KING COUNTY SUPERIOR COURT
STATE OF WASHINGTON

STATE OF WASHINGTON, Plaintiff, v. JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation, a wholly owned subsidiary of JOHNSON & JOHNSON; ETHICON US, LLC, a New Jersey Company, a wholly owned subsidiary of JOHNSON & JOHNSON; and DOES 1 through 100, inclusive, Defendants.	NO. COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

I. INTRODUCTION

1.1 Plaintiff, the State of Washington (the State), by and through Attorney General Robert W. Ferguson, Senior Counsel Elizabeth J. Erwin, and Assistant Attorneys General Andrea Alegrett and Leilani Fisher, brings this action against Defendants Johnson & Johnson, Ethicon, Inc., Ethicon US, LLC, and DOES 1 through 100 ("Defendants") for violations of the Consumer Protection Act, RCW 19.86 ("CPA"). The CPA declares unlawful and prohibits unfair or deceptive acts or practices in the conduct of any trade or commerce. RCW 19.86.020.

1.2 Defendants manufacture, market, and sell surgical mesh medical devices designed to treat common pelvic floor conditions in women, specifically pelvic organ prolapse

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and stress urinary incontinence. These are conditions that one-third to one-half of all women will face in their lifetime. Defendants' surgical mesh is composed of woven synthetic polypropylene (plastic) threads that are used to prop up organs that have dropped down or protruded into the vagina. The mesh is inserted into the body through the vagina, pulled through an incision in the vaginal canal, and then anchored permanently in the body. Defendants sold almost 12,000 mesh devices in the State of Washington between 2005 and 2015.

1.3 Defendants marketed their products to doctors as a "new and revolutionary" product that would reduce time in the operating room and increase profits. Defendants made these representations without disclosing to doctors the serious complications their mesh can cause women. Defendants also marketed their mesh products as improvements over traditional repair methods (i.e. native tissue repair) when they knew such claims were inaccurate.

1.4 Defendants knew at all relevant times that the presence of polypropylene in the body and the process of implanting mesh through the vagina could cause severe and unavoidable complications. These unavoidable lifelong complications include for example, permanent loss of sexual function, painful sexual intercourse, near impossibility of removal of the device when complications arise, permanent urinary dysfunction, lifelong risk of infection, and chronic pelvic pain. Defendants knew these complications are caused by the design and placement of the mesh and cannot be avoided by good surgical technique alone.

1.5 Due to the severity and type of complications associated with surgical mesh devices, the impact on a woman's quality of life can be devastating. Some women become permanently disabled or require accommodations from their employers. Women and their partners have suffered loss of physical intimacy. One mesh patient's complaint to Defendants from August 2008, is illustrative of the toll that surgical mesh has taken on people's lives:

> [I] had all kinds of problems with chronic pain, bleeding, dyspareunia [painful sexual intercourse] (even my husband

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> complained of scraping and poking) . . . The pelvic pain was keeping me awake at night, and the only relief was to sit on a tennis ball. The thought living like that, sitting on a ball, wearing a diaper, splinting my perineum to have a bowel movement, having infrequent and miserable sex, and marital problems was almost more than I could bear.

In August 2011, another woman informed Defendants:

> I experienced excruciating pain from day one. I felt as though my urethra was being strangled, I couldn't pee, walking was out of the question, sitting was agony, & I couldn't lie on my left side due to severe pain . . . Over the course of the next 14 weeks I visited/was admitted to the [hospital] 10 times . . . I had no quality of life. My consultant likened the mesh removal as to trying to remove chewing gum from hair.

1.6 In an attempt to treat complications such as these, women often need multiple mesh removal surgeries. However, their suffering may never be alleviated because it is nearly impossible to completely remove mesh from the body. Moreover, the mesh removal surgeries can present additional complications and result in recurrence of the original pelvic floor condition. The suffering by these women is even more egregious considering that the underlying condition the mesh is meant to treat is not life threatening. Further, women have a non-mesh surgical alternative (i.e. the use of native tissue) that has been used for decades. Native tissue repair does not pose the same risks as mesh and can be just as effective for treating pelvic floor conditions.

1.7 Despite Defendants' knowledge of these complications, Defendants' informational and marketing materials misrepresented the safety and effectiveness of their products and omitted known serious risks and complications. Defendants' campaign of deception caused thousands of women in Washington to unknowingly take risks with their bodies. Defendants' conduct deprived doctors and patients of the information necessary to make informed decisions regarding Defendants' products. Defendants' misrepresentations and

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omissions to consumers are a serious women's health issue. Defendants are thus liable for civil penalties, injunctive relief, restitution, and other appropriate relief under the Washington CPA, as set forth herein.

II. PARTIES

2.1 Plaintiff is the State of Washington. The Attorney General is authorized to commence this action pursuant to RCW 19.86.080 and RCW 19.86.140.

2.2 Defendant Johnson & Johnson ("J&J") is a publically-held company that is organized and exists under the laws of the State of New Jersey. Its principal place of business is located at 1 Johnson & Johnson Plaza, New Brunswick, NJ 08933. According to its website, J&J is the "world's most comprehensive medical devices business" with "265 operating companies in more than 60 countries," including the United States and the State of Washington. J&J has an open account with the Washington State Department of Revenue, UBI No. 601 925 329, and provided a local business location of 5615 82nd Ave W, University Place, WA 98467.

2.3 Defendant Ethicon Inc. and Defendant Ethicon US, LLC (UBI 603 369 484) (collectively "Ethicon") are wholly owned subsidiaries of J&J and are located in New Jersey. Ethicon's website proclaims it to be "Part of the Johnson & Johnson Family of Companies." J&J's company structure is divided into three sectors: medical devices, consumer healthcare, and pharmaceuticals. The "Ethicon Franchise" is a business unit in J&J's medical devices sector. Upon information and belief, the Ethicon Franchise is comprised of companies controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon US, LLC, and Ethicon LTD.

2.4 At J&J's direction and independently, Ethicon designs, develops, promotes, markets, reports, tests, distributes, and sells synthetic polypropylene pelvic floor repair products and trains doctors on these products. Further, J&J together with Ethicon, sold mesh products, placing both their corporate brand names on the packaging for each of their mesh

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products. (*See* Photographs of Prolift+M, attached as Exhibit A; and Photographs of TVT, attached as Exhibit B.)

2.5 J&J participated in, controlled, knew about, and approved of, Ethicon's conduct in the development, design, sales, and marketing of Defendants' mesh products, including the training of doctors. J&J is therefore liable for Ethicon's conduct under the Washington CPA.

2.6 J&J, Ethicon, and DOES 1-100 are collectively referred to as "Defendants." Plaintiff is not aware of the true names and capacities of Defendants sued herein as DOES 1 through 100 and therefore sues these defendants by fictitious names. Plaintiff will amend this Complaint to add the true names of the fictitiously named defendants once they are discovered. Acts done by one Defendant were done in furtherance of the business practices of the other. Defendants directed, created, executed, participated in, controlled, had the authority to control or participate in, and had knowledge of the acts and practices set forth in this Complaint. Upon information and belief, all Defendants received significant proceeds from the business practices identified in this Complaint.

2.7 At all relevant times, each Defendant engaged in the business of placing polypropylene mesh medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, and/or selling such devices, including the Prolene Mesh/Prolene Soft Mesh, Gynemesh, Gynemesh PS, TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact, TVT Abbrevo, Prolift, Prolift+M, Prosima, Artisyn and other polypropylene mesh products unknown at the present ("Polypropylene Mesh Products").

2.8 At all relevant times, each Defendant acted individually or jointly with every other named Defendant in committing all acts alleged in this Complaint.

2.9 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.

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2.10 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.

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

III. JURISDICTION AND VENUE

3.1 The Attorney General is authorized under RCW 19.86.020, RCW 19.86.080, and RCW 19.86.140 to bring suit to enforce the CPA's prohibitions on unfair or deceptive acts or practices in the conduct of trade or commerce.

3.2 This Court has personal jurisdiction over Defendants pursuant to RCW 4.28.180, RCW 4.28.185, and RCW 19.86.160 because Defendants have transacted substantial business in this State and the acts alleged have been committed in this State. Defendants knowingly placed their Polypropylene Mesh Products into the stream of commerce through designing, manufacturing, testing, training, marketing, promoting, packaging, and selling such devices. Defendants promoted, marketed, and sold their Polypropylene Mesh Products in the State of Washington and throughout King County. Further, Defendants derived substantial profits from Washington consumers, hospitals, clinics, and health care providers from the sale of their Polypropylene Mesh Products. Their products were ultimately surgically placed in Washington consumers.

3.3 Upon information and belief, Defendants sold approximately 11,728 mesh products in the State of Washington between 2005 and 2015.

3.4 Upon information and belief, Defendants had thousands of sales and marketing contacts to promote Polypropylene Mesh Products in the State of Washington and in King County, including but not limited to: Defendants' sales representative and other employee had contacts with doctors; medical and other trainings offered to Washington licensed-doctors; poster presentations received by doctors; paid consultants promoted Defendants'

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Polypropylene 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.

3.5 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 Washington State Constitution.

3.6 Venue is proper in King County pursuant to RCW 4.12.025 because Defendants transacted business in King County at the time the causes of action in this Complaint arose and continue to do so as of filing this action.

3.7 Defendants' actions in Washington were directed to numerous Washington consumers, doctors, and patients and thus affect the public interest.

IV. FACTS

4.1 Defendants promoted their Polypropylene Mesh Products directly to consumers, including doctors and patients. Defendants mislead consumers through informational and marketing materials that misrepresented the safety and effectiveness of their products and omitted serious risks and complications. Further, Defendants received large numbers of complaints from doctors and patients regarding complications caused by their Polypropylene Mesh Products. Despite this knowledge, Defendants failed to update their informational and promotional materials with these serious complications.

A. BACKGROUND OF SUI AND POP TREATMENT

4.2 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 occurs when the muscles or other supporting tissues that control urine flow do not work properly, resulting in involuntary urine leakage during everyday activities such as laughing,

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coughing, or exercise. POP occurs when the muscles or other supporting tissues of the pelvic floor can no longer support the pelvic organs, causing various organs to drop downwards and, in some cases, press into and bulge out of the vagina.

4.3 SUI and POP are conditions that pose lifestyle limitations and, in the case of POP, some mild pain, but they are not life threatening. SUI and POP affect a large percentage of the female population. An estimated 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.

4.4 Defendants developed surgical mesh products intended to treat SUI and POP. Defendants' Polypropylene Mesh Products are derived from polypropylene threads that are weaved together. Polypropylene is derived from crude oil and is used to manufacture thousands of consumer and other goods—everything from rug backing to automobile parts. Defendants' mesh has openings in its weave known at 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. The mesh then becomes integrated into the patient's surrounding tissue and is intended to remain permanently implanted in the body.

4.5 Defendants' mesh products are placed transvaginally. "Transvaginal placement" means that 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. 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 any involuntary leakage of urine during periods of increased abdominal pressure (such as laughing, coughing, or sneezing). For POP products, mesh is inserted into the body through the vagina, pulled through an incision in the vaginal canal, and placed in different locations in front of or behind the vaginal canal to act as a hammock for the prolapsing organ. 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.

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Organs that are typically involved in POP procedures include the bladder, small intestine, uterus, rectum, and sometimes the vagina itself.

4.6 POP and SUI may be treated non-surgically through behavioral changes (such as diet, exercise, and weight loss), vaginal and/or tibial stimulation, pelvic floor exercises, or using a removable device called a pessary that is placed into the vagina to support areas of prolapse. Some women, however, may choose surgery for treatment. Surgical options include creating a sling with the patient's own tissue, cadaver tissue, or other tissue, abdominal implantation of mesh, transvaginal implantation of mesh, or a combination of these options. Notably, the U.S. Food and Drug Administration (FDA) has found that use of a patient's native tissue is just as effective as transvaginal mesh and does not pose the same risks as mesh.

B. DEFENDANTS' POLYPROPYLENE MESH PRODUCTS

4.7 Between 2005 and 2015, Defendants sold at least 11,728 Polypropylene Mesh Products in Washington. Beginning in 1998, Defendants began making, marketing, and selling various SUI mesh treatment options. Their first product was called TVT. This was a "tension free vaginal mesh" also called a "mid-urethral" sling. Defendants continue to make, market, and sell similar devices for the treatment of SUI today. Defendants offered, and continue to offer the original TVT in multiple and significant variations, including but not limited to the TVT, TVT-Obturator (TVT-O), TVT-Secur (TVT-S), TVT Exact, and TVT Abbrevo. All references to TVT include all variations. Upon information and belief, Defendants sold thousands of TVT products in Washington, including in King County.

4.8 In 2002, Defendants began making, marketing, and selling Gynemesh for the treatment of SUI and POP. All references to Gynemesh include all variations of Gynemesh, including but not limited to Gynemesh PS Nonabsorbable Prolene Soft Mesh. Upon information and belief, Defendants sold Gynemesh products in Washington, including in King County.

4.9 In 2005, Defendants began making, marketing, and selling the Prolift System.

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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. Defendants sold this product by misrepresenting in their informational and marketing materials and through their sales representatives that the FDA "approved" the marketing of Prolift when the device was never "approved" by the FDA.

4.10 In 2007, Defendants updated the Prolift System with the Prolift+M System. All references to the Prolift and the Prolift+M Systems include by reference all variations. Upon information and belief, Defendants sold Prolift and Prolift+M products in Washington, including in King County.

4.11 In 2010, Defendants began making, marketing, and selling their Prosima System for the treatment of POP. All references to Prosima include by reference all variations. Upon information and belief, Defendants sold Prosima products in Washington, including in King County.

4.12 In 2012, Defendants began making, marketing, and selling a mesh products called Artisyn, designed to treat POP that is 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). For the first time, Defendants included the following safety warning in materials for Artisyn: "The safety and effectiveness of this product has not been validated in clinical trials." No such warning was offered to consumers, doctors, and patients for the products sold by Defendants from 1998–2013. Rather, during that time period Defendants misled the public by advertising and promoting their other Polypropylene Mesh Products as safe and effective.

C. DEFENDANTS MISREPRESENTED THE SAFETY AND EFFECTIVENESS OF THEIR PRODUCTS TO WASHINGTON CONSUMERS

4.13 Defendants did not conduct human trials prior to the initial sale of their

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Polypropylene Mesh Products in 1998. Defendants destroyed the underlying data they claimed supported the safety and effectiveness of their original SUI products. Defendants never tested the long term safety of their POP mesh products prior to sale. While some mesh products were tested in rats prior to sale, animal results cannot reliably be extrapolated to how mesh devices will perform in women. Many independent studies involving transvaginal mesh have actually demonstrated severe and serious complications associated with the use of polypropylene, including Defendants' products.

4.14 Despite lacking sufficient data, Defendants represented that their products had a "history of safety" and "proven efficacy" while disregarding known serious risks and complications. These misrepresentations were made directly to doctors through educational trainings, sales representative contacts, in person meetings, doctor opinion papers, instructions for use (IFUs), and other informational and marketing materials. IFUs accompany the actual device. They are designed to disclose any relevant hazards, contraindications, side effects, and precautions. As an Ethicon Medical Director admitted, Ethicon should in its IFUs "list each of the adverse reactions that were known" to Ethicon.

4.15 Defendants also 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. These misrepresentations include advertising 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."

4.16 Defendants made misrepresentations in their marketing, promotional, informational, and educational materials about complication rates of mesh, citing to studies that did not actually support the Defendants' propositions. Dr. Ulf Ulmsten, creator of the TVT product, sold the rights of the TVT device to Defendants. In marketing the TVT product, Defendants used several studies of Dr. Ulmsten and failed disclose their financial relationship.

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Defendants also failed to disclose that Dr. Ulmsten contractually agreed that he would only get paid by Defendants a specific sum if his future studies produced favorable results regarding the product.

4.17 Many of Defendants' informational and marketing materials advised patients to "talk to their doctors." However, doctors lacked accurate information to give to their patients because Defendants made safety and effectiveness misrepresentations directly to doctors. Defendants withheld key information that would have allowed consumers, doctors, and patients to understand the risks of these products and make informed medical decisions. These misrepresentations are material and have the capacity to deceive a substantial number of consumers in Washington State.

1. Defendants Misrepresented the Safety of Their Products by Failing to Disclose Risks and Complications Associated with Pelvic Floor Surgery

4.18 Defendants represented that their Polypropylene Mesh Products offer "a new and revolutionary surgical procedure" for the treatment of POP and SUI. Yet Defendants failed to disclose that their mesh devices carry similar risks as other pelvic floor surgeries and additional risks caused by the mesh.

4.19 Defendants' informational and marketing materials consistently failed to disclose pelvic floor complications, including but not limited to: abscess, *de novo* urge incontinence, defecatory dysfunction, dyspareunia (difficult or painful intercourse), dysuria (painful urination), fistula formation (abnormal permanent passageway between two organs), hematoma, hemorrhage, pain to partner during intercourse, permanent urinary dysfunction, recurrence, temporary and transitory pain, urinary tract infection, urinary tract obstruction, vaginal scarring, and worsening incontinence.

4.20 Defendants not only knew that their mesh devices can cause these pelvic floor general complications, but they also knew that such complications can last a lifetime and may develop several years after the initial procedure. And yet, Defendants did not disclose these

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risks.

4.21 Defendants misrepresented the risks of their mesh products by claiming certain complications were common in all pelvic floor surgeries. For example, Defendants claimed that only patients with compromised immune systems may have healing risks. In fact, any patient who experienced a chronic infection and chronic inflammation from a mesh implant could develop a healing risk due to mesh. Although all of Defendants' products were used in contaminated areas–the vagina, Defendants misrepresented that "if the mesh implant is to be used in contaminated areas, it must be only with the understanding that subsequent infection may require its removal."

4.22 Additionally, Defendants did not disclose, until well after the sale of thousands of devices, that their mesh could cause pelvic pain or pain with intercourse. When Defendants finally did disclose these risks, the disclosures were inadequate. Rather, they stated, "potential adverse reaction 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 that receive native tissue repair.

4.23 In order to increase sales of their products and to appear superior to native tissue repair, Defendants represented their products to consumers as having "small risk[s] of exposure," "allow[ing] for restoration of sexual function," having "low incidence of reported serious complications," and remaining "soft" and "flexible".

2. Defendants Misrepresented Material Complications and Risks Caused By Their Products

4.24 Defendants misled consumers, doctors, and patients regarding serious risks that are increased by the use of mesh and that are not present in native tissue repair. Such complications cannot be avoided by doctors or patients because they are caused by the products' implantation method and how polypropylene is processed by the body.

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4.25 Defendants represented in informational and marketing materials that their Polypropylene Mesh Products do not potentiate infection. This is a misrepresentation because the transvaginal design of Defendants' Polypropylene Mesh Products 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 can never be completely sterilized. Because Defendants' Polypropylene Mesh Products is a fabric made of woven strands bacterial microcolonies can become embedded 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.

4.26 Also, Defendants represented in their informational and marketing materials that their polypropylene mesh products are "inert"— meaning that they do not trigger a chronic foreign body reaction or degrade in the body. Defendants further represented in promotional and informational materials that the body does not react to mesh material and that it is biologically compatible in the pelvic floor. This is a misrepresentation because polypropylene incites a chronic foreign body reaction. 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. This chronic foreign body reaction then causes chronic inflammation.

4.27 The risks of chronic infection, chronic foreign body reaction, and chronic inflammation caused by the Polypropylene Mesh Products trigger a number of adverse reactions in the human body. For example, the mesh hardens, contracts, erodes into other body organs, and becomes so rigid and distorted that complete mesh removal is extremely difficult and often impossible. Other complications that ultimately result from mesh include but are not limited to: chronic infection, chronic foreign body reaction, chronic inflammation, mesh hardening, mesh contracture, erosion into other body organs, mesh exposure (migration of mesh into the vagina), mesh extrusion, mesh degradation (breakdown of mesh particles),

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permanent dyspareunia, chronic pain, vaginal shortening, vaginal stiffness, vaginal distortion, sexual dysfunction, injury to sexual partners, urinary and bowel dysfunction, and other lifelong problems.

4.28 Defendants misrepresented the safety of their Polypropylene Mesh Products by failing to disclose that the mesh cannot be removed effectively upon device failure. Mesh removal is the only treatment option for most continuing mesh complications. Removal often requires multiple surgeries, which may or may not resolve complications, and may in fact result in new problems. One doctor described removing mesh as "akin to taking a hammer and chisel and trying to remove the rebar from a sidewalk, while leaving the cement otherwise intact and not damage the water mains and power lines below." Yet, Defendants failed to disclose the lack of a safe and effective means for removal.

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

4.30 Because mesh remains in the body forever, erosion into the vaginal wall or one of the pelvic organs can occur at any time. 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. Erosion can be debilitating, leading to severe pelvic pain, painful intercourse, or an inability to engage in intercourse.

4.31 Defendants knew prior to sale about each complication identified in this Complaint. For example, an internal document entitled "LIGHTning Critical Strategy," dated September 26, 2006, demonstrates Defendants' knowledge regarding shrinkage and impact on sexual function:

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

4.32 Defendants also knew that claims of softness were "illusory." Nevertheless, Defendants misrepresented that their mesh is "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 flux and movement associated with bladder, bowel and sexual function. Yet, Defendants misrepresented and concealed the risk that mesh can harden and become rigid within the body. This will in turn cause pain, sexual and urinary dysfunction.

4.33 Despite the fact that the foreign body reaction and inflammation triggered by Polypropylene Mesh Products can be chronic and lifelong, Defendants misrepresented in promotional and informational materials that the foreign body response triggered by mesh is only temporary. Defendants stated in physician brochures, physician trainings, and other materials, for examples, that polypropylene mesh response is "transitory."

4.34 These examples are representative of many misrepresentations made by Defendants throughout their promotional and informational materials.

3. Defendants Misrepresented the Safety and Effectiveness of Their Pelvic Mesh Products by Marketing their Products as "FDA Approved"

4.35 Defendants misrepresented in their informational and marketing materials that their Polypropylene Mesh Products are "FDA Approved." FDA approved devices undergo a rigorous evaluation of their safety and efficacy. To obtain FDA approval, the safety and effectiveness of a medical device must be demonstrated through adequate clinical trials.

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However, Defendants' mesh products never underwent the FDA approval process. Rather, Defendants' mesh products were "cleared" by the FDA under the 510(k) equivalency process. The 510(k) clearance process does not verify safety or efficacy of the product at issue and does not typically require clinical trials.

4.36 Defendants' Polypropylene Mesh Products have never been approved by the FDA. Yet Defendants instructed their sales representatives to tell doctors that they sold "the only FDA approved partially absorbable pelvic floor mesh."

4.37 By claiming that their Polypropylene Mesh Products 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.

4. Defendants Misrepresented the Effectiveness of Their Polypropylene Mesh Products As Compared to Native Tissue Repair

4.38 Defendants misrepresented the effectiveness of their Polypropylene Mesh Products by claiming their products are superior to traditional pelvic floor repairs while failing to disclose serious complications caused by their products. Defendants' misrepresentations and omissions are material given that Defendants' Polypropylene Mesh Products are in fact not uniformly superior to native tissue repair and, as discussed above, Defendants' mesh may cause irreversible and debilitating long-term complications that are not present with native tissue repair.

4.39 These misrepresentations and omissions are found in informational and marketing materials Defendants provided to doctors, i.e. IFUs, doctor brochures, sales representatives, and doctor training sessions, as well as information that Defendants provided directly to consumers and patients through their patient brochures, radio and television advertisements, on Defendants' websites, and in other materials.

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D. DEFENDANTS FAILED TO UPDATE INFORMATIONAL AND MARKETING MATERIALS

4.40 Defendants failed to update or revise their informational and marketing materials with known risks and complications caused by their Polypropylene Mesh Products. Defendants' failure to update their materials is particularly critical because the device is a permanent implant.

4.41 Defendants knew the problems were associated with their Polypropylene Mesh Products 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 Defendants that they now suffer from permanent urinary and/or defecatory dysfunction that has resulted in a loss of dignity, inability to function in a work place, and inability to participate in everyday family life.

4.42 Defendants received complaints that some women suffer from permanent dyspareunia, making it impossible to have comfortable sexual relations. For example, 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 . . ."

4.43 While Defendants purportedly had systems 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, a medical director in the complaint review department, informed management on numerous occasions of patient complaints regarding complications associated with their Polypropylene Mesh Products. Dr. Chen proposed adding dyspareunia to the TVT IFU based on patient complaints and how those complications were negatively affecting quality of life. Below is a meeting agenda by Dr. Chen describing her observations from patient complaints:

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1. Tape exposure/erosion/extrusion very frequently reported
2. Patients did not feel there were adequate pre-op consent or risk benefit assessment[s]
3. Patient-specific concerns
   a. The three Es
   b. The incontinence recurrence
   c. Post-operative dyspareunia and pain affect quality of life and affect daily routine
   d. Re-operations-tape excision, removal, re-do sling procedure[s]
   e. Type and intensity of the post-operative complications disportion[ate] to pre-operative consent-expectations.

4.44 Defendants never acted on Dr. Chen's recommendations. Defendants continued to conceal the material risks of dyspareunia and pain affecting quality of life in their informational and marketing materials.

4.45 In 2005, Dr. Axel Arnaud, an Ethicon medical director and one of the creators of Prolift, also suggested adding the following warning to the Prolift 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 suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.**

4.46 This warning never made its way into product information that went to consumers and doctors. This is all notwithstanding the fact that Defendants knew about each and every risk and complication stated in this Complaint before selling their SUI products 1997 and their POP products in 2005.

4.47 Importantly, Defendants did not disclose the risk of dyspareunia in their TVT IFU until 2015. Not until 2012 did Defendants mention the risk of infection in their TVT brochures or the complication of vaginal scarring and contracture.

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V. FIRST CAUSE OF ACTION

Misrepresentations and Omissions Regarding Safety

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

5.2 Defendants are "persons" within the meaning of the Consumer Protection Act, RCW 19.86.010(1).

5.3 Defendants conduct "trade" or "commerce" within the meaning of the Consumer Protection Act, RCW 19.86.010(2).

5.4 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by representing their Polypropylene Mesh Products were safe while misrepresenting and omitting risks and complications associated with pelvic floor surgeries.

5.5 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by representing their Polypropylene Mesh Products were safe while misrepresenting and omitting risks and complications caused by their mesh products.

5.6 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by representing their Polypropylene Mesh Products were safe by marketing their Polypropylene Mesh Products as "FDA Approved."

5.7 As alleged herein, these representations are deceptive and/or unfair because Defendants misrepresented material information as alleged in this Complaint to consumers, doctors, and patients; and/or material information was omitted from informational and marketing materials.

5.8 The Consumer Protection Act prohibits unfair or deceptive acts or practices in trade or commence. RCW 19.86.020. Defendants' misrepresentations are deceptive because they have the capacity to mislead a substantial number of consumers.

5.9 An act or practice may be unfair if it offends public policy, is immoral,

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unethical, oppressive, unconscionable, or if it causes injury to consumers. Defendants' acts or practices as alleged in this Complaint are unfair.

5.10 Defendants' conduct affected and continues to affect the public.

5.11 Defendants' acts and practices as alleged in this Complaint violate RCW 19.86.020.

VI. SECOND CAUSE OF ACTION

Misrepresentations or Omissions Regarding Efficacy

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

6.2 Defendants are "persons" within the meaning of the Consumer Protection Act, RCW 19.86.010(1).

6.3 Defendants conduct "trade" or "commerce" within the meaning of the Consumer Protection Act, RCW 19.86.010(2).

6.4 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by representing their Polypropylene Mesh Products were effective while misrepresenting their products' effectiveness in comparison to non-mesh alternatives.

6.5 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by representing their Polypropylene Mesh Products were effective by marketing their Polypropylene Mesh Products as "FDA Approved."

6.6 As alleged herein, these representations are deceptive and/or unfair because Defendants misrepresented material information as alleged in this Complaint to consumers, doctors, and patients; and/or material information was omitted from informational and marketing materials.

6.7 The Consumer Protection Act prohibits unfair and/or deceptive acts or practices in trade or commence. RCW 19.86.020. Defendants' misrepresentations are deceptive because they have the capacity to mislead a substantial number of consumers.

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6.8 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.

6.9 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by failing to disclose material information to consumers, doctors, and patients in marketing and informational materials.

6.10 Defendants' conduct affected and continues to affect the public interest.

6.11 Defendants' acts and practices as alleged in this Complaint violate RCW 19.86.020.

VII. THIRD CAUSE OF ACTION

Failure To Update Information Provided To Consumers

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

7.2 Defendants are "persons" within the meaning of the Consumer Protection Act, RCW 19.86.010(1).

7.3 Defendants conduct "trade" or "commerce" within the meaning of the Consumer Protection Act, RCW 19.86.010(2).

7.4 Defendants engaged in unfair and/or deceptive acts or practices within the meaning of RCW 19.86.020 by failing to update their informational and marketing materials with known, material risk and complication information.

7.5 The Consumer Protection Act prohibits unfair and/or deceptive acts or practices in trade or commence. RCW 19.86.020. Defendants' misrepresentations are deceptive because they have the capacity to mislead a substantial number of consumers.

7.6 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.

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7.7 Defendants' conduct affected and continues to affect the public interest.

7.8 Defendants' acts or practices as alleged in this Complaint violate RCW 19.86.020.

VIII. RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of Washington, prays for relief pursuant to each cause of action set forth in this Complaint as follows:

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

B. That the Court adjudge and decree that the acts and practices complained of herein constitute unfair and/or deceptive acts or practices in violation of the Consumer Protection Act, RCW 19.86;

C. 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, 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 Polypropylene Mesh Products in Washington in violation of the Consumer Protection Act, RCW 19.86;

D. That the Court assess civil penalties, pursuant to RCW 19.86.140, of two thousand dollars ($2,000) per violation against Defendants for each and every violation of RCW 19.86.020;

E. That the Court make such orders pursuant to RCW 19.86.080 as it deems appropriate to provide for restitution to consumers of money or property acquired by Defendants as a result of the conduct complained of herein;

F. That the Court make such orders pursuant to RCW 19.86.080 to provide that Plaintiff, the State of Washington, recovers the costs of this action, including reasonable attorneys' fees;

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G. That the Court grant Plaintiff leave to amend the Complaint to conform to the evidence presented at trial; and

H. That the Court order such other or further relief as the Court may deem just and proper.

DATED this 24 day of May, 2016.

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