IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

STATE OF OREGON, ex rel. ELLEN F. ROSENBLUM, Attorney General for the State of Oregon,

Plaintiff,

vs.

JOHNSON & JOHNSON, a New Jersey corporation,
and
ETHICON, INC, a subsidiary of Johnson & Johnson,
and
ETHICON U.S., LLC, a subsidiary of Johnson & Johnson,

Defendants.

Case No. _____

COMPLAINT

Unlawful Trade Practices Act

Not Subject to Mandatory Arbitration

Filing fee not collectible pursuant to ORS 21.259

DEMAND FOR JURY TRIAL

Plaintiff, for its complaint against defendants, alleges as follows:

INTRODUCTION

1.

The State of Oregon brings this action against Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (together, J&J or Defendants) for deceptive marketing of surgical mesh medical devices for women. Transvaginal mesh (or 'surgical mesh') is a synthetic woven fabric implanted through the vagina to treat common pelvic floor conditions that 30% to 50% of all women face in their lifetime. J&J deceptively marketed its surgical mesh devices by failing to disclose dangerous characteristics of the mesh and a host of dangerous complications caused by

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these devices. By failing to disclose clinically relevant information material to decisions about treatment options, J&J impaired doctors' ability to accurately counsel patients and women's ability to make informed choices about whether to have such devices permanently implanted in their bodies.

2.

J&J concealed, failed to disclose, and misrepresented to doctors and patients many of the unique and dangerous characteristics of the mesh and the risks of adverse events associated with these devices, including but not limited to chronic pelvic pain, chronic vaginal pain, chronic buttock pain, urinary and/or defecatory dysfunction, pain with sexual intercourse and/or loss of sexual function, vaginal scarring and disfigurement, multiple and untreatable erosions, inability to remove the devices, vaginal discharge and odor, severe and untreatable groin, leg and thigh pain, “His”pareunia (male partner’s pain with sexual intercourse) and the potentially irreversible nature of these complications. J&J further misrepresented clinically relevant risks unique to surgical mesh that are not present with non-mesh surgical alternatives, including but not limited to degradation of the mesh, deformation of the mesh, chronic inflammatory response, chronic foreign body reaction, scar platting, rolling/curling/folding/roping of the mesh and injuries from trocar and route of placement.

3.

J&J marketed surgical mesh to doctors and patients as minimally invasive with minimal risk, without disclosing the potential for permanent, debilitating complications. J&J did this despite being urged by its own medical advisors and employees to use different mesh in some of its devices and to warn doctors and patients of pain with intercourse, sexual dysfunction, and impact on quality of life. J&J persisted in misrepresenting the risks of these devices after receiving complaints from doctors and patients about severe complications.

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4.

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, unable to work or requiring accommodations from their employers. Marriages have suffered the loss of physical intimacy. Women have undergone multiple removal surgeries only to continue suffering from complications because the mesh cannot be completely removed and/or the complications are irreversible.

5.

By misrepresenting (1) the full range of possible surgical mesh complications; (2) the risks that surgical mesh poses, which are unique to mesh and not present in non-mesh repair; and (3) the frequency and severity of the risks that were disclosed, J&J denied women the ability to make informed choices regarding their health and caused them to unknowingly take risks with their well-being. J&J's concealment of the unique and dangerous severity of the risks associated with its surgical mesh devices is all the more egregious because women suffering from POP and SUI could have chosen (1) a non-mesh surgical alternative with fewer dangers, (2) non-surgical treatment that did not carry these dangers, or (3) no treatment because POP and SUI are not life-threatening conditions.

PARTIES, JURISDICTION, AND VENUE

6.

Ellen Rosenblum is the Attorney General of plaintiff, the State of Oregon.

7.

Defendant Johnson & Johnson is a multinational corporation engaged in the manufacture and sale of medical devices, pharmaceuticals, and consumer goods. Johnson & Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. At all relevant times, Johnson & Johnson has transacted and continues to transact business throughout the State, including Multnomah County.

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8.

Defendant Ethicon, Inc. (Ethicon) is a subsidiary of Johnson & Johnson; Ethicon is a New Jersey corporation headquartered in Summerville, New Jersey. At all relevant times, Ethicon has transacted and continues to transact business throughout the State, including Multnomah County.

9.

Defendant Ethicon US, LLC, is a subsidiary of Johnson & Johnson incorporated in Texas. At all relevant times, Ethicon US has transacted and continues to transact business in the State.

10.

Subject matter jurisdiction is conferred on this Court by ORS 14.030.

11.

This Court has personal jurisdiction over Defendants pursuant to ORCP 4 A(4) because Defendants are engaged in substantial and not isolated marketing, promotion, and sales of products in Oregon; and ORCP 4 E(4) because this action arises out of products received in Oregon from Defendants.

12.

Venue in Multnomah County is proper pursuant to ORS 14.080(1) because the cause of action arose in Multnomah County.

SUMMARY OF THE ACTION

I. The State of Oregon has sued Johnson & Johnson, Ethicon, Inc, and Ethicon U.S., LLC on multiple claims for injunctive relief and civil penalties.

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13.

Surgical mesh is a synthetic fabric woven or knitted from polypropylene threads (sometimes combined with other substances). Polypropylene is a synthetic substance derived from crude oil and is used to manufacture everything from rugs to lab equipment and auto parts.

14.

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 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. An estimated 30% to 50% of women are affected by incontinence, and nearly 50% of women between 50 and 79 have some form of POP. SUI and POP therefore affect a large percentage of the female population.

15.

There are a variety of surgical and non-surgical treatment options to address SUI and POP. Surgical options include: (1) non-mesh repair using the patient's native tissue; and (2) repair using a synthetic material like surgical mesh, where the mesh is implanted through the vagina. Non-mesh surgical alternatives are effective and do not pose the same set of risks that surgical mesh does. There are a number of safer alternatives for the treatment of POP that do not involve the use of Ethicon polypropylene transvaginal mesh products, including but not limited to: (1) the use of sutures, including delayed absorbable sutures like PDS, in a uterosacral ligament suspension and a sacrospinous fixation; an anterior colporrhaphy; a sacrocolpopexy; (2) autologous fascia lata POP repair, (3) animal or cadaveric fascia POP repair. There are a number of safer alternatives for the treatment of SUI that do not involve the use of Ethicon's TVT mesh, including but not limited to: (1) the use of sutures, including delayed absorbable sutures like

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PDS, in a colposuspension procedure, like the Burch; (2) an autologous fascia lata and an autologous fascia sling; (3) an allograft sling; and (4) a sling with less polypropylene.

16.

J&J has marketed and sold a number of surgical mesh devices to treat SUI and POP transvaginally. J&J began selling the TVT sling line of products in 1997 to treat SUI and continues to sell many of these devices today. This line of products includes among others the TVT Retropubic, TVT Exact, TVT Obturator, TVT Abbrevo and TVT Secur (collectively, TVT). J&J began marketing and selling its POP pelvic floor repair kits with the Prolift product in 2005. Its POP line of products eventually included variations of the Prolift+M and the Prosima.

17.

J&J marketed and sold its SUI and POP surgical mesh devices as involving minimal risk, even though there are many complications associated with these devices.

18.

In addition to the general risks associated with pelvic floor surgery, J&J's surgical mesh devices present unique risks and/or heightened risks, due in part to the nature of mesh and its reaction within the body, including a chronic inflammatory response and a chronic foreign body reaction. Complications associated with the use of J&J's synthetic mesh in transvaginal repair include the following: erosion, exposure, and extrusion (i.e., mesh implanted in the pelvic floor can erode of out of the vagina and/or into other pelvic organs); a chronic foreign body response to the mesh and resulting chronic inflammation; bacterial colonization of mesh and mesh related infection (a risk heightened by implantation through the vagina); and mesh contracture or shrinkage inside the body (which can lead to vaginal stiffness, scar plating, shortening, distortion, and nerve entrapment). These mesh-related complications can lead to further problems for women, including but not limited to chronic pelvic pain, chronic vaginal pain, chronic buttock pain, urinary and/or defecatory dysfunction, pain with sexual intercourse and/or loss of sexual function, vaginal scarring and disfigurement, multiple and untreatable erosions,

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inability to remove the devices, vaginal discharge and odor, severe and untreatable groin, leg and thigh pain, “His”pareunia and the potentially irreversible nature of these complications. The risk of these mesh-related complications is lifelong and mesh complications can arise years after insertion.

19.

In many cases, mesh removal surgery is required to treat complications. Complete mesh removal, however, is extremely difficult and often impossible -- akin to trying to remove rebar from concrete without damaging the overall structure. Because it is so difficult to remove surgical mesh, removal can require multiple surgeries and may or may not resolve complications. The additional surgeries can further damage and scar the pelvic floor tissues, often causing even more complications.

20.

Complications resulting from transvaginal mesh surgery can have a crippling effect on a woman's ability to work, her sex life, her daily activities, and her overall quality of life. J&J knew about the risk of the grave complications associated with its surgical mesh devices but misrepresented them to doctors and patients alike.

J&J MISREPRESENTED THE RISKS OF ITS PRODUCTS

21.

As part of J&J’s acts and practices in the conduct of trade and commerce in the United States, including the State of Oregon, J&J engaged in a marketing campaign to promote its surgical mesh devices to both doctors and patients, using unconscionable, false, misleading and/or deceptive advertising which misrepresented the risks, benefits, and other attributes of its surgical mesh products.

22.

J&J misrepresented to doctors and patients the characteristics, performance, complication rates, severity of complications, and comparative risks of surgical mesh to alternative treatment

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options. J&J misleadingly cited studies in order to overstate the failure rates of non-mesh repair while at the same time creating the impression of low complication rates for mesh. J&J omitted and/or misrepresented many of the serious risks specifically associated with its surgical devices, including but not limited to chronic pelvic pain, chronic vaginal pain, chronic buttock pain, urinary and/or defecatory dysfunction, pain with sexual intercourse and/or loss of sexual function, vaginal scarring and disfigurement, multiple and untreatable erosions, inability to remove the devices, vaginal discharge and odor, severe and untreatable groin, leg and thigh pain, "His"pareunia and the potentially irreversible nature of these complications despite, according to its clinical and regulatory employees, knowing about these risks prior to launching its products. J&J further misrepresented in its doctor- and patient-directed marketing materials the serious risks unique to or heightened by surgical mesh that are not present with non-mesh surgical alternatives by presenting them as risks common to all pelvic floor surgeries or suggesting that they could be avoided by surgical technique.

23.

J&J made these misrepresentations to doctors and patients in the State of Oregon and elsewhere. J&J intended doctors and patients to rely upon the information it provided. The misrepresentations and/or omissions directed to doctors were clinically relevant to decisions about treatment options and the misrepresentations and/or omissions directed to patients were material in that they were likely to affect patients' treatment decisions. J&J's misrepresentations to doctors and patients were intended to and likely to deceive the reasonable doctor and patient audience. Although not a necessary element pursuant to Oregon's Unfair Trade Practices Act, doctors and patients in the State of Oregon and elsewhere relied upon J&J's unconscionable, false, misleading and/or deceptive statements and overall marketing practices when making treatment related recommendations and decisions.

J&J MISREPRESENTED ITS SURGICAL MESH DEVICES AS WELL STUDIED WHEN THEY WERE NOT.

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24.

As part of J&J's acts and practices in the conduct of trade and commerce in the United States, including the State of Oregon, J&J engaged in unconscionable, false, misleading and/or deceptive marketing and advertising practices which included misrepresentations to doctors and patients that J&J's surgical mesh devices were well studied.

J&J MADE MISLEADING AND DECEPTIVE STATEMENTS THAT ITS PRODUCTS WERE FDA APPROVED WHEN THEY WERE NOT.

25.

J&J misrepresented in its marketing materials to doctors and patients, including to those in the State of Oregon, that its products were "FDA approved," even though J&J's surgical mesh devices were merely "cleared" by the FDA under the 510(k) equivalency process. J&J's surgical mesh products have never been approved by the FDA. Each of the following products was 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 in 2008

(j) Gynecare Prosima – 2007

(k) Gynecare Prolift and Prolift+M – 2008 (Prolift marketed prior to clearance)

(l) Gynecare TVT Exact - 2010

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(m) Gynecare TVT Abbrevo – 2010

26.

The difference between "cleared" and "approved" is significant. FDA "approved" devices undergo a rigorous evaluation of their safety and efficacy—a process involving approximately 1200 hours of intense FDA review. In contrast, FDA "cleared" devices need only demonstrate that they are "substantially equivalent" to a device already on the market—a review that lasts approximately 20 hours. The 510k process does not involve a de novo safety determination or require clinical studies.

27.

The distinction between FDA "approved" and FDA "cleared" is explicit in the FDA regulations and was known by J&J at the time of its misrepresentations to doctors and patients. For example, J&J's knowledge of the difference between FDA "approved" and FDA "cleared" is evidenced by J&J's receipt of correspondence from the FDA which cited to the specific FDA regulation prohibiting J&J from creating the impression of official FDA approval through its advertising and marketing practices.

28.

Despite this knowledge, J&J 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. J&J's misrepresentations related to FDA "approval" include the following:

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

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

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(c) J&J 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, J&J 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.

J&J MADE MISLEADING AND DECEPTIVE STATEMENTS RELATED TO THE ULMSTEN/NILSSON STUDIES.

29.

J&J's marketing materials to doctors and patients, including to those in the State of Oregon, included misrepresentations concerning the Ulmsten/Nilsson Studies. The first published version of the Ulmsten/Nilsson study was done in 1998. This 1998 publication evaluated 131 patients, and a 90-patient cohort was later evaluated at 5, 7, 11, and 17 years. Four follow-up publications were also issued following the original article, with five-year, seven-year, 11-year, and 17-year results being published in 2001, 2004, 2008, and 2013, respectively.

30.

J&J failed to disclose to patients and physicians that author Dr. Ulmsten and Medscand Medical had a financial stake in the results of this study, namely, that Dr. Ulmsten's company Medscand Medical had been paid $400,000 contingent on the safety and efficacy results of this study being no worse than that the results of the 1996 Ulmsten publication which described the TVT procedure. Dr. Ulmsten, a shareholder/owner of Medscand Medical, would have received a substantial portion of the twenty-million dollar purchase price paid by J&J for the TVT and worked as a paid consultant for J&J beginning in the late 1990s. While featuring this study in multiple patient brochures and physician advertisements, J&J failed to disclose to doctors and patients that the primary investigators and authors of the study were paid consultants for J&J and had a financial interest in the outcome of the study, including Ulmsten, Nilsson and Falconer.

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31.

J&J 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 its surgical mesh products did not carry the same complication risks as other mesh products. J&J further misrepresented that the Nilsson studies had proven the safety of both its mechanically and laser-cut TVT slings—two entirely different mesh products—when in fact the studies had looked only at mechanically cut slings.

32.

J&J misrepresented the 5-year Ulmsten/Nilsson study which was published in 2001. For example, J&J developed a doctor-directed marketing piece focused on this publication titled: 5 Years of Proven Performance. In this advertisement,

(a) J&J failed to advise doctors that over half of the study's authors were paid consultants of J&J at the time of the publication, including Nilsson, Falconer and Ulmsten.

(b) J&J did not explain that the device being sold at the time of the publication was different than the one evaluated in the study.

(c) J&J represented to physicians that most complications were minor and avoidable with adherence to technique and instructions for use when they were not.

(d) J&J failed to disclose that the study found that 3.3% of patients in the study experienced a retropubic hematoma.

(e) J&J also stated that 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. In fact, J&J's own medical director testified that, he knew at all relevant times that there would be a foreign body reaction any time the mesh was implanted into the woman's body.

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33.

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

34.

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

(a) J&J's 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 a 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 used by J&J 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) J&J 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) J&J 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.

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(d) J&J 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.

35.

J&J further misrepresented the 7-year study to physicians in their doctor-directed marketing materials. For example, J&J featured the results of the study in their doctor brochures with the tagline Only Gynecare TVT Has Long-term Results You Can See and Believe. J&J also 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 unconscionable, false, misleading, and/or deceptive information, including the following:

(a) J&J's advertisements failed to advise doctors that all three authors were paid consultants of Ethicon at the time of the study;

(b) J&J's advertisement reported a complication rate of less than 0.01%, but did not tell 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) J&J 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) J&J 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, J&J knew that the study did not evaluate all patients treated with Gynecare TVT and was limited to a carefully

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controlled subset of 90 patients treated in Scandinavian countries, of which only 80 were evaluated after 7 years.

36.

J&J also made misrepresentations concerning the 11-year studies in its doctor and patient related marketing materials. J&J knew the authors of the 11-year Nilsson/Ulmsten Study had incorrectly claimed no conflicts of interest in the underlying research, despite being paid consultants for J&J. However, J&J continued to use the 11-year study as a centerpiece of their marketing campaign to both patients and physicians without any disclosure of the conflicts. J&J's marketing materials also included the following unconscionable, false, misleading, and/or deceptive representations to doctors and patients:

(a) J&J's patient brochures stated that 97% of women were still dry or had significantly less leakage 11 years after the TVT treatment. This misrepresentation gave patients the false impression that J&J had surveyed all of the women treated with the TVT for over 11 years rather than just the small sampling of 90 patients treated in 1995 and 1996, of which only 69 or 77% were evaluated;

(b) J&J's patient brochures failed to inform patents that only 90.2% of these 69 patients were objectively cured, and that only 77% were subjectively cured according to the study's authors;

(c) None of J&J's patient brochures touting the results of the Ulmsten/Nilsson study disclosed the fact that the TVT did not exist in its current form in 1995 and 1996, therefore the results being reported in the patient brochures were actually for a different device, the Intravaginal Slingplasty Device (IVS);

(d) J&J's brochures omitted or ignored studies in which the cure rate for TVT was known to be much lower than the 97 to 98% reported, including J&J's own clinical study – comparing TVT to the Burch procedure – where a 63% cure rate was found after two years according to the study's primary outcome measure;

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(e) J&J developed and utilized doctor-directed advertisements, such as the clinical sales aid entitled Make DATA and SAFETY YOUR CHOICE, which touted the results of the 11-year Nilsson study as the "longest term follow-up of any kind" and its Gynecare TVT Family Doctor Brochure which claimed that the 11-year study was the "longest study of its kind". However, J&J failed to disclose that this study did not actually evaluate the TVT device in its current form and that the majority of the study authors were paid consultants of J&J; and

(f) J&J's doctor-directed brochures used the 11-year study to imply that lower complication rates were associated with their products when they knew otherwise. For example, J&J's Gynecare TVT Family Doctor Brochure announced there were "No late onset adverse events in an 11-year follow-up study", "No tape erosion" and "No tissue reactions", and its GYNECARE TVT Family of Products doctor brochure stated "In a clinical study at an average of 11.5 years of follow-up, not a single case of tape erosions, tissue reactions, or other adverse effects of the tape were found." J&J's statements related to the 11-year study implied that there were no adverse effects of the surgical mesh products when J&J had knowledge of multiple complications through its own clinical studies, third-party literature, and doctor complaints. J&J's own medical director testified that the overall rate of erosions is 2-3%, the President of Ethicon testified that the overall rate of erosions is between 5-10%, and some randomized clinical studies of the TVT showed the erosion rate as high as 19%.

J&J MADE MISLEADING AND DECEPTIVE STATEMENTS RELATED TO OTHER STUDIES.

37.

J&J's marketing to doctors and patients, including to those in the State of Oregon, also included unconscionable, false, misleading and/or deceptive statements concerning other research studies. For example:

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(a) In J&J's doctor brochures, including one entitled Only GYNECARE TVT Has Long-term Results You Can See…and Believe, J&J stated that there were "No reported urethral erosions in multiple clinical studies of 50+ patients". This misrepresentation gives the false impression that J&J was not aware of any cases of urethral erosions, and that none have been reported in the literature when urethral erosions are well-documented in the literature and a substantial number of urethral erosions have been directly reported to the company;

(b) In J&J's clinical sales aids to both doctors and patients, J&J routinely referred to their surgical mesh products as "clinically proven" to be "safe", "effective", and "success[ful]". However, J&J omitted known information concerning the complications and long-term adverse effects of their products, researcher bias and conflicts of interest, the limited scope of the studies relied upon, and the fact that the studies relied upon did not relate to the actual product being manufactured and advertised at the time of the publication;

(c) In J&J's patient brochures, including The Choice to End Urinary Incontinence: Find out how to stop urine leakage like Bonnie did, J&J made misleading and deceptive statements such as "Trusted in over 1 Million patients" which implied that J&J actually had data on file indicating that over 1 million patients were satisfied with their surgical mesh products, when no such data exists.

38.

J&J's misrepresentations and/or omissions directed to doctors, including to those in the State of Oregon, were clinically relevant to doctors' decisions about treatment options and the misrepresentations and/or omissions directed to patients, including to those in the State of Oregon, were material in that they were likely to affect patients' treatment decisions. J&J's misrepresentations to doctors and patients were intended to and likely to deceive the reasonable doctor and patient audience. Although not a necessary element pursuant to Oregon's Unfair

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Trade Practices Act, doctors relied upon J&J's unconscionable, false, misleading and/or deceptive information when advising their patients and making treatment-related recommendations and decisions, and patients were not provided adequate information concerning the use of J&J's surgical mesh products as a part of their medical treatment.

J&J MISREPRESENTED THE FULL RANGE OF RISKS AND COMPLICATIONS ASSOCIATED WITH ITS SURGICAL MESH DEVICES

39.

J&J misrepresented the risks of its surgical mesh products by failing to disclose known risks and complications to doctors and patients, including to those in the State of Oregon, which would have been material information for doctors and patients in considering treatment options. For many years, J&J's acts and practices in the conduct of trade and commerce in the United States, including the State of Oregon, included the unconscionable, false, misleading and/or deceptive use of marketing and promotional materials which purported to provide complete risk information but failed to include significant and/or common risks. Although not a necessary element of the Oregon Unfair Trade Practices Act, doctors relied upon J&J's unconscionable, false, misleading, and/or deceptive information when prescribing J&J products to patients and patients relied upon J&J's unconscionable, false, misleading, and/or deceptive information when making decisions concerning their treatment and care.

J&J MISREPRESENTED THE FULL RANGE OF RISKS AND COMPLICATIONS ASSOCIATED WITH ITS SURGICAL MESH DEVICES TO DOCTORS.

40.

J&J's communications to doctors, including doctors in the State of Oregon, (including but not limited to brochures, educational materials, training materials, device inserts, communications through sales representatives, and information disseminated at medical conferences) misrepresented the full range of complications associated with its surgical mesh

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devices by deceptively omitting known material risks and complications associated with surgical mesh devices.

41.

In its doctor-directed materials, J&J omitted significant and/or common complications associated with its surgical mesh devices. For example, the following is a non-exhaustive list of the risks and complications which were missing or omitted from the Instructions For Use ("IFU") accompanying TVT slings sold and distributed in the State of Oregon 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) permanent dyspareunia,

(f) mesh contracture,

(g) chronic pelvic pain,

(h) chronic groin pain, leg and thigh pain

(i) chronic vaginal and buttock pain

(j) obturator injuries

(k) erosions requiring reoperation and removal,

(l) recurrence of incontinence,

(m) pain to partner during sex,

(n) sarcoma (cancer), and

(o) vaginal scarring

(p) permanency/difficulty of removal

(q) degradation of the mesh

(r) folding, roping, curling of the mesh

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(s) scar plating of the mesh

J&J's medical directors have testified that J&J knew before launching its products that women could suffer from risks and complications, including chronic, debilitating groin pain and dyspareunia after implantation; and, J&J knew that it should have included in the IFU, but failed to do so.

42.

Moreover, J&J's IFUs distributed with the surgical mesh products, including those distributed and sold within the State of Oregon, included the following misrepresentations:

(a) The IFUs 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 that Defendants were aware that the foreign body reaction would be chronic.

(b) The IFUs stated that the products were not "subject to degradation", despite numerous scientific peer-reviewed articles, internal studies and testing performed by J&J's own consultants and scientists that concluded the mesh material degrades over time in the body. For example, Ethicon Research Scientist Thomas Barbolt testified, as the spokesperson for Ethicon, that the fact that degradation can occur was well known by Ethicon in 1992.

43.

J&J's product labels also contained doctor-directed misrepresentations. These misrepresentations included statements that the surgical mesh was "soft and pliable", "affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth", and "bi-directional elastic propert[ies]". For example, each of these misrepresentations was included in the product labeling for the Gynecare PROLIFT Pelvic Floor

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Repair Systems. Defendants have since admitted under oath that they do not have sufficient data to support these statements.

44.

J&J's internal documents and scientists confirm J&J knew that their surgical mesh products were small pore mesh and heavy weight. J&J's own experts have testified that the mesh used in J&J's TVT device is a small-pore, standard weight mesh. However, J&J's doctor brochures and marketing materials included statements that its products' "large pores result in good incorporation". For example, this misrepresentation was included in J&J's doctor-directed advertising entitled Only GYNECARE TVT Has Long-term Results You Can See… and Believe.

45.

J&J knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. J&J, however, misrepresented in its 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". For example, the misrepresentations were included in J&J's clinical sales aids entitled Minimally Invasive Surgery…Highly Effective Tension-free Support and 5 Years of Proven Performance.

46.

J&J also knew that its mesh products could migrate but, misrepresented in its clinical sales aids that its product "maintains its position". For example, this misrepresentation was included in J&J's doctor brochure entitled Minimally Invasive Surgery…Highly Effective Tension-free Support.

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47.

J&J misrepresented to both doctors and patients that the use of surgical mesh would allow patients to return to normal activity, when J&J knew that contraction and erosion of the mesh through the vaginal wall could lead to pain and to all of the complications discussed above and herein for women patients.

48.

The following is a non-exhaustive list of examples of unconscionable, false, misleading or deceptive claims about surgical mesh devices that J&J made in materials and communications directed to doctors, including to those in the State of Oregon.

(a) J&J claimed its mesh product "does not potentiate infection" although it actually heightened the risk of infection. As an example, this misrepresentation was included in J&J's 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) J&J claimed its 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 J&J's doctor-directed brochure entitled You know where you want to go… GPS for Pelvic Floor Repair. When J&J developed a newer mesh product, it marketed the products as delivering a "Softer, more supple tissue", as reflected in its doctor brochures entitled "Is the science of living better" and "Her body will love this graft as much as you will".

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

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(d) J&J falsely claimed "no late onset adverse events". For example, this misrepresentation was included in J&J's clinical sales aid entitled Delivering Data, Safety & Choice.

(e) J&J claimed false or misleadingly low rates of serious complications. For example, these misrepresentations were included in J&J's clinical sales aid entitled The Gynecare TVT Family of Products: 3 SUI Solutions.

(f) J&J claimed a less than 3% urinary retention rate. For example, this misrepresentation was included in J&J's clinical sales aid entitled The Gynecare TVT Family of Products: 3 SUI Solutions.

(g) J&J claimed that its POP mesh was a "proven mesh for success" with "demonstrated mesh results" when the product was experimental and had no established safety record. As an example, these statements were included in J&J's You know where you want to go… GPS for Pelvic Floor Repair doctor-directed brochure.

(h) J&J claimed that leg pain would only last 24-48 hours when it knew that leg pain can be long term. For example, this misrepresentation was 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) J&J claimed a 7.2% dyspareunia rate. As an example, this misrepresentation was included in the doctor-directed brochures entitled Is the science of living better and Her body will love this graft as much as you will.

49.

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

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50.

J&J concealed and failed to disclose this risk information from doctors despite knowing about these complications before launching its products and despite discovering additional complications while its products continued on the market. Therefore, doctors were not adequately informed about the risks of mesh and were not in a position to pass this risk information on to patients.

51.

J&J made these misrepresentations to doctors in the State of Oregon and elsewhere. J&J intended doctors to rely upon the information it provided. The misrepresentations and/or omissions directed to doctors were clinically relevant to decisions about treatment options. J&J's misrepresentations to doctors were intended to and likely to deceive the reasonable doctor audience. Although not a necessary element pursuant to Oregon's Unfair Trade Practices Act, doctors in the State of Oregon and elsewhere relied upon J&J's unconscionable, false, deceptive and/or misleading statements and overall marketing practices when making treatment related recommendations and decisions.

J&J MISREPRESENTED THE FULL RANGE OF RISKS AND COMPLICATIONS ASSOCIATED WITH ITS SURGICAL MESH DEVICES TO PATIENTS.

52.

J&J also aggressively advertised directly to women, including those in the State of Oregon, through patient labeling, brochures, on-hold recordings, radio messages, its website, and other media. These advertisements touted surgical mesh implantation as a "minimally invasive" and "safe" procedure with a "quick" recovery while misrepresenting, concealing, and minimizing the associated complications and other facts needed to accurately weigh risks versus benefits of surgical mesh products.

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53.

Patient labeling is intended to inform patients about the risks and benefits of a medical device in language patients can understand. Patient labeling should include a balanced presentation of the adverse events and the risks and benefits of the device. Risk benefit information is particularly material in patient decision making related to Ethicon's pelvic mesh products as they are intended to treat a non-life-threatening conditions, stress urinary incontinence and pelvic organ prolapse. During the lifetime of J&J's surgical mesh product, J&J routinely distributed patient brochures which minimized the risk and the invasiveness of the procedure, even though J&J knew that in many cases, the patient brochure would be the company's only opportunity to interact with the patient.

54.

J&J aggressively marketed its surgical mesh products to physician groups, including but not limited to the American Urogynecologic Society, (AUGS) the Society of Urodynamics, (SUFU), the American College of Obstetricians and Gynecologists, (ACOG) and the International Urogynecological Association (IUGA). J&J has paid over ten million dollars to these physician groups in order to influence doctors who belong to these groups and to convince them that Ethicon's polypropylene mesh products are safe and effective for the treatment of SUI and POP. This included paying additional fees to become "corporate members" of some of these organizations, which includes special access to leadership and board members of these organizations. In addition, J&J employs and continues to employ key members of these organizations, including board members and other in leadership positions, as paid consultants of the company. J&J has used the influence purchased from these organizations to lobby members behind the scenes, resulting, for example, in ACOG changing their treatment guidelines in 2007 to no longer describe treatment of pelvic organ prolapse with transvaginal polypropylene mesh kits such as the Prolift as "experimental." J&J also used its influence to convince AUGS, SUFU, and other organizations to publish statements endorsing the use of full length, polypropylene

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mid-urethral slings, while concealing the fact that the authors of these statements were paid consultants of the company.

55.

J&J's advertising practices included the distribution of promotional material that routinely underestimated risk, lacked fair balance, failed to disclose key conflicts, misrepresented efficacy rates, and omitted material information. The centerpiece of J&J's marketing campaign was the Nilsson and Ulmsten studies, which J&J has used in their patient brochures from 2004 to the present to misrepresent the success rate of the TVT device as stated supra. J&J used this data to promote all of its TVT products, despite differences between the products which created different safety, efficacy, and complication profiles for the products. J&J concealed and failed to disclose those differences in safety, efficacy, and complication profiles from the public. J&J concealed and failed to disclose the fact that Dr. Nilsson stated that the data from the Nilsson and Ulmsten studies could only be used to support the original TVT retropubic device.

56.

J&J knew of defects in the mechanically cut mesh used in the TVT and TVT-O products but concealed and failed to disclose those defects from the public. J&J knew that the mechanically cut mesh in these products had a number of defects, including but not limited to fraying, coping, curling, narrowing to the point of a string, linting, degradation, and particle loss. J&J corporate representatives have admitted in sworn testimony that the mesh had defects. J&J knew that these defects could cause a number of complications, including but not limited to erosion, extrusion, exposure, pelvic pain, dyspareunia, urinary dysfunction, urinary retention, and one or more surgeries to treat these complications. J&J knew that these defects were inherent in the construction of the mechanically cut mesh and that J&J needed a solution to address these problems. J&J attempted to correct these defects by introducing laser cut TVT mesh. J&J launched 3 new TVT products after 2006 but did not offer any of these new products with the defective mechanically cut mesh. Despite knowing of the defects in the mechanically

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cut TVT mesh, J&J continues to sell the TVT and the TVT-O with this mesh and continues to conceal the defects of the mechanically cut mesh and the associated risks from doctors and patients.

57.

J&J knew of defects in their laser cut mesh used in the TVT family of products but concealed and failed to disclose those defects from the public. J&J knew that the laser cut mesh in these products led to a number of defects in the products, including but not limited to the mesh being three times stiffer and needing to be tensioned differently in order to be effective and to prevent complications. J&J knew that these defects could cause a number of complications, including but not limited to erosion, extrusion, exposure, pelvic pain, dyspareunia, urinary dysfunction, urinary retention, and one or more additional surgeries to treat these complications. J&J concealed and failed to disclose the fact that the inventor of the TVT-O informed the company that the increased stiffness of the laser cut mesh was leading to more erosions and complications in patients. J&J concealed and failed to disclose the fact that the co-inventor of the TVT product refused to use the laser cut TVT mesh because it did not have the same safety profile of the original mesh. Ethicon's first laser cut TVT product, the TVT-Secur, was removed from the market due to poor results, a fact routinely reported in the medical literature, but one that J&J continues to deny and conceal to this day. Despite knowing of the defects in the laser cut TVT mesh, J&J continues to sell the TVT, TVT-O, TVT-Exact, and TVT-Abbrevo with this mesh, and continues to conceal the defects of the laser cut mesh and the associated risks from doctors and patients.

58.

By way of example, the patient education materials and brochures for the Prolift device and the Gynecare TVT state that "[f]ew patients experience complications" or that complications

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are "rare"[1]. 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. The U.S. arm of the study showed an even higher rate of mesh exposures, at 14.1%. Thus, J&J had actual knowledge that complications were more than "rare". As discussed in the report of Defense expert Michael Woods, M.D., studies have revealed the following complication rates: minor voiding difficulties (7.6%), bladder perforation (3.8%), retention (2.5%), and retropubic hematoma (1.9%). In addition, former Ethicon President Renee Selman has estimated the erosion rate with TVT products to be approximately 5-10%. J&J was aware of full risks and complications of its surgical mesh devices and even the FDA stated that mesh complications are "not rare", categorizing the devices as "high risk". Nevertheless, J&J's patient brochures indicated complications were "rare" and suggested 98% of women had a successful result.

59.

The following is a non-exhaustive list of risks and complications missing from J&J's TVT brochures at various points in time:

(a) 1997-2008 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, de novo urgency incontinence, detrimental impact on quality of life, dyspareunia, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal, difficulty and potential impossibility of removal, nerve damage, pain, chronic pain, pain to partner during sex, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, vaginal scarring, and worsening incontinence;

(b) 2008-2011 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, de novo urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal,

[1] As stated in Ethicon's standard operating procedures, the word "rare" is a term of art, to be used when complications occur in approximately 0.1% of users.

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difficulty and potential impossibility of removal, nerve damage, chronic pain, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, and worsening incontinence;

(c) 2011-2012 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, de novo urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, difficulty and potential impossibility of removal, chronic pain, permanent urinary dysfunction, sarcoma (cancer), and worsening incontinence.

(d) 2012- present TVT patient brochures: potential impossibility of removal. In addition, the present TVT brochure misleadingly points patients to the differences between SUI and POP implantation, rather than SUI and non-mesh procedures.

60.

J&J's marketing and promotional materials for its other SUI mesh devices, and its POP mesh devices, similarly concealed and failed to disclose known risks and complications.

61.

J&J misrepresented and failed to disclose known material risks in its informational and educational materials directed to patients, including to those in the State of Oregon. For example:

(a) J&J's Gynecare TVT patient brochures, such as Stress Urinary Incontinence in Women: What YOU can do about it…, indicated that leg pain would be "transient", only last 24-48 hours when J&J knew that leg pain can be long term.

(b) J&J knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. However, J&J's TVT patient brochures indicated that the foreign body response triggered by mesh was "transitory", despite knowing the "reaction never goes away." Defendants' own medical director Chen Meng has testified that, "…from what I see each day, these patient experiences are not 'transitory' at all." As an example, J&J's above-referenced misrepresentations were included in J&J's patient brochures entitled Remember…

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You're Not Alone, and Support Is Just a Phone Call Away and Stress Urinary Incontinence in Women: What YOU can do about it… .

(c) J&J was aware of research indicating 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, J&J's 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". For example, these misrepresentations were included in J&J's patient brochure entitled Stress Urinary Incontinence in Women: What YOU can do about it….

(d) J&J's patient brochures described J&J's mesh as "ribbon-like", "soft", and "supple". However, J&J's internal documents and historical testimony have confirmed J&J's knowledge that the mesh was "too stiff for use in vaginal tissue", had "rough sides", was "too sharp on the edges", like a "Scotch-Brite pad". J&J received complaints that doctors and patients that they 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." Ethicon's own medical director, Dr. Hinoul, admitted that the sharp edges of the mesh can irritate tissue, cause pain, and lead to erosion.

62.

J&J deceptively omitted information about the inherent and/or increased risks associated with the use of mesh from brochures, Q&A sheets, leaflets, websites and other materials circulated to patients. Patients could not obtain complete and correct information about the inherent risks of mesh from patient materials or through their doctors, thereby denying patients access to critical information that would have enabled them to make informed choices between mesh and non-mesh options.

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63.

J&J made these misrepresentations to patients in the State of Oregon and elsewhere. J&J intended patients to rely upon the information it provided. The misrepresentations and/or omissions directed to patients were material in that they were likely to affect patients' treatment decisions. J&J's misrepresentations to patients were intended to and likely to deceive the reasonable patient audience. Although not a necessary element pursuant to Oregon's Unlawful Trade Practices Act, patients in the State of Oregon and elsewhere relied upon J&J's unconscionable, false, deceptive and/or misleading statements and overall marketing practices when making treatment related decisions. In the State of Oregon, at least 3700 women had these devices implanted without J&J providing sufficient information to allow them to adequately weigh the risks and benefits of the full range of treatment options. J&J's unconscionable, false, misleading and/or deceptive representations and advertising prevented these women from having complete clinical information to make a potentially life-changing decision about their health.

J&J'S EMPLOYEES URGED THE COMPANY TO WARN OF SIGNIFICANT DANGERS

64.

J&J persisted in misrepresenting the risks and benefits of its surgical mesh products despite the urging of its own high-level employees to more fully disclose known dangers. For example, J&J's medical director, Dr. Axel Arnaud, believed POP devices to pose such risks to sexual function that he suggested including a warning specifically aimed towards sexually active women. In a June 2005 email, he proposed adding the following disclosure:

> **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**

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must be taken in consideration when the procedure is planned in a sexually active woman.

However, J&J never incorporated this statement into any of its doctor-directed or patient-directed marketing or promotional materials.

65.

With regard to SUI devices, Dr. Meng Chen, a medical director in the complaint review department, was concerned about the adequacy of the company's 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's describing her observations from patient complaints:

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 disproportion[ate] to pre-operative consent-expectations.**

(**emphasis** added)

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J&J, however, continued to conceal the material risks of dyspareunia and pain affecting quality of life in its marketing and promotional materials.

J&J MISREPRESENTED THE RISKS ASSOCIATED WITH SURGICAL MESH THAT ARE NOT PRESENT IN NON-MESH SURGICAL OPTIONS

66.

As a part of J&J's acts and practices in the conduct of trade and commerce in the United States, including the State of Oregon, J&J's unconscionable, false, misleading and/or deceptive advertising suggested that, aside from mesh erosion, surgical mesh did not cause additional or heightened risks compared with other non-mesh surgical options.

67.

J&J misrepresented serious risks unique to surgical mesh that are not present in native tissue repair and/or risks that are increased by the use of mesh as compared with non-mesh surgical repair, by presenting them as risks common to all pelvic floor surgeries or suggesting that they could be avoided by surgical technique.

68.

J&J circulated these unconscionable, false, misleading and/or deceptive statements through various media, including but not limited to brochures, educational materials, training materials, device inserts, IFUs, and upon information and belief through training materials, communications through sales representatives, and information disseminated at medical conferences.

69.

For example, J&J 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) J&J knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. J&J, however,

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misrepresented the foreign body response triggered by mesh as "transitory" despite knowing the reaction never goes away. J&J's patient brochures stated that 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. Among other advertising materials, these misrepresentations were included in J&J's IFUs for its TVT Tension-free Vaginal Tape System and Gynecare Proflift Pelvic Floor System, and in patient brochures, including Remember… You're Not Alone, and Support Is Just a Phone Call Away and Stress Urinary Incontinence in Women: What YOU can do about it….

(b) J&J knew that the implantation of surgical mesh transvaginally can create a heightened risk of infection because of the (i) bacterial contamination that occurs due to implantation of mesh through the vagina, which is a clean-contaminated environment that cannot be sterilized; and (ii) the bacterial colonization that occurs in the woven mesh. J&J not only failed to disclose this heightened risk of chronic infection but represented that mesh "does not potentiate infection" in its marketing materials, including its brochures Delivery Data, Safety & Choice" and "You Know where you want to go… GPS for Pelvic Floor Repair. Moreover, when J&J did disclose its products' ability to "potentiate" infection, it 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) J&J knew that mesh can shrink, harden, and become rigid. An internal document entitled "LIGHTning Critical Strategy," dated September 26, 2006, demonstrates J&J's 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.

J&J also knew that claims of softness were "illusory." Nevertheless, J&J misrepresented that its mesh is "supple," "remains soft and pliable" and has a "bi-directional elastic property [that] allows adaptation to various stresses encountered in the body." The company 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, J&J deliberately misrepresented, concealed, and failed to disclose 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, J&J falsely represented in presentations to doctors and other professional education materials that its "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.

70.

J&J concealed and failed to disclose its knowledge that surgical mesh itself causes complications, and instead misrepresented to doctors that complications such as erosion are the result of poor surgical technique. In materials addressed to doctors, including to those in the State of Oregon, J&J further failed to disclose the degree to which the inherent properties of mesh (chronic foreign body reaction, shrinkage, contraction) caused complications such as pain, dyspareunia and sexual dysfunction.

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71.

J&J misleadingly failed to disclose that there was no safe and effective means for removal of its surgical mesh products. Mesh removal is often the only treatment option for continuing mesh complications. Removal can require multiple surgeries, which may or may not resolve complications, and may in fact result in new problems. In most cases, complete removal of mesh is impossible and for many women, complications remain irreversible even after multiple surgeries. Yet, J&J 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.

72.

J&J failed to disclose that erosions can arise at any time after the implantation of its 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. J&J 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.

73.

J&J 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. J&J falsely represented that use of surgical mesh would have no negative impact on patients' sex lives when J&J 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. J&J misleadingly touted the return of sexual

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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.

74.

At the same time J&J misrepresented the safety of its surgical mesh products by concealing risks unique to and inherent in the use of mesh, J&J touted surgical mesh as superior to native tissue repair by falsely inflating the failure rates of the non-mesh surgical options.

75.

J&J concealed and failed to disclose key safety information regarding the C4001 polypropylene homopolymer material used in their pelvic mesh products received from the supplier of that material, Sunoco, Inc. This includes but is not limited to the fact that testing on laboratory rats by subcutaneous implantation of polypropylene discs induced local sarcomas at the site of implantation. The supplier also warned that strong oxidizers such as peroxides are incompatible with the polypropylene. The vagina is a natural source of peroxides, and oxidization of polypropylene can lead to embrittlement and degradation of the material.

J&J MISREPRESENTED THE SEVERITY AND FREQUENCY OF THE COMPLICATIONS THAT IT DID DISCLOSE

76.

For the complications that it did disclose, J&J misrepresented the severity and frequency of the complications associated with surgical mesh. As part of J&J's acts and practices in the conduct of trade and commerce in the United States, including the State of Oregon, J&J's marketing materials were unconscionable, false, misleading and/or deceptive in that they overstated benefits and understated risks which did not give doctors and patients the information they needed to perform a valid risk-benefit analysis when deciding whether or not to use the TVT product. For example:

(a) J&J made false and misleading statements in its marketing, promotional, informational, and educational materials about complication rates of mesh, selectively

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citing outcomes that appeared positive, while not disclosing clinically relevant information about negative findings in those same studies.

(b) J&J knowingly cited to studies for which results were scientifically questionable due to study design and/or conflicts of interest. For example, J&J used the result of the Ulmsten study to sell its SUI products when J&J had (1) purchased the rights to the SUI device from Dr. Ulmsten and (2) contractually agreed with Dr. Ulmsten that he would only get paid a specific sum if his study produced favorable results regarding the product.

(c) J&J claimed in its doctor-directed marketing materials that its surgical mesh products had "minor complications", a "very low likelihood of urethral erosion", and "no foreign body reaction".

(d) J&J's product labeling suggested leg pain was a transient complication, lasting only 48 hours, and can be treated with Tylenol. However, Defendants' medical directors have admitted that leg and groin pain can be chronic, a fact which is supported by the literature and Defendants' own internal documents. Defendants' own medical director, Dr. Piet Hinoul, stated, "I am personally convinced that, having published on the vicinity of the nerve branches of the obturator to the tape's trajectory, that the presence of this foreign body will induce more pain and will be responsible for some of the chronic pain syndromes."

(e) J&J's advertisements included the misleading and deceptive statement "One day you have urine leakage. The next day you don't. End of Story." Such statements minimized and downplayed the risks of the procedure while further reinforcing the misleading statements contained in the advertisements that the cure rate for TVT is around 97 or 98%, when the actual cure rate for TVT is closer to 80%.

(f) J&J's 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 J&J's own research data regarding

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health time. Specifically, J&J's 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. These misrepresentations were included in J&J's brochures entitled The Choice to End Stress Urinary Incontinence and Remember… You're Not Alone, and Support Is Just a Phone Call Away, among other advertising materials.

(g) J&J's 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. …there are safe and effective minimally invasive procedures…" For example, these misrepresentations were included in the 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 as they underestimate the rate and severity of the complications seen in clinical practice as a result of the TVT. For example, as of December 31, 2006, twelve deaths had been associated with the Gynecare TVT. In another study involving 112 patients treated with the TVT device, over 12% of the patients suffered voiding difficulties lasting over 15 days, and over 10 percent suffered a urinary tract infection. In all, 29.4% of the patients suffered some kind of post-operative complication. A different study, which was sponsored by J&J, reported a total complication rate of 39% for patients receiving TVT.

77.

J&J made these misrepresentations to doctors and patients in the State of Oregon and elsewhere. J&J intended doctors and patients to rely upon the information it provided. The misrepresentations and/or omissions directed to doctors were clinically relevant to decisions about treatment options and the misrepresentations and/or omissions directed to patients were material in that they were likely to affect patients' treatment decisions. J&J's misrepresentations to doctors and patients were intended to and likely to deceive the reasonable doctor and patient

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audience. Although not a necessary element pursuant to Oregon's Unfair Trade Practices Act, doctors and patients in the State of Oregon and elsewhere relied upon J&J's deceptive and misleading statements and overall marketing practices when making treatment related recommendations and decisions.

78.

At least 3,700 Oregon women were implanted with surgical mesh without knowing the full risks of the decision because the company misrepresented (1) the full range of possible complications; (2) the risks that surgical mesh poses, which are not present in the alternative non-mesh repair; and (3) the frequency and severity of the risks that it did disclose.

79.

Defendants have engaged in unconscionable, false, misleading, and deceptive acts or practices in violation of ORS 646.605 et seq. These acts or practices include, but are not limited to, material misrepresentations and/or omissions by Defendants regarding the risks of surgical mesh products for pelvic floor repair, and the unlawful practices in connection with the marketing, promotion, and sale of Defendants surgical mesh devices.

80.

Defendants committed unconscionable, false, misleading, and deceptive acts through their deceptive marketing of surgical mesh devices. J&J misrepresentations and omissions to doctors and patients about the hazards of surgical mesh devices had the capacity to deceive Oregon patients and their doctors. J&J failed to accurately disclose information clinically relevant to choices of medical care and informed consent to surgical procedures. Defendants committed unlawful acts by disseminating false and misleading statements to the public in violation ORS 646.605 et seq., including false and misleading claims purporting to be based on factual, objective, or clinical evidence and/or comparing the products' effectiveness to that of other products.

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81.

The examples of J&J's unconscionable, false, misleading and/or deceptive acts and practices contained herein are representative of J&J's conduct in the State of Oregon but are not intended to be an all-inclusive list or a comprehensive identification of Defendants' unconscionable, false, misleading and/or deceptive acts and practices in the State.

82.

Defendants' conduct violating ORS 646.605 et seq. as alleged herein was willful. Defendants knew or should have known that their conduct as alleged herein was in violation of the law.

83.

Defendants were given the notice required by ORS 646.632(2) that they have allegedly violated the Oregon Unfair Trade Practices Act, and the relief to be sought. Defendants have failed to deliver an Assurance of Voluntary Compliance that complies with the requirements of ORS 646.632(3).

CLAIM FOR RELIEF

(Unlawful Trade Practices Act)

84.

The Attorney General re-alleges paragraphs 1 through 83, and incorporates the allegations herein, as if fully set forth.

Count 1 – Violation of ORS 646.607(1)

85.

Defendants willfully violated ORS 646.607(1) by employing unconscionable tactics in connection with the sale of surgical mesh in the State of Oregon by:

a. Misrepresenting the risks, characteristics, performance, complication rates, and severity of complications of its surgical mesh products, and misrepresented comparative risks of surgical mesh to alternative treatment options, as described above in paragraphs 21-23;

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b. Misrepresenting its surgical mesh devices as well studied, and FDA approved, when they were not, as described above in paragraphs 24-28;

c. Misrepresenting and making deceptive statements related to the Ulmsten/Nilsson studies and other studies in the course of marketing and selling its surgical mesh devices, as described above in paragraphs 29-38;

d. Misrepresenting the full range of risks and complications of its surgical mesh devices to doctors, as described above in paragraphs 39-51;

e. Misrepresenting the full range of risks and complications of its surgical mesh devices to patients, as described above in paragraphs 52-63;

f. Ignoring and failing to heed urgings by its own employees to strengthen its warnings to doctors and patients regarding the risks and complications of its surgical mesh devices, as described above in paragraphs 64-65;

g. Misrepresenting the risks associated with its surgical mesh devices that are not present in non-surgical treatment options for the same conditions treated by its surgical mesh devices, as described above in paragraphs 66-75; and

h. Misrepresenting the severity and frequency of complications that it did disclose to doctors and patients, as described above in paragraphs 76-78.

86.

Pursuant to ORS 646.632(1), the Attorney General seeks an injunction prohibiting Defendants from continuing to promote surgical mesh in Oregon.

87.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each willful violation of ORS 646.607(1) described above.

88.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count.

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Count 2 – Violation of ORS 646.608(1)(b)

89.

Defendants willfully violated ORS 646.608(1)(b) by creating likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of its surgical mesh products by making misleading and deceptive statements that its products were FDA approved when they were not FDA but had merely been "cleared" as described in paragraphs 25 to 28.

90.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each willful violation of ORS 646.601(1)(b) described above.

91.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count

Count 3 – Violation of ORS 646.608(1)(e)

92.

Defendants willfully violated ORS 646.608(1)(e) by representing that Defendants' surgical mesh has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that they do not have by:

a. Misrepresenting the risks, characteristics, performance, complication rates, and severity of complications of its surgical mesh products, and misrepresented comparative risks of surgical mesh to alternative treatment options, as described above in paragraphs 21-23;
b. Misrepresenting its surgical mesh devices as well studied, and FDA approved, when they were not, as described above in paragraphs 24-28;
c. Misrepresenting and making deceptive statements related to the Ulmsten/Nilsson studies and other studies in the course of marketing and selling its surgical mesh devices, as described above in paragraphs 29-38;

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d. Misrepresenting the full range of risks and complications of its surgical mesh devices to doctors, as described above in paragraphs 39-51;

e. Misrepresenting the full range of risks and complications of its surgical mesh devices to patients, as described above in paragraphs 52-63;

f. Misrepresenting the risks associated with its surgical mesh devices that are not present in non-surgical treatment options for the same conditions treated by its surgical mesh devices, as described above in paragraphs 66-75; and

g. Misrepresenting the severity and frequency of complications that it did disclose to doctors and patients, as described above in paragraphs 76-78.

93.

Pursuant to ORS 646.632(1), the Attorney General seeks an injunction prohibiting Purdue from continuing to promote surgical mesh in Oregon.

94.

Pursuant to ORS 646.642(3), the Attorney General seeks a civil penalty of up to $25,000 for each violation of ORS 646.608(1)(e) described above.

95.

Pursuant to ORS 646.632(8), the Attorney General seeks her reasonable attorney fees incurred in bringing this count.

PRAYER FOR RELIEF

WHEREFORE, plaintiff State of Oregon, by and through Attorney General Rosenblum, prays for relief against defendants as follows:

a. On count 1, for a judgment against Defendants in the amount of $25,000 for each willful violation of ORS 646.607 and an injunction prohibiting Defendants from promoting surgical mesh in Oregon;

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b. On count 2, for a judgment in favor of State of Oregon and against Defendants in the amount of $25,000 for each willful violation of ORS 646.608(1)(b) and an injunction prohibiting Defendants from promoting surgical mesh in Oregon;

c. On count 3, for a judgment in favor of the State of Oregon and against Defendants in the amount of $25,000 for each willful violation of ORS 646.608(1)(e) and an injunction prohibiting Defendants from promoting surgical mesh in Oregon.

d. An order for further injunctive relief that orders Defendants to comply with the Oregon Unfair Trade Practices Act in specific respects when doing business in the State of Oregon;

e. An order for restitution for any person in the State of Oregon who suffered a loss of property as a result of a violation of ORS 646.607 or 646.608;

f. An award of reasonable attorney fees, pursuant to ORS 646.632(8).

g. Such other relief as the Court deems appropriate.

DATED this 3rd day of December, 2019.

Respectfully submitted,

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s/ David A. Hart

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