.

III. BACKGROUND

A. SUI and POP

17. Stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") are common conditions caused by weakened or damaged tissues and muscles in the pelvic floor area. SUI and POP affect a large percentage of the female population. It is estimated that thirty to fifty

percent of women are affected by incontinence, and nearly half of women between the ages of 50 and 79 have some form of POP. SUI and POP are conditions that pose lifestyle limitations and, in the case of POP, some mild pain, but they are not life threatening.

18. SUI occurs when muscles that control urine flow do not work properly, resulting in involuntary urine leakage during everyday activities such as laughing, coughing or exercise. POP occurs when the muscles of the pelvic floor can no longer support the pelvic organs, causing the organs to drop downwards, and in some cases, bulge out of the vagina.

B. Medical Treatment of SUI and POP

19. There are a variety of surgical and non-surgical treatment options that address SUI and POP. Non-surgical treatment options include behavioral changes (such as diet, exercise, and weight loss), vaginal and/or tibial nerve stimulation, pelvic floor exercises, or a removable device called a pessary that is placed in the vagina to support areas of prolapse. Surgical options include: (1) repair using the patient's native tissue; and (2) repair using a synthetic material like surgical mesh.

20. Non-mesh surgical alternatives are effective and do not pose the same set of risks as surgical mesh. The U.S. Food and Drug Administration ("FDA") has found that the use of a patient's native tissue is just as effective as transvaginal mesh and does not pose the same risks as mesh.

21. Surgically implanted mesh devices, known collectively as Polypropylene Mesh Products ("PMP," "vaginal mesh," or "polypropylene mesh"), is derived from woven polypropylene threads with openings in the weave known as pores. Tissue grows into and through these pores, which eventually creates a hammock consisting of mesh and tissue to support the organs that need support. PMP is introduced through surgical procedure, becomes integrated into the patient's surrounding tissue, and is intended to remain permanently implanted in the body.

22. Defendants' mesh products are placed transvaginally or through the abdomen. "Transvaginal placement" means the polypropylene mesh is surgically implanted through the vagina for pelvic floor repairs, as opposed to the past practice of surgical repair through a woman's abdomen.

23. For SUI products, the mesh is pulled through an incision in the vagina and placed under the urethra. The mesh lifts the urethra up to stop an involuntary leakage of urine during periods of increased abdominal pressure (such as laughing, coughing or sneezing).

24. For POP, the polypropylene mesh is inserted into the body through the vagina, pulled through an incision in the vaginal canal to act as a hammock for the prolapsing organ(s). Once implanted, the mesh then acts to keep the organ(s) that have dropped onto the vagina from continuing to descend into and out of the vagina. Organs that are typically involved in POP procedures include the bladder, small intestine, uterus, rectum, and sometimes the vagina itself.

C. Defendants' Surgically Implanted PMP

25. Defendants design, develop, market, promote, test and sell a variety of synthetic polypropylene pelvic floor repair products - surgically implanted pelvic mesh devices collectively known as PMP - to treat SUI and POP.

26. Defendants began selling SUI mesh treatment options in 1998. Their first product was called TVT ("tension-free vaginal tape"), sometimes referred to as a "mid-urethral" sling. Defendants continue to offer the original TVT today. The tension-free vaginal tape line of products includes, among others: TVT, TVT Retropubic, TVT Exact, TVT Obturator (TVT-O), TVT Abbrevo and TVT Secure (TVT-S). Any reference to "TVT" includes all variations.

27. In 2002, Defendants began making, marketing, and selling Gynemesh for treatment of SUI and POP. All references to Gynemesh include all variations of Gynemesh, including but not limited to Gynemesh PSA and Nonabsorbable Prolene Soft Mesh.

28. Defendants began marketing and selling their POP pelvic floor repair kits with the Prolift product in 2005. The Prolift is made from pre-cut pieces of Gynemesh with added "arms" designed to be attached to various fixation points within the patient's pelvis.

29. In 2007, Defendants updated the Prolift System with the Prolift+M System. All references to the Prolift and Prolift+M Systems include by reference all variations.

30. In 2010, Defendants began making, marketing, and selling their Prosima System for treatment of POP. All references to Prosima include by reference all variations.

31. In 2012, Defendants began making, marketing, and selling mesh products called Artisyn, designed to treat POP placed through the abdomen rather than transvaginally. Shortly thereafter in 2013, Defendants abandoned their POP mesh products that were placed transvaginally (i.e., Prolift and Prosima).

32. At all relevant times, Defendants engaged in the business of placing their PMP into the stream of commerce, including brand names Prolene Mesh/Prolene Soft Mesh, Gynemesh, Gynemesh PS, TVT, TVT-Obdurator (TVT-O), TVT-SECUR (TVT-S), TVT Exact, TVT Abbrevo, Prolift, Prolift +M, Prosima, Artisyn, and other PMP unknown at the present.

33. Although there are general risks associated with pelvic floor surgery, Defendants' surgical mesh devices present unique and/or heightened risks, due in part to the nature of its mesh and the reaction within the body.

D. Complications and Risks Associated with Defendants' PMPs

34. In a July 2011 notice titled "Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse," the FDA concluded that "the risks of serious complications associated with transvaginal POP repair with mesh are not rare."

35. Complications associated with the use of Defendants' synthetic mesh in transvaginal repair include: (a) vaginal mesh erosion (mesh implanted in the pelvic floor with

erosion out of the vagina and/or into other pelvic organs); (b) extrusion, exposure or protrusion; (c) severe and chronic pain (including painful sexual intercourse); (d) infection (bacterial colonization of mesh and mesh-related infection - a risk heightened by implantation through the vagina); (e) urinary dysfunction; (f) bleeding and organ perforation; (g) recurrent prolapse; (h) neuro-muscular problems; (i) vaginal scarring/shrinkage; (j) emotional problems; (k) chronic foreign body response to the mesh with resulting chronic inflammation; (l) mesh contracture or shrinkage inside the body which can lead to vaginal stiffness, shortening distortion, and nerve entrapment; (m) permanent dyspareunia; and (n) defecatory dysfunction. The risk of mesh-related complications is lifelong and can arise years after surgical insertion.

36. The transvaginal design of Defendants' PMP presents a risk of chronic infection from bacterial contamination. This risk is greater than the risk of infection posed by non-transvaginal implants because the vagina is a cavity that is never completely sterilized. Because Defendants' PMP is a fabric made of woven strands, the bacterial micro-colonies can become imbedded in the mesh during implantation. The chronic infection can also cause chronic inflammation. Post-surgical infections have been found in mesh removed years after implantation.

37. Polypropylene degrades and oxidizes in the body over time. Chronic foreign body reaction occurs when the immune system continuously fights and tries to remove a foreign object – whether a sliver of wood or polypropylene – that has entered the human body. The chronic foreign body reaction then causes chronic inflammation.

38. The risks of chronic infection, chronic foreign body reaction, and chronic inflammation caused by PMP trigger a number of adverse reactions in the human body. For example, mesh hardens, contracts, erodes into other body organs, and becomes so rigid and distorted that complete mesh removal is extremely difficult and often impossible.

39. In recent years, cancer has also been raised as a possible risk of mesh implantation in the body due to chronic inflammatory reactions incited by mesh. Due to the dormancy period for cancer, the true risk from use of Defendants' mesh devices may not be apparent for another decade or more.

40. Because mesh remains in the body forever, erosion of the vaginal wall or one of the pelvic organs may occur at any time. Erosion is the most common and consistently reported mesh-related complication; erosion can be debilitating, leading to severe pelvic pain, painful intercourse, or inability to engage in intercourse.

41. Mesh removal is the only treatment option for most continuing mesh complications. Removal often requires multiple surgeries which may not resolve complications and may, in fact, result in new problems. Experts who have testified in court, including Ethicon's then medical director, Piet Hinoul, M.D., indicate injuries reported from the TVT required additional very difficult surgeries with about 30 percent of women requiring more than one surgery to treat mesh complications, and further concluding that there is no way to excise mesh completely.

IV. PRELIMINARY FACTS

42. The WVCCPA provides that unfair or deceptive acts or practices in the conduct of trade or commerce are unlawful. W. Va. Code § 46A-6-104.

43. Defendants are "persons" within the meaning of the WVCCPA, W.Va. Code § 46A-1-102(31).

44. Defendants conduct "trade" or "commerce" within the meaning of the WVCCPA, W.Va. Code § 46A-6-102(6).

45. The WVCCPA defines unfair or deceptive acts or practices to mean and include:

> Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services, W. Va. Code § 46A-6-102(7)(B);

> Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with or certification by another, W. Va. Code § 46A-6-102(7)(C);
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> * * * *
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> Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have, W. Va. Code § 46A-6-102(7)(E);
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> * * * *
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> Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding, W. Va. Code § 46A-6-102(7)(L);
>
> The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby, W. Va. Code § 46A-6-102(7)(M).

46. Defendants are experienced, well-funded and knowledgeable sellers of consumer medical devices.

47. Defendants' representations are deceptive because they have the capacity to mislead consumers.

48. An act or practice may be unfair if it offends public policy, is immoral, unethical, oppressive, unconscionable, or if it causes injury to consumers. Defendants' acts or practices as alleged in this Complaint are unfair and deceptive.

49. Defendants have engaged in unfair or deceptive acts or practices in the conduct of trade or commerce in violation of W. Va. Code § 46A-6-104 as set forth below.

V. MISREPRESENTING, CONCEALING AND/OR OMITTING MATERIAL FACTS ABOUT DEFENDANTS' SURGICAL MESH PRODUCTS

A. Generally

50. As part of Defendants' acts and practices in the conduct of trade and commerce in West Virginia, Defendants engaged in unfair, false, misleading and/or deceptive marketing and advertising practices which included misrepresentations to doctors and patients that Defendants' surgical mesh devices were well studied and endorsed by respected, independent, neutral and competent government and medical organizations.

51. Communications to doctors, including those in West Virginia, involved brochures, educational materials, training materials, device inserts, instructions for use, communications through sales representatives, and information disseminated at medical conferences, among others. Communications to doctors misrepresented the full range of known material risks and complications associated with their surgical mesh devices, by deceptively omitting known material risks and complications associated with surgical mesh devices. As a matter of common practice, doctors often provided this information to their patients.

52. Defendants made these misrepresentations to doctors and their patients in West Virginia, with the intention that doctors and patients would rely upon the information they provided. The misrepresentations and/or omissions directed to patients were material because they were likely to affect the patients' treatment decisions. Defendants' misrepresentations to doctors and patients were intended to, and were likely to, deceive the reasonable doctor and patient audience.

B. Defendants Misrepresented PMP by Marketing as "FDA Approved"

53. Medical devices reach the United States market through the FDA by one of three separate application processes. This medical device review process originates from the 1976

Medical Devices Amendments ("MDA") to the Food, Drug and Cosmetic Act, to "impose a regime of detailed federal oversight" of medical devices. *See*, *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008).

54. When the FDA clears, approves, and regulates a device they may: (a) be exempt from application processes; (b) be marketed through a process called Premarket Notification (also known as the 510(k) process); or (c) undergo the most rigorous process, Premarket Approval (PMA). A PMA submission must provide valid scientific evidence collected from human clinical trials showing the device is safe and effective for its intended use. Products that receive Premarket Approval are "FDA approved." Nygaard, Ingrid, "*What Does 'FDA Approved' Mean for Medical Devices,*" Obstetrics & Gynecology, Vol 111, No 1, January 2008 (ACOG).

55. However the vast majority of marketed devices in the United States circumvent the stringent regulatory control provided by PMA and instead, gain clearance (rather than actual approval) through Premarket Notification 510(k) process ("510(k)"). Under 510(k), before a manufacturer can market a medical device, the manufacturer must demonstrate to the FDA's satisfaction that the device is substantially equivalent to a device already on the market, termed a "predicate device." Substantial equivalence means the new device has the same intended use as the predicate device and has either the same or different technological characteristics but is theoretically as safe and effective as the predicate device. No clinical information is required. *Nygaard, supra.*

56. FDA "approved" devices undergo a rigorous evaluation of their safety and efficacy – a process involving approximately 1200 hours of intense FDA review. The PMA process requires the applicant to demonstrate "reasonable assurance" that the device is both "safe ... [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed

labeling. . ." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (addressing FDA approval of orthopedic bone screws), quoting 21 U.S.C. § 360e(d)(2)(A), (B).

57. In contrast, FDA 510(k) process "cleared" devices need only demonstrate that they are "the substantial equivalent" to a device already on the market – a review that lasts approximately 20 hours. The 510(k) process does not involve a *de novo* safety determination or require clinical studies. *Buckman, supra* at 348.

58. The 510(k) process is cursory when compared to the strenuous PMA review. In contrast to the 1200 hours necessary to complete a PMA review, 510(k) review is completed in an average of only 20 hours. *Medtronic, Inc. v Lohr*, 518 U.S. 470, 478-479 (1996). Section 510(k) notification requires little information, rarely elicits negative response from the FDA, and gets processed very quickly. *Id.* at 479.

59. The FDA 510(k) process to approve a medical device for market and public use is "'focused on equivalence, not safety', premarket approval is focused on safety, not equivalence." *Riegel v. Medtronic, Inc., supra* at 323 (internal citation omitted). The difference between a medical device "cleared" by the FDA for market and a medical device "approved" by the FDA for market is significant.

60. Defendants' mesh products were cleared by the FDA under the 510(k) equivalency process, not the complete, thorough PMA process which requires the applicant to demonstrate reasonable assurance that the device is both safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

61. The distinction between FDA "approved" and FDA "cleared" is explicit in the FDA Regulations: Premarket Notification 510(k) – 21 CFR Part 807 Subpart E; and, Premarket Approval (PMA) – 21 CFR Part 814. However, Defendants' marketing materials addressed to doctors and patients advertised that their PMP products were "FDA approved," a material

misrepresentation because PMP products were merely "cleared" by the FDA under the "510(k) equivalency process," a distinction of medical substance.

62. Focusing on equivalence, not safety, each of the following of the Defendants' products were merely "cleared" for market through the FDA's 510(k) clearance process, on or about the following dates:

a. Prolene Polypropylene Mesh – 1996
b. Gynecare TVT System (Retropubic) – 1998
c. Prolene Soft Mesh – 2000
d. Gynecare TVT System (Modified) – 2001
e. Gynecare Prolene Soft Mesh – 2002
f. Ultrapro Mesh – 2004
g. Gynecare TVT Obturator System – 2003
h. Gynecare TVT Secure System – 2005
i. Prolift (marketed without clearance starting in 2005, cleared 2008)
j. Gynecare Prosima – 2007
k. Gynecare Prolift and Prolift+M – 2008 (marketed prior to clearance)
l. Gynecare TVT Exact – 2010
m. Gynecare TVT Abbrevo – 2010

63. Despite knowledge of the FDA medical device approval process, Defendants made misrepresentations to doctors and patients that its surgical mesh products were FDA "approved," understanding that the "FDA approved" designation leads doctors and patients to believe that a medical product has been well studied and scrutinized under the PMA analysis. Defendants' misrepresentations related to FDA "approval" include the following:

a. Defendants made presentations to doctors concerning its FDA "approved" surgical mesh devices, including but not limited to webinars for the PROLIFT +M wherein Defendants' representatives stated its product "has been FDA approved for use."

b. Defendants instructed their sales representatives to tell doctors that they sold "the only FDA approved partially absorbable pelvic floor mesh."

c. Defendants made affirmative misrepresentations about FDA approval to doctors in written and verbal communications such as emails urging doctors to purchase surgical mesh devices and as part of mesh product promotions during professional conferences.

d. On information and belief, Defendants made affirmative misrepresentations regarding FDA approval directly to patients through a variety of informational and/or marketing materials such as consent forms for participating in clinical studies.

64. By claiming that their PMP were FDA approved, Defendants misled consumers, doctors and patients into believing that their mesh devices had been well-studied, undergone clinical trials, and were scrutinized robustly by the FDA. 510(k) clearance of Defendants' pelvic mesh products does not constitute a finding by the FDA that the products were safe or effective. FDA regulations also note that 510(k) clearance "does not in any way denote official approval of the device. 21 CFR § 807.97 (2012). The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the FDA. *See id.* "Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." *Lewis v Johnson & Johnson*, 991 F. Supp. 2d 748, 751-56, (S.D. W.Va. 2014), quoting 21 C.F.R. § 807.97(2012).

C. Misrepresentations in the "Instructions For Use"

65. Instructions For Use (IFU) accompany the actual device. One purpose of IFU is to disclose intended use, adequate directions, any relevant hazards, contraindications, side effects, and precautions to apprise a reader of the risks and benefits of a vaginal mesh implantation. 21 CFR Part 801, General Device Labeling Requirements.

66. Charlotte Owen, M.D., Ethicon's worldwide medical director from 2003 to 2005, has testified the IFU had to be clear, unambiguous, accurate, and supported by data, noting the IFU communicated all contraindications, warnings, precautions, and adverse reactions to physicians, and further acknowledged in trial testimony that the IFU was approved even though she knew there might be long-term complications. *Lynda Gross v. Gynecare, Ethicon and Johnson & Johnson,* March 29, 2016; Appellate Division Superior Court of New Jersey, Docket No. A-00011-14T2, and *Hammons v. Ethicon, Inc., et al*, 190 A.3d 1248, 1272 (Pa. Super. 2018), appeal granted on other grounds, 206 A.3d 495 (Pa.2019). However, in practice, those noted IFU requirements were not satisfied.

67. In March 2005, Defendants began marketing Prolift and contemporaneously issued an IFU which stated, *inter alia*:

"WARNINGS AND PRECAUTIONS

****

Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g., cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities. Avoid placing excessive tension on the mesh implant during handling.

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The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.

Transient leg pain may occur and can usually be managed with mild analgesics.

Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.

> Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair."

Hammons v. Ethicon, supra at 1271.

68. Prior trial testimony indicates Defendants' IFU and brochures failed to disclose the full extent of the risks posed by Prolift—risks that Defendants knew about prior to the March 2005 product launch, noting that in November 2004, French surgeons who had been using the Prolift kit for several years published an article addressing Gynemesh Soft, the same mesh material used in the Prolift system, opining that retraction was impossible to forecast and highly variable with after-effects that included dyspareunia (painful sexual intercourse). *Hammons v. Ethicon, supra.*

69. Sworn testimony reflects also that in 2005, before the product launch of the Prolift kit, Dr. Axel Arnaud, the scientific director of Gynecare Europe, sent an email to Ophelie Berthier, the product director who oversaw the marketing launch of Prolift worldwide, proposing to add the following warning to the IFU:

> Warning: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggests the risk of such a complication is increased in cases of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

Berthier advised it was urgent to incorporate the changes in the IFU version in the procedure CD–ROM. *Hammons, supra* at 1271-1272.

70. Berthier's email was forwarded to Dr. Owens at the time of the product launch in 2005 and to Sean O'Bryan, Ethicon senior project manager for regulatory affairs, along with a question whether it was acceptable to add this warning without FDA approval. On January 13, 2005, Mr. O'Bryan responded that he would leave it to the medical director and to the research and project manager, to decide. The project's research and development project leader replied several

minutes later, "We have already printed launch stock. This would be a next revision addition, but they want it in there ASAP." *Id.*

71. Apparently, the Defendants rejected Dr. Arnaud's suggestion because incorporating it into the IFU would require replacing the previously printed IFUs, thus incurring additional costs and delaying the product launch. *Id.*

72. While Defendants purportedly had a system in place to update their marketing and informational materials as information came in, Defendants failed to implement changes based on suggestions from key staff doctors. For example, Dr. Meng Chen, Ethicon's Associate Medical Director in the complaint review department, informed management on numerous occasions of patient complaints regarding complications with PMP. Dr. Chen proposed adding dyspareunia (difficult or painful sexual intercourse) to the TVT IFU based on patient complaints and how those complaints were negatively affecting quality of life.

73. Regarding SUI devices, Dr. Chen was concerned about the adequacy of the companies' disclosures. She noted on more than one occasion the difference between the pre-operative consent expectations and post-operative complaint experience. She noted, "one of the paths for a better pre-operative consent is to provide an updated IFU [Instructions for Use] to the operating physicians that reflecting [*sic*] the current knowledge of the manufacturers on the potential adverse reaction." Below is a meeting agenda drafted by Dr. Chen describing her observations from patient complaints:

a. Tape exposure/erosion/extrusion very frequently reported.

b. Patients did not feel there were adequate pre-op consent or risk benefit assessment[s].

c. Patient-specific concerns.

d. The incontinence recurrence.

e. Post-operative dyspareunia and pain affect quality of life and affect daily routine.

f. Re-operations-tape excision, removal, re-do sling procedure[s].

g. Type and intensity of the post-operative complications disproportionate to pre-operative consent-expectations.

Defendants never acted on Dr. Chen's recommendations.

74. Defendants continued to conceal the material risks of dyspareunia and pain affecting quality of life in their informational and marketing materials. In *Huskey et al, v. Ethicon* (2:12-cv-05201) (S.D. W. Va.), the first bellwether jury trial naming Ethicon in this multidistrict litigation, Dr. Chen, testified that the Instructions for Use (IFU) are supposed to contain all of the information an implanting doctor would need to know about a device before instructing a patient on the benefits versus risks and was aware of many adverse events which were being called into the company, and she told Ethicon, "I did see every day that the patient reports contained their description of their experience are not transitory at all." Yet, despite Dr. Chen's recommendations, they did not make it to the IFU.

75. Defendants knew the problems were associated with their PMP because, among other reasons, Defendants' products generated thousands of complaints from doctors and patients that were submitted directly to Defendants. Defendants received complaints that some women cannot sit or walk comfortably for any extended period of time. Other women informed doctors that they now suffer from permanent urinary and/or defecatory dysfunction that has resulted in a loss of dignity, inability to function in the workplace, and inability to participate in everyday family life.

76. Testimony of record further indicates that, at the time of the product launch, Dr. Owens understood the IFU had to be clear, unambiguous, accurate, and supported by data, and claimed the IFU communicated all contraindications, warnings, precautions, and adverse reactions

to physicians. Dr. Owens approved the IFU even though she knew there might be long-term complications. On January 14, 2005, relying on a Gynemesh PS clinical study, the Dr. Owens issued a clinical expert report to document the safety and functionality of the Prolift system to treat pelvic floor repair. But at the time the Dr. Owens authored this clinical expert report, she was familiar with the 2004 article published by the French surgeons that identified retraction as a potential complication along with such aftereffects as severe pain, but did not cite the French surgeons' article in her report or discuss the possibility of retraction. Dr. Owens also admitted that before Prolift's market launch, she knew the mesh could erode, migrate, or lead to inflammation, and that removal of mesh could be very difficult even though Ethicon did not conduct studies on how to remove it.

77. Likewise, in sworn testimony, Piet Hinoul, M.D. - a urogynecologist who joined Gynecare in 2008 as a worldwide medical director - confirmed that on the day of the launch Defendants were aware of potential complications, such as urinary incontinence, urinary retention or obstruction, ureteral obstruction, voiding dysfunction, pain, pelvic pain, and pain with intercourse. *Id.*

78. There were many other known complications associated with the devices. For example, the following is a non-exhaustive list of the risks and complications which were missing or omitted from the IFU for TVT slings at various points in time from 1997 to 2012:

a. chronic foreign body reaction
b. defecatory dysfunction
c. detrimental impact on quality of life
d. dyspareunia
e. mesh contracture
f. chronic pelvic pain
g. chronic groin pain
h. erosions requiring reoperation and removal
i. recurrence of incontinence
j. pain to partner during sex
k. sarcoma (cancer)

l. vaginal scarring
m. permanency/difficulty removal

See, *Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse, July 2011*, FDA Center for Devices and Radiological Heath; *Hammons*, *supra* at 212-217.

79. Defendants' IFU includes the following misrepresentations:

a. The IFU suggested that the foreign body response triggered by the insertion of the surgical mesh product was merely "transitory," eliciting a "minimal inflammatory response" or "minimal inflammatory reaction . . . which is transient," despite knowing that the reaction never goes away. Defendants' own medical directors and experts have testified that inflammation is permanent and Defendants were aware that the foreign body reaction would be chronic.

b. The IFU stated that the products were not "subject to degradation," despite internal studies and testing performed by Defendants' own consultants and scientists that concluded the mesh material degrades over time in the body. This was well known by the Defendants since 1992.

D. The Ulmsten/Nilsson Scientific and Medical Studies

80. Public trust in the scientific process and the credibility of published articles depends, in part, on how transparently conflicts of interest are handled during planning, implementation, writing, peer review, editing and publication of scientific work. *See*, Resnik, David B, *Scientific Research and the Public Trust,* SCI Eng. Ethics. 2011 Sep; 17(3): 399-409.

81. A conflict of interest exists when professional judgment concerning a primary interest such as a patient's welfare or the validity of research may be influenced by a secondary interest such as financial gain. *See*, JAMA, January 25, 2006, Vol 295, No.4; and, AMA Code of Medical Ethics, E-8.03, 8.031, 8.0315, *et al*; Conflicts of Interest: Guidelines.

82. Defendants made false and misleading statements in its marketing, promotional, informational, and educational materials about complication rates of mesh, and other relevant factors, based on scientific studies, selectively citing outcomes that appeared positive, while not disclosing clinically relevant information about negative findings in those same studies.

83. Defendants' marketing materials to doctors and patients included misrepresentations about a series of medical studies and articles about surgical mesh referred to herein as the "Ulmsten/Nilsson" studies.

84. Defendants claimed the "Ulmsten/Nilsson" studies established evidence to support the use and long term safety of vaginal mesh and cited the studies as evidence of safe and effective medical procedures to treat stress urinary incontinence, and to promote TVT products. *See e.g.,* Ulmsten, U., et al., *Int Urogynecol J Pelvic Floor Dysfunct.* 1998; 9(4):210-3.

85. In 1996, Ulf Ulmsten published a paper reporting the results of a surgical treatment to treat SUI. This surgical treatment, a mid-urethral sling procedure, used plastic mesh tape to act as a sling to support the urethra. This later came to be known as the tension-free vaginal tape ("TVT") procedure.

86. In February 1997, Ulmsten filed a patent application listing himself and a colleague as the inventors of the TVT procedure and assigned the patent to his company, Medscand.

87. The following month, Defendants and Medscand signed a licensing agreement wherein Defendants agreed to pay Medscand $1 million over a period of time if the second trial upheld the positive findings of the first. If the tests did not produce positive results, Medscand would receive no money.

88. Defendants used the result of the Ulmsten study to sell its SUI products when Defendants had (i) purchased the rights to the SUI device from Dr. Ulmsten, and (ii) contractually

agreed with Dr. Ulmsten that he would only get paid a specific sum if his study produced favorable results regarding the product.

89. Ulmsten's second study came out with better results than the first. Ulmsten's company, Medscand, received its $1 million payment and in 1999 Defendants paid Medscand over $24 million for all assets associated with its TVT business.

90. While featuring this study in multiple patient brochures and physician advertisements, Defendants failed to disclose to doctors and patients that the primary investigators and authors of the study were paid consultants for Defendants or that they had a financial interest in the outcome of the study.

91. Defendants falsely claimed that studies by Dr. Carl Nilsson provided support for the long term safety of mesh and used the results of these studies to claim that their surgical mesh products did not carry the same complication risks as other mesh products.

92. Defendants misrepresented that the Nilsson studies had proven the safety of both mechanically and laser-cut TVT slings – two entirely different mesh products – when in fact the studies had looked only at mechanically cut slings.

93. Defendants developed and disseminated a doctor-directed marketing piece focused on the Ulmsten/Nilsson studies published in 2001 titled: *5 Years of Proven Performance*. In this advertisement, Defendants misrepresented, concealed or omitted the following information from doctors:

a. Over half of the studies' authors were paid consultants of Defendants at the time of the publication.

b. The device sold at the time of the publication was different than the one evaluated in the study.

c. That most complications were minor and avoidable with the adherence to technique and instructions when they were not.

d. The study found 3.3% of patients involved experienced a retropubic hematoma.

e. That their product had "proven biocompatibility" and "no foreign body reaction" after mesh implantation despite knowledge that a foreign body reaction would not only occur, but would be permanent in nature.

f. That there would be a foreign body reaction any time the mesh was implanted into a woman's body.

94. But contrary to well recognized and established scientific ethical and legal standards, while featuring the Ulmsten/Nilsson study in multiple patient brochures, physician advertisements, disseminated doctor and patient literature, and brochures, Defendants failed to disclose to doctors and patients that the primary investigators and authors of the study were paid consultants for the Defendants and had a financial interest in the outcome of the study. *See*, Goozner M., et al, "*A Common Standard for Conflict of Interest Disclosure," Ctr. of Science in the Public Interest*, July 2008.

95. In another cited study employed by Defendants in their patient and physician directed marketing literature to promote the efficacy and success rate of TVT product (published by Drs. Nilsson, Falconer and Rezapour (2004)), Defendants again failed to disclose that the study authors worked for Defendants as paid consultants.

E. Misrepresentations in Materials Directed to Physicians and Patients

96. Defendants' brochures, product labels, and marketing materials, among other advertising materials, provided to physicians contained unfair, false, misleading or deceptive claims about surgical mesh devices, claiming for instance, that their surgical mesh products had

"minor complications," a "very low likelihood of urethral erosion," and "no foreign body reaction." However, evidence deduced at trials show studies known to Defendants that demonstrated nearly twenty percent of women suffered mesh shrinkage with pain during intercourse, and another approximately twenty percent suffered mesh erosions within a year of implantation. *See*, *Hammons, supra* at 1258.

97. Defendants misrepresented the following properties of mesh material, which, if disclosed to doctors, would have provided material information regarding the additional risks and dangers associated with the use of synthetic mesh as opposed to native tissue repair surgery:

a. Defendants knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. Defendants, however, misrepresented the foreign body response triggered by mesh as "transitory" despite knowing the reaction never goes away. Defendants' patient brochures stated the mesh material would be "well tolerated" by the patient's body. The body's chronic and permanent reaction to mesh plays a material role in the (i) lifelong risk of erosion/exposure of mesh; and (ii) contraction (i.e., shrinking and folding) and hardening of mesh inside the body, which can lead to chronic pain and dyspareunia.

b. Defendants knew that the implantation of surgical mesh transvaginally can create a heightened risk of infection because: the (i) bacterial contamination occurs when the mesh is implanted through the vagina, because the vaginal environment cannot be sterilized; and (ii) bacterial colonization occurs in the woven mesh. Defendants not only failed to disclose this heightened risk of chronic infection, but represented that mesh "does not potentiate infection" in its marketing materials. Moreover, when Defendants did disclose its products' ability to "potentiate"

infection, they misleadingly equated that risk with that of any other implanted material. The infection associated with mesh plays a significant role in mesh erosion and exposure, which can lead to severe pain and dyspareunia.

c. Defendants also knew that claims of softness were illusory. Nevertheless, Defendants misrepresented their mesh as "supple," "remains soft and pliable" and has a "bi-directional elastic property [that] allows adaptation to various stresses encountered in the body." Defendants knew the importance that doctors place on pliability and elasticity in the pelvis, which needs to accommodate the flex and movement associated with bladder, bowel and sexual function. With full knowledge, Defendants deliberately misrepresented and concealed the risk that mesh can harden and become rigid within the body, which in turn can cause pain and sexual and urinary dysfunction.

d. Despite knowledge to the contrary, Defendants falsely represented in presentations to doctors and other professional education materials that their "mesh is inert." This misrepresentation conveyed to doctors and patients that mesh would not trigger the chronic foreign body response, contracture, and hardening that leads to major complications of mesh, including erosion, dyspareunia, pain, and urinary dysfunction.

98. Defendants made misrepresentations directly to consumers through consumer-directed brochures, radio advertisements, television advertisements, internet advertisements, phone scripts, product advertisements, and through other informational and marketing materials.

99. Recently, trial evidence established that Defendants knew before launch that Prolift failed frequently and shortly after implantation; knew that nearly twenty percent of women would suffer from mesh shrinkage that caused pain with sexual intercourse and ambulation, and

approximately twenty percent would suffer from mesh erosion of surrounding vaginal tissue and other organs within one year of implantation. Additionally, post-launch clinical data corroborated evidence that Prolift had significant risks of injury and high rates of complications. *See*, *Gross v. Gynecare*, 2016 WL 1192556, at *26-27 (N.J. Super. App. Div. 2016), certification denied, 2016 WL 7666693 (N.J. 2016).

100. In Defendants' brochure entitled *The Choice to End Stress Urinary Incontinence and Remember . . . You're Not Alone*, and *Support is Just a Phone Call Away*, Defendants' marketing materials to doctors (and patients) promised a "short recovery period and quick return to normal activities," misleadingly minimalizing the invasiveness of the surgical mesh procedure in direct conflict with Defendants' own research data regarding health time. Specifically, Defendants' own data showed that over 15% of TVT patients took 4 weeks or more to return to normal activities, and over 25% of TVT patients did not return to work for 4 weeks or longer.

101. The following is a non-exhaustive list of other examples of unfair, false, misleading or deceptive claims about surgical mesh devices that Defendants made in clinical sales aids, brochures, materials and communications directed to doctors:

a. Defendants claimed its mesh product "does not potentiate infection" although it actually heightened the risk of infection. As an example, this misrepresentation was included in Defendants' clinical sales aids entitled *You know where you want to go . . . GPS for Pelvic Floor Repair* and *The Gynecare TVT Family of Products: 3 SUI Solutions*.

b. Defendants claimed their mesh was "lightweight, soft and supple" when it knew that mesh hardened inside the vagina causing scarring, erosion, or other complications. For example, this misrepresentation was included in Defendants' doctor-directed brochure entitled *You know where you want to go . . . GPS for Pelvic*

Floor Repair. When Defendants developed a newer mesh product, they marketed the products as delivering a "Softer, more supple tissue," as reflected in its doctor brochures entitled, *Biocompatibility is the science of living better* and *Her body will love this graft as much as you will.*

c. Defendants misleadingly implied that their TVT mesh had no erosion or tissue reactions when studies showed erosion rates as high as 19%. For example, Defendants' *Delivering Data, Safety & Choice* brochure claimed, "no tape erosion" and "no tissue reactions;" Defendants' *Five Years of Proven Performance* brochure stated "very low likelihood of urethral erosion;" and, Defendants' *Only GYNECARE TVT Has Long-term Results You Can See . . . and Believe* brochure indicated there were "[n]o reported urethral erosions."

d. Defendants falsely claimed "no late onset adverse events," a misrepresentation included in Defendants' clinical sales aid entitled *Delivering Data, Safety & Choice*.

e. Defendants claimed false or misleadingly low rates of serious complications, misrepresentations that were included in Defendants' clinical sales aid entitled *The Gynecare TVT Family of Products: 3 SUI Solutions*.

f. Defendants claimed a less than 3% urinary retention rate in Defendants' clinical sales aid entitled *The Gynecare TVT Family of Products: 3 SUI Solutions*.

g. Defendants claimed that their POP mesh was a "proven mesh for success" with "demonstrated mesh results" when the product was experimental and had no established safety record. These statements were included in Defendants' *You know where you want to go . . . GPS for Pelvic Floor Repair* doctor-directed brochure.

h. Defendants claimed that leg pain would only last 24 – 48 hours when it knew that leg pain can be long term, a misrepresentation included in the product labeling for the Gynecare TVT Obturator System, Gynecare Prolift Pelvic Floor Repair Systems, and the Gynecare TVT Abbrevo Continence System.

i. Defendants claimed a 7.2% dyspareunia rate, a misrepresentation included in the doctor-directed brochures entitled *Biocompatibility is the science of living better* and *Her body will love this graft as much as you will.*

102. Included in Defendants' doctor–directed brochure entitled *You know where you want to go . . . GPS for Pelvic Floor Repair*, Defendants misrepresented that their mesh was "lightweight, soft and supple," "remains soft and pliable," and has less "bi-directional elastic property [that] allows adaptation to various stresses encountered in the body." Defendants knew the importance that doctors place on pliability and elasticity in the pelvis, which needs to accommodate the flux and movement associated with bladder, bowel and sexual function. Yet, Defendants misrepresented, omitted and concealed the fact that mesh can harden and become rigid within the body, which will in turn cause pain, sexual and urinary dysfunction.

103. Defendants featured the results of another study in their doctor brochures with the tagline *Only Gynecare TVT Has Long-term Results You Can See and Believe,* and issued a related press release entitled *New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates*. These doctor-directed advertisements included unfair, false, misleading, and/or deceptive information, including the following:

a. Defendants' advertisements failed to advise doctors that all three authors were paid consultants of Defendants at the time of the study.

b. Defendants' advertisement reported a complication rate of less than 0.01%, but Defendants did not inform doctors that 7.5% of women evaluated in the study

had recurrent urinary tract infections, 6.3% had *de novo* urge symptoms, and 22.5% of women had urge incontinence symptoms.

c. Defendants' failed to advise that the TVT device as sold at the time of the advertisement was different than the device evaluated in the study; and,

d. Defendants' claimed "97% of women undergoing treatment for stress urinary incontinence with GYNECARE TVT Tension-free Support for Incontinence remained dry or significantly improved seven years postoperatively." However, Defendants knew that the study was limited to a carefully controlled subset of 90 patients treated in Scandinavian countries, of which only 80 were evaluated after 7 years.

104. Defendants' doctor-directed marketing campaign was specifically designed to mislead doctors into believing that the dangers associated with surgical mesh were caused by failures in surgical technique, not by the mesh itself. For example, in Defendants' doctor-directed advertisement *5 Years of Proven Performance*, Defendants stated, "most complications are minor and are avoidable with adherence to procedural technique and instructions for use."

105. Defendants concealed this risk information from doctors despite knowing about these complications before launching their products and despite discovering additional complications while their products continued on the market. Accordingly, doctors were not adequately informed about the risks of mesh and were not in a position to pass this risk information on to patients.

106. Defendants made these misrepresentations to doctors in West Virginia. Defendants intended doctors to rely upon the information they provided. The misrepresentations and/or omissions directed to doctors were clinically relevant and material to decisions about treatment

options. Defendants intended that doctors rely upon their unfair, false, deceptive and/or misleading statements when making treatment related recommendations and decisions.

107. Dr. Bruce Rosenzweig, a medical expert from Rush University in Chicago who removes problematic mesh, testified in trial in West Virginia that the heavyweight, laser-cut mesh in the TVT-O led to mesh shrinkage and contraction and foreign body response near muscles and nerves – all contributing to pain. *Huskey v. Ethicon*, 848 F.3d. 151, 157 (2017), *cert. denied, Ethicon v. Huskey*, 138 S.Ct. 107 (2017).

108. Defendants' internal documents and scientists confirm Defendants knew that their surgical mesh products were small pore mesh and heavy weight and marketing materials included statements that its products were large pore mesh that "result in good incorporation." Defendants included this misrepresentation in its doctor-directed advertising entitled *Only GYNECARE TVT Has Long-term Results You Can See . . . and Believe.*

109. Defendants knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. Defendants, however, misrepresented in their TVT doctor-directed clinical sales aids that some of the "Numerous Safety Advantages" of their product was that the product had "Few Complications," claiming "proven biocompatibility" and "no foreign body reaction," or describing the foreign body response triggered by mesh as "transitory" or "minimally reactive." The misrepresentations were included in Defendants' clinical sales aids entitled *Minimally Invasive Surgery . . . Highly Effective Tension-free Support and 5 Years of Proven Performance.*

110. Defendants also knew that their mesh products could migrate, but misrepresented in their clinical sales aids that the product "maintains its position." This misrepresentation was included in Defendants' doctor brochure entitled *Minimally Invasive Surgery . . . Highly Effective Tension-free Support.*

111. Defendants made misrepresentations concerning the 7 year Nilsson/Ulmsten study, published by Drs. Nilsson, Falconer and Rezapour in 2004. All of the authors worked for Defendants as paid consultants at the time of the publication; however, Defendants omitted these conflicts in their patient and physician directed marketing materials which relied upon and otherwise reported the results of the study. Defendants also misrepresented the efficacy and success rate of the TVT product to women in their patient and doctor directed marketing materials.

112. In communications intended to go to patients, such as patient brochures, Defendants' misrepresentations related to the 7-year study, included but are not limited to the following examples:

a. Defendants' patient brochure entitled *Stress Urinary Incontinence in Women: What YOU can do about it . . .* states that "98% of women treated with Gynecare TVT are still dry or reported significantly less leakage seven years after treatment." This statement falsely implies that the data reflects all patients treated with Gynecare TVT after 7 years, and not carefully controlled subset of 90 patients treated in Scandinavian countries, of which only 80 were evaluated after 7 years. This 98% number also differs from a separate advertisement entitled *Only GYNECARE TVT Has Long-term Results You Can See . . . and Believe*, which relied upon the same study but, reported a 97% overall success rate.

b. Defendants failed to inform patients reading its brochures that both the objective and subjective cure rate for this study was 81.3%, and that 7.5% of the women evaluated experienced recurrent urinary tract infections.

c. Defendants failed to disclose that the data used to support this 98% statement was not based upon the TVT device that existed at the time of the 2004 study.

d. Defendants knew that other clinical trials, including a study published in 2004 entitled *A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up*, had shown much lower cure rates for the TVT, with only a 63% cure rate at two years, but omitted that information in its brochures.

113. Patient education materials and brochures for the Prolift device and the Gynecare TVT state that "[f]ew patients experience complications" or that complications are "rare." However, a three-year French study completed on January 6, 2006, showed a mesh exposure rate of 10% and an infection rate of almost 17%, with 5.6% of patients requiring surgical intervention. In the context of the U.S. arm of the study, an even higher rate of mesh exposures at 14.1% was demonstrated. Defendants had actual knowledge that complications were more than "rare." *See, Hammons, supra* at 1271-1272.

114. Defendants' printed materials made statements such as "Today's minimally-invasive procedures offer safe and effective ways to treat sudden urine loss" and "you don't have to suffer with it. [T]here are safe and effective minimally invasive procedures . . . ." These misrepresentations were included in Defendants' patient brochures *The Choice to End Stress Urinary Incontinence* and *Stress Urinary Incontinence in Women: What YOU can do about it . ...* These statements are misleading and deceptive because they underestimate the rate and severity of the complications observed in clinical practice related to use of the TVT.

115. Defendants misrepresented the safety of their PMP by concealing or omitting the fact that the mesh cannot be removed effectively upon device failure.

116. Defendants' Gynecare TVT patient brochures, such as *Stress Urinary Incontinence in Women: What YOU can do about it . . .*, indicated that leg pain would be transient and only last 24-48 hours when Defendants knew that leg pain can be long term.

117. Defendants' misrepresentations, including that foreign body response triggered by mesh was "transitory" despite knowing the "reaction never goes away" were included in Defendants' patient brochures entitled *Remember . . . You're Not Alone, Support is Just a Phone Call Away* and *Stress Urinary Incontinence in Women: What YOU can do about it.*

118. Defendants knew research indicated failure rates as high as 40% one year after implantation; knew that excision surgery may be required; and knew that the mesh material could degrade in the body, migrate, and/or cause a serious foreign body response. However, Defendants' patient brochures misrepresented these risks stating that their mesh products were "permanent material," with "permanent results that would support your urethra for the rest of your life." These misrepresentations were included in Defendants' patient brochure entitled *Stress Urinary Incontinence In Women: What YOU can do about it . . . .*

119. Defendants' patient brochures described Defendants' mesh as "ribbon-like," "soft," and "supple." However, Defendants' internal documents and historical testimony have confirmed Defendants' knowledge that the mesh was "too stiff for use in vaginal tissue," had "rough sides," was "too sharp on the edges," and like a "Scotch-Brite pad." Defendants received complaints that doctors and patients could feel a "sand burr or a sharpness" on the product with "frayed edges of the mesh . . . coming through the vaginal wall," "pieces of fray sticking through the vaginal wall," and "the tape . . . frayed [with] tiny fibers . . . protruding through the anterior vaginal wall."

120. Defendants failed to disclose the risk of new (*de novo*) sexual problems arising after implantation of its surgical mesh products. While surgical mesh surgeries are undertaken in part to address underlying sexual dysfunction, they also carry the risk of the mesh itself causing new sexual problems such as erosion, chronic dyspareunia, and sexual dysfunction. Defendants falsely represented that use of surgical mesh would not negatively impact patients' sex lives when Defendants knew that erosion of the mesh out of the vaginal wall could lead to pain for the woman,

and abrasion, pain, and injury to a male sexual partner. Defendants misleadingly touted the return of sexual function for its POP patients while failing to adequately disclose the potential risk of permanent dyspareunia and other sexual problems that can arise as a result of transvaginal mesh surgery.

121. Defendants' clinical sales aids entitled, *Minimally Invasive Surgery . . . Highly Effective Tension-free Support,* include representations that their products have a "[l]ow incidence of reported serious complications," have a "small risk of exposure," "allow for restoration of sexual function," and remain "soft" and "flexible," and that PMP offered "a new and revolutionary surgical procedure" for the treatment of POP and SUI.

122. Defendants initially misrepresented, concealed or omitted the fact that their mesh could cause pelvic pain or pain with intercourse. Later, Defendants stated that "[p]otential adverse reactions are those typically associated with POP repair procedures, including pelvic pain and pain with intercourse. These may resolve with time." In fact, the rate of these complications is much higher in mesh patients than those who receive native tissue repair. Reale, D., *Native tissue is superior to vaginal mesh for prolapse repair, two studies report* (OBG Manag. 2013 April; 25(4).)

123. Defendants misrepresented to patients and doctors that their mesh products had "small risk[s] of [mesh] exposure," "allow[ed] for restoration of sexual function," had "low incidence of reported serious complications," and remained "soft" and "flexible."

124. An internal document entitled "LIGHTning Critical Strategy" dated September 26, 2006, demonstrates Defendants' knowledge regarding shrinkage and impact on sexual function:

> Mesh retraction ("shrinkage") . . . . can cause vaginal anatomic distortion, which may eventually have a negative impact on sexual function. Its treatment is difficult. Additionally, the scarplate that forms with the in-growth of tissue into the mesh can cause stiffness of the vagina that further impacts sexual function in a negative manner.

125. As previously noted, Defendants' medical director, Dr. Axel Arnaud, believed POP devices posed such risks to sexual function that he suggested in 2005 including a warning specifically aimed towards sexually active women.

126. Defendants never incorporated this warning into any of their doctor-directed or patient-directed marketing or promotional materials.

127. Defendants received complaints that some women suffer from dyspareunia, making it impossible to have comfortable sexual relations. One surgeon described a Prolift patient in a February 2009 email to Defendants: "She will likely lose any coital function as her vaginal length is now 3 cm . . . this patient will have a permanently destroyed vagina . . . ." Despite this knowledge, Defendants omitted and concealed this information in their informational and promotional materials.

128. Defendants did not disclose the risk of dyspareunia in their TVT IFU until 2015.

129. Defendants misrepresented the effectiveness of their PMP by claiming the products are superior to traditional pelvic floor repairs while failing to disclose serious complications caused by their products.

130. Defendants omitted and/or concealed the fact that there was no safe effective means for removal of its surgical mesh products. In most cases, complete removal of mesh is impossible and for many women, complications remain irreversible even after multiple surgeries. Yet, Defendants failed to disclose the lack of a safe and effective means for removal to doctors and patients, and therefore the potential irreversibility and permanent disability associated with its serious complications.

131. Defendants failed to disclose that erosions can arise at any time after the implantation of their surgical mesh products. Because mesh remains in the body forever, erosion into the vaginal wall or one of the pelvic organs can occur many years after implantation.

Defendants failed to disclose this lifelong risk of erosion despite knowing that "there is no safe time for erosion when permanent materials are used." This omission is significant because erosion is the most common and consistently reported mesh-related complication and can be debilitating, leading to severe pelvic pain, painful sexual intercourse or an inability to engage in intercourse.

FIRST CAUSE OF ACTION
Misrepresentations, Concealing and/or Omitting Material Facts as to the Safety of Defendants' Surgical Mesh Products (PMPs)

132. Plaintiff realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

133. Defendants engaged in unfair or deceptive acts or practices as defined in W. Va. Code § 46A-6-102(7)(M), by, among other allegations aforementioned, misrepresenting that their PMPs were safe or safer than other products and procedures to treat the pelvic floor surgeries when they were not. This conduct violates W. Va. Code § 46A-6-104.

134. Defendants engaged in unfair and/or deceptive acts or practices as defined in W. Va. Code § 46A-6-102(7)(M), by, among other allegations aforementioned, concealing or omitting material facts related to the risks and complications associated with their PMPs, thereby misrepresenting and omitting risks and complications caused by their mesh products. This conduct violates W. Va. Code § 46A-6-104.

135. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(M) by, among other allegations aforementioned, misrepresenting, concealing and/or omitting the material facts regarding the results of studies related to their PMPs, more specifically, that the persons conducting these studies had conflicts of interest concerning the validity and results of research which may be influenced by financial gain. This conduct violates W. Va. Code § 46A-6-104.

136. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(M) by, among other allegations aforementioned, misrepresenting, concealing and/or omitting material facts from their directed marketing literature that they distributed to patients and doctors. This conduct violates W. Va. Code § 46A-6-104.

137. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(M) by, among other allegations aforementioned, misrepresenting, concealing and/or omitting material facts as to the full range of complications associated with their PMPs in advertising, practice aids, and instructions for use. This conduct violates W. Va. Code § 46A-6-104.

138. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(M) by, among other allegations aforementioned, misrepresenting that the risks associated with the use of their PMPs were not comparatively higher than non-surgical mesh procedures. This conduct violates W. Va. Code § 46A-6-104.

139. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(M) by, among other allegations aforementioned, misrepresenting the effectiveness of their PMPs as compared to native tissue repair. This conduct violates W. Va. Code § 46A-6-104.

SECOND CAUSE OF ACTION
Causing Likelihood of Confusion or of Misunderstanding as to FDA Approval of Defendants' PMPs

140. Plaintiff realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

141. Defendants engaged in unfair or deceptive acts or practices as defined by W. Va. Code § 46A-6-102(7)(B), -(C) by, among other allegations aforementioned, representing their

PMPs were "FDA Approved" when they were not. This conduct violates W. Va. Code § 46A-6-104.

VI. RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of West Virginia *ex rel.* Patrick Morrisey, Attorney General, prays for relief pursuant to each cause of action set forth in this Complaint as follows:

A. That the Court conduct a hearing on this matter as soon as possible pursuant to W. Va. Code § 46A-7-110;

B. That upon final hearing, the Court enter judgment in favor of the State of West Virginia and against Defendants as follows:

1. That the Court adjudge and decree that Defendants have engaged in the acts and practices complained of herein;

2. That the Court adjudge and decree that the acts and practices complained of herein constitute unfair and deceptive acts or practices in violation of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-6-104;

3. That the Court issue a permanent injunction prohibiting and restraining Defendants and their representatives, successors, assigns, officers, agents, servants, employees, and all other persons acting or claiming to act for, or on behalf of, or in active concert or participation with Defendants from continuing or engaging in the unlawful conduct complained of herein, namely engaging in the business of marketing, advertising, promoting, offering for sale, distributing or selling their PMPs in West Virginia in violation of the West Virginia Consumer Credit and Protection Act;

4. That the Court issue a permanent injunction prohibiting and restraining Defendants and their representatives, successors, assigns, officers, agents, servants employees, and all other persons acting or claiming to act for, or on behalf of, or in active concert or participation with Defendants from making unfair or deceptive statements regarding surgical mesh, including statements about risks associated with the devices.

5. That the Court issue a permanent injunction directing Defendants and their representatives, successors, assigns, officers, agents, servants, employees, and all other persons acting or claiming to act for, or on behalf of, or in active concert or participation with Defendants that if Defendants learn about new, significant risks associated with their surgical mesh, they must disclose those risks.

6. That the Court issue a permanent injunction directing Defendants and their representatives, successors, assigns, officers, agents, servants, employees, and all other persons acting or claiming to act for, or on behalf of, or in active concert or participation with Defendants that Defendants' promotional material must be truthful, accurate, and presented in a balanced way, and further, if Defendants sponsor a study or research and cites that study or research in promotional materials, they must disclose their sponsorship.

7. That the Court find Defendants have engaged in a course of repeated and willful violations of the West Virginia Consumer Credit and Protection Act, W. Va. Code Chapter 46A, and assess civil penalties for each and every

violation pursuant to the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-7-111(2);

8. That the Court order Defendants to pay the State all its attorney's fees, court costs, investigation costs, and other costs associated with the maintenance and prosecution of this action; and,

C. Grant other and further relief as the Court deems just and appropriate.

Respectfully submitted:

STATE OF WEST VIRGINIA ex rel.
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By Counsel

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