The Honorable Suzanne R. Parisien
Hearing Date: December 14, 2018, at 1:00 pm
WITH ORAL ARGUMENT

STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

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. 16-2-12186-1 SEA STATE OF WASHINGTON'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON LIABILITY AS TO INSTRUCTIONS FOR USE FOR DEFENDANTS' TVT DEVICES

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TABLE OF CONTENTS

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ATTORNEY GENERAL OF WASHINGTON
Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
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TABLE OF AUTHORITIES

Cases

ATTORNEY GENERAL OF WASHINGTON
Consumer Protection Division
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Statutes

Rules

Regulations

ATTORNEY GENERAL OF WASHINGTON
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I. INTRODUCTION AND RELIEF REQUESTED

Defendants make and sell transvaginal mesh devices that are woven from plastic and implanted in a woman's body to treat stress urinary incontinence. Once implanted in the body, transvaginal mesh is extremely difficult—if not impossible—to remove. The risks associated with transvaginal mesh can be severe and include, among other risks, chronic, lifelong pain; painful sexual intercourse for the woman and her partner; chronic inflammation; recurrence of the stress urinary incontinence; and other urinary conditions. These risks are such that numerous countries have taken recent regulatory action in response to transvaginal mesh, ranging from requiring enhanced disclosures to limiting its use. On October 10, 2018, the Australian Health Minister issued a national apology to all of the women who suffered agony and pain as a result of transvaginal mesh implantation.

Women here in Washington have also suffered as a result of Defendants' transvaginal mesh products.[1] One Washington woman describes her complications as a "nightmare." She cannot urinate without a catheter and suffers from chronic urinary tract infections, constant lower back pain, and cramps in the back of her entire leg. Another Washington woman experiences pain during sexual intercourse, bowel movements, urinating, and lifting. She ultimately had to have several revision surgeries to reverse the complications caused by Defendants' transvaginal mesh.

Since 1999, Defendants have made a number of transvaginal mesh devices to treat stress urinary incontinence (incontinence that is triggered by physical activity like coughing, sneezing, running, or lifting). These products are branded as the "TVT" family of devices. In the Instructions for Use (IFUs) that accompanied the TVT devices from 1999 to late 2015, Defendants knowingly omitted serious, debilitating, and life-altering complications associated

[1] The State does not dispute that many women have had positive outcomes with Defendants' TVT devices, and does not seek to restrict access to these devices. Rather, the State's case is about Defendants' many failures to disclose known risks associated with their transvaginal mesh devices and misrepresentations regarding the characteristics of those devices.

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with the transvaginal mesh devices. As Defendants acknowledge, the IFUs are a critical source of information for doctors who permanently implant the transvaginal mesh in women's bodies. For nearly 16 years, Defendants knew that their TVT devices could cause chronic, life-long pain and other adverse consequences but failed to disclose those risks and consequences in the IFUs.

Along with these significant omissions about the risks, Defendants also misrepresented the nature of certain complications arising from their TVT products. For example, Defendants misrepresented that the TVT could cause only transitory pain or a transitory foreign body response in women, when Defendants knew the pain could be chronic and the mesh would elicit a chronic foreign body/inflammatory response which in some women could be severe. In late 2015, Defendants finally updated their TVT IFUs to include the above and numerous additional omitted risks and adverse events—[redacted]

Both the State of Washington and Defendants have extensive expert reports addressing issues of science, medicine, and regulatory affairs. In support of this motion, the State is not submitting expert reports or expert testimony. Such is needless. Defendants' own testimony, documents, and actions provide ample evidence that Defendants violated of the Consumer Protection Act. The risks of the devices at issue in this motion are not in dispute. That Defendants knew of these risks at the time of product launch is not in dispute. That Defendants omitted these known risks from the IFUs is also not in dispute.[2]

As a matter of law, Defendants' omissions and misrepresentations in the IFUs for the TVT devices are unfair and deceptive in violation of the Consumer Protection Act. Pursuant to CR 56(a) and (c), the State respectfully requests the Court grant summary judgment on liability

[2] Defendants' IFU omissions and misrepresentations are part of a larger strategy that included doctor and patient marketing. This threshold motion relates only to certain omissions from and misrepresentations in Defendants' IFUs for the TVT mesh devices. The State intends to address Defendants' marketing materials and campaigns in later motions and at trial (if necessary). Further, should this case proceed to trial, the State intends to pursue additional serious misrepresentations and omissions in the IFUs.

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for Defendants' IFUs for the TVT devices from their release until they were updated in late 2015.

II. STATEMENT OF PERTINENT FACTS

Defendants sell or have sold two major categories of transvaginal mesh devices: those marketed for the treatment of stress urinary incontinence (SUI) and those marketed for the treatment of pelvic organ prolapse (POP). This motion focuses on the SUI devices; a companion motion addresses the POP devices.[3] Through December 2012, Defendants sold and distributed in Washington the TVT through Defendant Ethicon, Inc.; after December 2012, they sold the TVT through Ethicon US, LLC. Declaration of Breena Roos in Support of State's (1) Motion for Summary Judgment on Liability as to Instructions for Use for Defendants' TVT Devices and (2) Motion for Summary Judgment on Liability as to Instructions for Use for Defendants' POP Devices ("Roos Decl."),[4] Ex. 3; *see also* Dkt. 46 ¶ 3.2. Defendant Johnson & Johnson is the parent corporation to both Ethicon entities and has agreed to accept liability for the actions of its subsidiaries. *Id.*; Dkt. 168.

A. Defendants' TVT Devices for Treatment of SUI

SUI is the involuntary leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercising. Ex. 10. SUI can happen when the muscles and supporting ligaments in the pelvis weaken from pregnancy, childbirth, aging, or prior pelvic surgery. *Id.* SUI can be treated non-surgically, through pelvic floor exercises, a pessary (a removable device inserted into the vagina), bulking agents, electrical stimulation, or behavior modification, and surgically, using native tissue, sutures, or synthetic mesh. *See generally id.*

In 1998, Defendants introduced the TVT-Classic (sometimes also referred to as the "TVT-Retropubic") for the treatment of SUI. Ex. 70. The TVT-Classic is sold as a kit that includes a pre-cut polypropylene Prolene mesh strip (sometimes called "tape") referred to as a "mid-urethral sling;" tools for implantation; and a specifically prescribed surgical procedure for

[3] *See* Motion for Partial Summary Judgment on Liability as to Instructions for Use for Defendants' POP Devices ("POP MSJ").

[4] Unless otherwise noted, all citations to "Ex." herein refer to Exhibits to the Roos Declaration.

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implanting the sling through two incisions in the vagina (i.e., "transvaginal" insertion). Ex. 1.A. Defendants later introduced various adaptations to the TVT-Classic, all of which consisted of pre-cut polypropylene Prolene mesh to be inserted transvaginally (with some modifications in shape, size, and placement within the body): the TVT-Obturator (referred to as the "TVT-O," released in 2004), TVT-Secur (a "mini-sling" released in 2005), TVT-Exact (released in 2010), and TVT-Abbrevo (released in 2010). Ex. 5; *see generally* Ex. 1.

In 2007, Defendants stopped further distribution of the TVT-Secur in Australia due to poor safety and efficacy outcomes, and to protect the safety of Australian consumers. Ex. 53 (Dep. of Aran Maree (4/17/18)) at 24:18-25:22. However, Defendants waited until May 2012 to remove the TVT-Secur from the United States market and never informed U.S. physicians they had stopped selling the TVT-Secur in Australia to protect consumer safety. *Id.* at 27:25-29:11; Ex. 72. From 2008 to 2012, 395 TVT-Secur devices were sold in Washington for implantation in women. Roos Decl., ¶ 5, Ex. 5.

In October 2008, the U.S. Food and Drug Administration (FDA) began examining issues regarding serious complications associated with transvaginal mesh devices for the treatment of both SUI and POP, which included Defendants' TVT devices. On October 20, 2008, the FDA issued a Public Health Notification ("PHN") addressed to healthcare providers which stated, "[a]though rare" transvaginal mesh devices can have "serious consequences," including "erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." Ex. 59. The FDA also noted that in some cases, "vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia." Among other things, the FDA stated that "contributing factors may include…the mesh material, [and] the size and shape of the mesh…" *Id.* The FDA also advised healthcare providers should "[i]nform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair). *Id.*

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Defendants continue to sell the TVT-Classic, TVT-Obturator, TVT-Exact, and TVT-Abbrevo in Washington.[5] From 2002 through September 2015, Defendants sold 10,701 TVT devices in Washington. Roos Decl., ¶ 5, Ex. 5.

B. Defendants' Instructions for Use for the TVT Devices

1. Each TVT device must be accompanied by an IFU that identifies all adverse reactions reasonably associated with the use of the device

Medical devices such as Defendants' POP devices must contain an IFU detailing "any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely." 21 C.F.R. § 801.109(c)-(d); *see also* 21 U.S.C. § 321(m). The IFU, sometimes also referred to as the "package insert," is considered "labeling" under federal law. *Id.* It is undisputed that each of the TVT devices shipped to Washington contained an IFU. Ex. 6 (CR 30(b)(6) Deposition of Eric Dunn ("Dunn 30(b)(6) Dep.") (6/6/18)) at 63:19-64:14.

In a "guidance" for medical device manufacturers referred to as the "Blue Book," the FDA states that IFUs must include, in an "Adverse Reactions"[6] section, "**all adverse reactions reasonably associated with the device**," which should also be "listed in descending order according to their clinical significance." Ex. 12 (Blue Book) at 5-6 (emphasis added). An adverse reaction is "**an undesirable effect, reasonably associated with the use of the device**, that may occur as part of the effect of the device or may be unpredictable in its occurrence." *Id.* at 5 (emphasis added); *see also* Ex. 11 (FRCP 30(b)(6) Dep. of Susan Lin ("Lin 30(b)(6) Dep.") (3/13/13)) at 488:17-25 (Ethicon adopts this definition). Serious adverse reactions, and steps that should be taken if they occur, should also be listed in the "Warnings" section of the IFU. Ex. 12

[5] The sale of mesh devices has been limited in other parts of the world. For example, in the United Kingdom, regulators have ordered health boards to halt the use of vaginal mesh implants for SUI and POP in all but exceptional circumstances. *See* Ex. 69.

[6] The Blue Book refers to "adverse reactions," a term that Defendants adopt in their IFUs, *see generally* Exs. 1 & 2, although their witnesses sometimes use the term "adverse events."

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at 4-5.

The Blue Book is an industry standard that Defendants recognize and have adopted. Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 481:15-20 [redacted], 484:18-24 [redacted] Ex. 13 (Lin 30(b)(6) Dep. (5/2/13)) at 548:20-549:4, 549:20-23 [redacted] 556:25-557:2; *see also* Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 481:21-483:15, 490:2-10, 490:20-491:15; Ex. 13 (Lin 30(b)(6) Dep (5/2/13)) at 549:20-23; Ex. 15 (CR 30(b)(6) Dep. of Bryan Lisa (6/1/17)) at 528:15-529:14.

Defendants acknowledge the IFU is [redacted] Ex. 14 (Lin 30(b)(6) Dep. (8/1/13)) at 1162:10-13. In this regard, Defendants also agree [redacted] Ex. 9 (FRCP 30(b)(6) Dep. of Piet Hinoul, M.D. ("Hinoul 30(b)(6) Dep.") (1/14/14)) at 1207:18-25 [redacted] Ex. 39 (Dep. of Ethicon Associate Medical Director Meng Chen, M.D., Ph.D. ("Chen Dep.") (10/29/13)) at 78:14-79:1 [redacted] 201:11-202:10 [redacted]

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[redacted]; *see also* Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1208:1-22; Ex. 17 (CR 30(b)(6) Dep. of Jennifer Paine ("Paine 30(b)(6) Dep.") (2/9/12)) at 319:10-14; Ex. 18 (Paine 30(b)(6) Dep. (9/27/12)) at 678:1-24; Ex. 39 (Chen Dep. (10/29/13)) at 79:20-80:6, 80:20-24; Ex. 43 (Chen Dep. (10/30/13)) at 230:8-12, 231:20-232:24; Ex. 58 (Dep. of David Robinson, M.D. ("Robinson Dep.") (9/11/13)) at 1046:1-8, 1046:23-1047:8. Indeed, even Ethicon's own Medical Director, Martin Weisberg, M.D., testified [redacted]

Ex. 22 (FRCP 30(b)(6) Dep. of Martin Weisberg, M.D. ("Weisberg 30(b)(6) Dep.") (8/9/13)) at 664:1-14, 667:8-17 (emphasis added).

[redacted] Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 489:22-490:1 [redacted]

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[redacted] (emphasis added); Ex. 39 (Chen Dep. (10/29/13)) at 86:21-87:14 [redacted] *see also* Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 486:8-13, 489:1-9; Ex. 14 (Lin 30(b)(6) Dep. (8/1/13)) at 1050:13-17; Ex. 18 (Paine 30(b)(6) Dep. (9/27/12)) at 641:22-642:6; Ex. 38 (Dep. of Catherine Beath ("Beath Dep.") (7/12/13)) at 592:7-11; Ex. 39 (Chen Dep. (10/29/13)) at 78:2-5; Ex. 54 (Dep. of Charlotte Owens, M.D. ("Owens Dep.") (9/12/12)) at 309:23-310:3; Ex. 58 (Robinson Dep. (9/11/13)) at 1046:9-13. [redacted] Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 487:10-21 [redacted] (emphasis added); Ex. 39 (Chen Dep. (10/29/13)) at 81:4-83:11, 85:23-86:3, 132:11-23.

[redacted] Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1208:14-22 [redacted] Ex. 16 (CR 30(b)(6) Dep. of Sean O'Bryan ("O'Bryan 30(b)(6) Dep.") (5/18/12)) at 106:16-107:2, 165:18-166:14; Ex. 22 (Weisberg 30(b)(6) Dep.) (8/9/13)) at 887:16-25, 889:20-890:2, 959:19-960:12; Ex. 35 (Deposition of Axel Arnaud ("Arnaud Dep.") (7/19/13)) at 20:11-21:1; Ex. 58 (Robinson Dep. (9/11/13)) at 1046:1-8; Ex. 19 (FRCP 30(b)(6) Dep. of Dan Smith ("Smith 30(b)(6) Dep.") (6/5/13)) at 1203:6-14 [redacted] Ex. 18 (Paine 30(b)(6) Dep.

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(9/27/12)) at 650:20-651:3 [redacted] *see also id*. at 652:16-653:13; Ex. 20 (Weisberg 30(b)(6) Dep. (5/24/12)) at 131:11-20; Ex. 49 (Dep. of Piet Hinoul ("Hinoul 30(b)(6) Dep.") (5/3/17)) at 601:11-18 [redacted] Ex. 20 (Weisberg 30(b)(6) Dep. (5/24/12)) at 131:11-20.

2. The TVT IFUs omitted known adverse reactions until late 2015, when Defendants revised the IFUs [redacted]

Defendants' TVT devices are associated with numerous adverse reactions known to Defendants; indeed, Defendants' current TVT IFUs include over 20 separate statements regarding the associated adverse reactions. *See* Appendix. Yet prior to late 2015, the IFUs for the TVT-Classic, TVT-Obturator, TVT-Exact, and TVT-Abbrevo contained only a sparse disclosure of adverse reactions associated with the devices:

> **ADVERSE REACTIONS**
> - Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
> - Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
> - As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
> - Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

See Appendix. The TVT-Secur IFU identified only one additional adverse reaction: "Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence." Ex. 1.P.

[redacted]

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[redacted]

Ex. 24 at ETH.MESH.16357665-6. [redacted] to [redacted]

[redacted] *Id.*

[redacted] Ex. 25. Nonetheless, in their response to Health Canada's inquiry in May 2014, [redacted]

[redacted]

Exs. 26 & 27.

Ultimately, in late 2015, Defendants updated the IFUs for the TVT-Classic, TVT-Obturator, TVT-Exact, and TVT-Abbrevo to reflect almost all of the adverse reactions [redacted] plus others. Exs. 26 & 27 [redacted]

[7] The TVT IFUs used in the United States are also used in Europe, Australia, Canada, and numerous other countries. Ex. 1.

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[redacted] Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/2015)) at 23:21-24:7. Defendants also [redacted] Ex. 26 & 31; Section II.B.3.a, *infra*. As noted above, in May 2012, Defendants decided to stop manufacturing and selling TVT-Secur; therefore, the IFU for this device was never updated. Exs. 4 & 72.

The 2015 updated TVT IFUs disclosed a large number of adverse reactions never previously disclosed, as reflected below:

TVT-Classic IFU, Sept. 2000 to Oct. 2015

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

TVT-Classic IFU, Oct. 2015-Present

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

Ex. 1.F & 1.H; *see also* Appendix. They did not, however, add mesh contraction and shrinkage, [redacted] *Id.*

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[redacted]

Following the 2015 updates to the TVT IFUs, in a deposition that dealing extensively with Defendants' 2015 IFU updates, their corporate designee [redacted] *See generally* Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)); Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)). For example, in a Rule 30(b)(6) deposition of Defendants through Medical Director Martin Weisberg, M.D., Defendants admitted that, [redacted]

Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 305:14-22, 307:10-16; *see also id.* at 361:9-379:16; Ex. 32 (Exhibit 1640 referenced above); Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 210:18-211:2. Dr. Weisberg admitted [redacted]

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[redacted] *Id.* at 212:12-18; Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 323:1-328:15; Ex. 33. [redacted] Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 307:23-308:3, 311:8-313:23; Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 211:15-19, 212:20-213:2.

Similarly, Piet Hinoul, M.D. (another Ethicon Medical Director testifying for Defendants) admitted that Ethicon knew that [redacted]. Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1241:24-1246:10 1395:9-14; *see also* Ex. 46 at ETH.MESH.03905069-70 ([redacted] Ex. 45 (Dep. of Piet Hinoul ("Hinoul Dep.") (6/27/13)) at 560:1-19, 562:1-3, 562:16-563:20, 564:10-13, 565:9-12, 566:1-19, 566:25-568:9, 574:16-575:16 (testifying that [redacted]

Indeed, in 2012, following a 2011 FDA safety communication regarding the use of transvaginal mesh for POP repair, *see* Exs. 60 & 61, Defendants finally updated their TVT patient brochure to identify not only "Risks Common to All Pelvic Surgeries," but also "Complications Associated with Synthetic Mesh":

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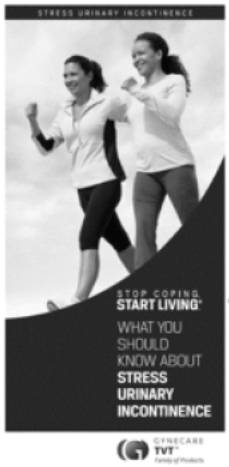

WHAT ARE THE RISKS?

Risks Common to All Pelvic Surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage (bleeding) or hematoma (collections of blood in the pelvis), injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula (holes between bladder or bowel and the vagina), injury to ureters (tubes bringing urine from kidneys to bladder), pelvic abscess formation and nerve damage.

Complications Associated with Synthetic Mesh:
There is a risk of the mesh material becoming exposed into the vagina. Mesh exposure can be associated with pain during intercourse for you and your partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room.

There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue). Pelvic pain, or pain with intercourse, may occur and may resolve with time. There is a risk of developing urinary incontinence or difficulty urinating. Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your surgeon and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.

Ex. 10. When asked about this update, Dr. Hinoul testified that [redacted]

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Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1492:12-1495:6 (emphases added).

Defendants' admissions regarding the TVT IFUs are discussed more fully below.

[redacted]Defendants misrepresented the foreign body reaction triggered by the TVT devices as "transitory," [redacted]

Unlike native tissue surgery that introduces no foreign material into the body, a transvaginal mesh surgery with Defendants' TVT devices involves the implantation of a material that will generate a **chronic** foreign body reaction and **chronic** inflammatory response. [redacted] Ex. 51 (Dep. of Joerg Holste ("Holste Dep.") (7/29/13)) at 51:25-53:17, 54:22-55:10; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1195:5-18. Erosion, extrusion, and exposure can be chronic and can cause chronic pain, dyspareunia, nerve entrapment, and the need for additional surgeries, among other things. Ex. 35 (Arnaud Dep. (7/19/13)) at 118:23-119:9; Ex. 8 (Hinoul 30(b)(6) Dep. (9/18/12)) at 701:24-702:11, 767:24-768:3; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1196:1-6; Ex. 51 (Holste Dep. (7/29/13)) at 52:13-53:17; Ex. 20 (Weisberg 30(b)(6) Dep. (5/24/12)) at 184:23-25.

Defendants acknowledge that "at all times" they knew the foreign body response/inflammatory response caused by the TVT mesh is chronic, rather than transitory. Ex. 50 (*Batiste v. Johnson & Johnson, Ethicon Inc., et al.*, DC-12-14350, Hinoul, Trial Tr. (3/28/14)) at 29:22-25 ("Q. Now, you know and your company knew at all times that when the TVT-O

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mesh was put in a woman's body, the foreign body reaction would be chronic, correct? A. Yes. It's a permanent implant."); Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1194:23-1195:18, 1198:10-22, 1199:3-6 [redacted] Ex. 84 [redacted] Ex. 23 (Wesiberg 30(b)(6) Dep. (11/12/15)) at 215:6-12 [redacted] *see also* Ex. 47 (Hinoul 30(b)(6) Dep. (1/17/17)) at 55:4-18, 120:14-20, 121:1-9; Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 216:11-217:1, 221:1-5. For example, in June 2006, Dr. Bernd Klosterhalfen, Defendants' pathology consultant, [redacted] Ex. 87 at ETH.MESH.00870467 [redacted] *see also* Ex. 89 at 8 [redacted]

Despite this knowledge, until late 2015, Defendants' TVT IFUs informed doctors that a "**transitory** foreign body response **may** occur." Appendix (emphasis added). The TVT-Obturator, TVT-Secur, and pre-November 2010 TVT-Classic IFUs also advised doctors that the mesh used in the TVT devices would induce only a "minimal" and "transient" inflammatory reaction (e.g., "PROLENE Mesh elicits a minimal inflammatory reaction in tissues, which is transient in nature"). *See* Appendix & Exs. 1.I-1.N, 1.P-1.T, and 1.A-1.E.

Defendants' Associate Medical Director of Worldwide Customer Quality, Meng Chen, M.D., Ph.D., [redacted] Ex. 44.

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[redacted] *Id.*; *see also* Ex. 43 (Chen Dep. (10/30/13)) at 248:9-249:3, 250:11-251:4, 252:19-253:9, 254:3-255:25, 256:15-257:5. Defendants ignored Dr. Chen's statements, and did not address the deceptive description of the foreign body/inflammatory response as "transitory" until late 2015 [redacted] Exs. 26 & 31.

b. Defendants omitted, and continue to omit, the risk of vaginal scarring and mesh contracture from their IFUs

Defendants know tissues around their transvaginal meshes can contract/shrink/retract after implantation, which Defendants admit squeezes the mesh such that mesh is enveloped in scar and retracts. According to Defendants' mesh engineer, Gene Kammerer, [redacted] Ex. 78. Defendants admit [redacted] Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1244:11-1245:8 [redacted] *id.* At 1494:6-9 [redacted] Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 115:7-14, 171:10-11 [redacted] Defendants know and agree that [redacted] Ex. 9 (Weisberg 30(b)(6) Dep. (11/12/15)) at 207:1-19; Ex. 51 (Holste Dep. (7/29/13)) at 51:25-53:17. Defendants admit [redacted] Ex. 47 (Hinoul 30(b)(6) Dep. (1/17/17)) at 195:24-196:9; Ex. 48 (Hinoul 30(b)(6) Dep. (1/18/17)) at 282:25-283:5,

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286:11-287:2.

[redacted] Ex. 24; *see also* Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 22:6-26:22.

[redacted] Ex. 24.

[redacted] Exs. 27 & 26.

[redacted] *Id*. at ETH.MESH.22631026.

[redacted] **they never did and still have not done so**. Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 198:10-21, 203:25-207:19; *see also* Ex. 1.

c. Defendants omitted other adverse reactions that are unique to mesh from the pre-2015 IFUs

Some of the most serious adverse reactions missing prior to the 2015 updated IFUs include a heightened risk of infection, chronic pain, dyspareunia, and urinary problems. Defendants knew that each of these adverse reactions were associated with the use of synthetic mesh such as the TVT. Further, Defendants knew that the difficulty of removing mesh once implanted would exponentially increase the impact of these adverse reactions.

Heightened Risk of Infections. [redacted] Ex. 7 (Hinoul 30(b)(6) Dep. (4/5/12)) at 112:3-5.

[redacted]. *Id*. at 112:8-13; Ex. 47 (Hinoul 30(b)(6) Dep. (1/17/17)) at 163:22-164:15.

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[redacted] Ex. 52 (Holste Dep. (7/30/13)) at 298:7-14; Ex. 8 (Hinoul 30(b)(6) Dep. (9/18/12)) at 679:3-7; 680:6-682:3. [redacted] Ex. 90 at 14 [redacted] *see also* Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1492:12-1495:6 [redacted] Ex. 10 (2012 patient brochure identifying infection as a "Complication[] Associated with Synthetic Mesh").

Chronic Pain. Dr. Hinoul (an Ethicon Medical Director) testified [redacted] Ex. 45 (Hinoul Dep. (6/27/13)) at 580:12-581:3. Dr. Hinoul further acknowledged [redacted] *Id.* Moreover, Dr. Hinoul acknowledged [redacted] *Id.* at 578:5-14. Similarly, David Robinson, M.D. (an Ethicon Medical Director) affirmed that [redacted] Ex. 58 (Robinson Dep. (9/11/13) at 977:22-978:7. Dr. Robinson acknowledged [redacted] *Id.* at 1079:3-7; *see also* Ex. 49 (Hinoul 30(b)(6) Dep. (5/3/17)) at 628:4-8 (acknowledging Defendants were aware of complaints to company from women suffering from severe pain and chronic pain); Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 320:7-10, 362:2-6.

Dyspareunia (Pain During Sexual Intercourse). [redacted] Ex. 39 (Chen Dep.

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(10/29/2013)) at 71:24-72:3,107:3-108:9, 156:6-18, 157:8-13, 158:4-9, 164:6-10, 167:15-20, 169:16-18; Ex. 40; *see also* Ex. 35 (Arnaud Dep. (7/19/13)) at 116:21-25, 125:15-126:6; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1245:9-11, 1492:12-1495:6 [redacted]. 10 (Ex. 3505 to 1/14/14 Hinoul Dep.) (2012 patient brochure identifying pain during intercourse for her patient and her partner as a "Complication[] Associated with Synthetic Mesh"); Ex. 49 (Hinoul 30(b)(6) Dep. (5/3/17) at 628:1-14 (admitting that company received complaints from women suffering persistent dyspareunia).

Urinary Problems. The IFUs informed doctors that the TVT devices were indicated for "treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency." Ex. 1. Yet, as discussed above, the IFUs failed to disclose the risk that patients treated with a TVT device could trade one urinary condition (SUI) for a long list of other urinary adverse reactions, including urge incontinence, urinary frequency, urinary retention, and voiding dysfunction. Defendants [redacted] Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 212:12-18; Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 323:1-328:15; Ex. 33; *see also* Ex. 35 (Arnaud Dep. (7/19/13)) at 117:12-15, 125:15-126:6; Ex. 45 (Hinoul Dep. (6/27/13)) at 581:4-583:1; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1492:12-1495:6 [redacted] Ex. 10 (2012 patient brochure identifying risk of developing urinary incontinence or difficulty urinating as "Complications Associated with Synthetic Mesh").

Difficulty of Removal. All of the adverse reactions discussed above are exacerbated by the difficulty of removal once mesh is implanted in the body. Defendants have acknowledged that [redacted]

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[redacted] Ex. 45 (Hinoul Dep. (6/27/13)) at 578:12-579:4. Indeed, [redacted] Ex. 37 (Arnaud Dep. (11/30/17)) at 57:1-22; *see also* Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 365:23-366:12; Ex. 8 (Hinoul 30(b)(6) Dep. (9/18/12)) at 701:24-702:11 [redacted] Ex. 58 (Robinson Dep. (9/11/13)) at 1138:7-19.

Again, Defendants did not disclose to doctors the difficulty of removal until late 2015, when they finally stated in the IFU:

> - One or more revision surgeries may be necessary to treat these adverse reactions.
> - PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

See Appendix. Further, Defendants have never issued guidelines for a mesh removal procedure. In fact, [redacted] Ex. 76; *see also* Ex. 57 (2008 email proposing project to train doctors using mesh to treat "their own complications").

d. Defendants misrepresented that the TVT-Obturator and TVT-Abbrevo would cause "transient" leg pain, [redacted]

For the TVT-Obturator and TVT-Abbrevo, chronic pain can occur in the leg/thigh/groin area because the devices are implanted in and through the inner thigh muscles. Defendants admit [redacted] Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 317:2-14 ("[redacted]

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[redacted] *see also* Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 258:3-9; Ex. 34 (Weisberg 30(b)(6) Dep. (11/13/15)) at 310:8-13.

Despite this risk, all of the IFUs for the TVT-Obturator and the TVT-Abbrevo included only the following:

> Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics.

See Appendix. Defendants' 30(b)(6) corporate witness regarding Regulatory Affairs agreed that, [redacted] Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 479:13-20.

4. Defendants knew of, but ignored, evidence that doctors were not aware of all of the risks associated with the TVT devices

In 2008 and 2009, [redacted]

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From: Chen, Meng [ETHUS]
Sent: Fri, 19 Dec 2008 17:02:17 GMT
To: Gadaleta, Sergio [ETHUS] <SGadale3@its.jnj.com>; Yale, Mark [ETHUS] <MYale1@its.jnj.com>
Subject: #10100080654 and TVT IFUs

Importance: High

Sergio and Mark: Just got the word from WCQ analyst that this case has been reclassified as a litigation file. While it is very difficulty to see patient suffering, I would want to share two findings from reading the patient's communication to the FDA and MHRA:
1. Most serious post surgical complications the patient has experienced are apparently stemming from her existing conditions not relating to urinary incontinence.
2. Her main concern was not the post-surgical complications themselves. She felt that she was not consented for the potential complications by the operating physician.

But when I read her letters in detail, I found that she did receive risk-benefit consultation before her surgery in 2005. And from the TVT IFU, she was given the most accurate consent for the potential adverse reaction known in 2005. However, we are in 2008 now, and there are two more TVT family products (TVTO and TVTS) on the market. Our post-market knowledge with these products are much more than what we have in the IFUs of all three types of TVTs (TVT-Abdominal, Obturator and Secur). My reason for bringing this point to you is may be you may look into it from senior management perspective and to facilitate the IFU update for all three TVTs, particularly in the area of "Potential Adverse Reactions". Thorough pre-operative consent is one the areas stressed by the FDA in the recent public health advisory on pelvic floor mesh products. One of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflecting the current knowledge of the manufacturer's on the potential adverse reactions. Thanks for your attention. Meng

Meng Chen, M.D., Ph.D.
The Associate Medical Director
Worldwide Customer Quality
ETHICON
a Johnson & Johnson Company

Ex. 42; *see also* Ex. 39 (Chen Dep. (10/29/13)) at 191:15-21, 192:3-8, 192:25-193:21, 201:11-202:10. Similarly, as discussed above, [redacted] Ex. 44; Ex. 43 (Chen Dep. (10/30/13)) at 248:9-249:3, 250:11-251:4, 252:19-253:9, 254:3-255:25, 256:15-257:5.

In February 2009, [redacted] Ex. 39 (Chen Dep. (10/29/13)) at 120:15-122:4; Ex. 41. [redacted]

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[redacted] *Id.* [redacted] Ex. 39 (Chen Dep. (10/29/13)) at 121:25-122:25. [redacted] Defendants again did not update the TVT IFUs.

Further, numerous peer-reviewed articles regarding TVT and other transvaginal mesh slings noted the lack of research regarding adverse reactions associated with the devices.[8] Ex. 64 (2009 "Data concerning safety are rare, follow-up is often less than two years, and risk factors for erosions are poorly described."); Ex. 66 (2011 "The extent of impact of mesh-related complications on quality of life has so far not been investigated thoroughly."); *see also* Exs. 67 & 65.

Defendants knew [redacted] Ex. 85. In a 2009 internal company memorandum, Dan Smith, Defendants' lead engineer on TVT-Obturator and TVT-Secur, [redacted] Ex. 83.

[8] Notably, Defendants themselves circulated some of these studies to doctors. However, when they did so, they circulated a summary "reprint" that omitted the statements regarding the lack of research on adverse events. *See, e.g.*, Ex. 88.

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C. Defendants' Misrepresentations and Omissions Have Had Real, Devastating Consequences for Washington Women

In 2006, Jean Giallombardo, a Rochester, Washington resident, was diagnosed with SUI and POP and implanted with both the TVT-Obturator and Defendants' Prolift (a device indicated to treat POP). Decl. of Jean Elizabeth Giallombardo ("Giallombardo Decl.") ¶ 3. The devices were implanted by a Washington urologist with no prior experience implanting a mesh device, with direction and oversight by Dr. Douglas Grier, a Seattle urologist. *Id.* At the time that Ms. Giallombardo received the device, the TVT IFU did not warn about the risks of voiding dysfunction, urinary tract infections, or chronic lower back pain and represented that leg pain associated with the device would be "transient." Ex. 1.K; *see also* POP MSJ, Section II.B. Consistent with these omissions from the IFU, her doctor did not warn her of these potential adverse reactions. *See* Giallombardo Decl. ¶¶ 7, 14. About four years after her implant, Ms. Giallombardo began to experience complications; after examination by a specialist she learned that the mesh had eroded and was exposed in her vagina. *Id.* ¶¶ 8-13. As a result, she now (12 years after her implant) cannot empty her bladder without a catheter, has chronic urinary tract infections, constant lower back pain, and cramps in the back of her entire left leg. *Id.* ¶¶ 8-11. Ms. Giallombardo describes her circumstances as a "nightmare" and, as a result of these complications, is largely homebound and suffers from depression and loneliness. *Id.* ¶¶ 12-13.

In 2007, Rose Montgomery, a Bremerton, Washington resident, was implanted with a TVT-Secur device for her SUI. Decl. of G. Rose Montgomery ("Montgomery Decl.") ¶¶ 2-3. The device was implanted by Dr. Randall Moeller, a Silverdale, a Washington urologist. *Id.* ¶¶ 3-4. At the time that she was implanted, the TVT-Secur IFU did not warn doctors about the risks of recurrence of incontinence, pain during sexual intercourse for the patient and her partner, chronic pain, or bleeding. Ex. 1.P. Consistent with these omissions from the IFU, Dr. Moeller did not warn her about these risks. Montgomery Decl., ¶ 2. Ms. Montgomery also reviewed a TVT brochure during her initial visit with Dr. Moeller, but the brochure did not warn her of any

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risks regarding the TVT device. *Id.* ¶¶ 6-7. About two years after implantation, Ms. Montgomery's incontinence returned. *Id.* ¶ 10. She began to experience pain during sexual intercourse, bowel movements, urinating, and lifting. *Id.* ¶¶ 10-11. During intercourse, her husband could feel the mesh and would also experience pain. *Id.* ¶ 10. After examination by Dr. Billy Vanasupa, she learned that the mesh from the TVT-Secur device had eroded and was cutting through her vagina. *Id.* ¶ 12. Dr. Vanasupa performed a partial excision of the mesh in September 2014, but was unable to remove all of the mesh because it was so deeply imbedded in her tissue. *Id.* ¶ 12. She has since had two revision surgeries using native tissue and is finally SUI-free. *Id.* ¶¶ 12-13.

III. STATEMENT OF THE ISSUE

Whether, under CR 56(a) and (c), the Court should grant partial summary judgment on liability for Defendants' misrepresentations and knowing omissions of adverse reactions from the TVT IFUs.

IV. EVIDENCE RELIED UPON

This Motion is based on the papers and pleadings on file and the Declaration of Breena Roos, the Declaration of G. Rose Montgomery, and the Declaration of Jean Elizabeth Giallombardo.

V. ARGUMENT

A. Legal Standards

Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. *W. Telepage, Inc. v. City of Tacoma Dep't of Fin.*, 140 Wn.2d 599, 607, 998 P.2d 884 (2000); *see also* CR 56(a) (allowing a plaintiff to move for summary judgment on "all or part" of its claims). To defeat summary judgment, the non-moving party must demonstrate that there is an issue of fact to be tried. *See Young v. Key Pharm., Inc.*, 112 Wn.2d 216, 225, 770 P.2d 182 (1989). The non-moving party must produce actual facts that dispute the movant's material facts. *Id.* The non-moving party may not rely on

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mere allegations, conclusions, or opinions to defeat summary judgment. *Grimwood v. Univ. of Puget Sound, Inc.*, 110 Wn.2d 355, 359-61, 753 P.2d 517 (1988).

To prevail under the CPA, the State must prove (1) an unfair or deceptive act or practice, (2) occurring in trade or commerce, and (3) a public interest impact. *State v. Mandatory Poster Agency*, 199 Wn. App. 506, 518, 398 P.3d 1271, *review denied*, 189 Wn.2d 1021, 404 P.3d 496 (2017). Unlike private plaintiffs, the State "is not required to prove causation or injury." *Id.* The CPA "shall be liberally construed [so] that its beneficial purposes may be served." RCW 19.86.920. As courts have repeatedly noted, the liberal construction directive ensures the protection of the public and the existence of fair and honest competition. *See, e.g.*, *State v. Ralph Williams' N.W. Chrysler Plymouth, Inc.*, 82 Wn.2d 265, 274, 510 P.2d 233 (1973); *Panag v. Farmers Ins. Co. of Wash.*, 166 Wn.2d 27, 37, 204 P.3d 885 (2009).

Whether an act or practice is unfair or deceptive under the CPA is a **question of law** for the court. *Leingang v. Pierce Cty. Med. Bureau, Inc.*, 131 Wn.2d 133, 150, 930 P.2d 288 (1997); *State v. LA Inv'rs, LLC*, 2 Wn. App. 2d 524, 538, 410 P.3d 1183, *review denied*, 190 Wn.2d 1023, 418 P.3d 796 (2018); *Mandatory Poster Agency*, 199 Wn. App. at 520. Thus, where there is no dispute about the defendant's actions, the court can decide that the actions were unfair or deceptive on a motion for summary judgment. *LA Inv'rs, LLC*, 2 Wn. App. 2d at 538-39. Here, there is no disputed issue of material fact about the content of the TVT IFUs or that the IFUs were distributed to health care providers in Washington. Therefore, the court may properly determine that Defendants violated the CPA through their IFU omissions and misrepresentations.

B. Defendants' IFUs Violated the CPA as a Matter of Law

1. Defendants' omissions and misrepresentations were unfair or deceptive under the CPA

Defendants omitted known, serious risks and adverse consequences about the TVT and affirmatively misrepresented the seriousness of adverse consequences in TVT IFUs. Defendants'

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omissions and misrepresentations are unfair and deceptive and violate the CPA. "Whether a particular act or practice is 'unfair or deceptive' is a question of law." *Panag*, 166 Wn.2d at 47 (citing *Leingang*, 131 Wn.2d at 150).

a. Defendants' omissions and misrepresentations were deceptive

A "knowing failure to reveal something of material importance is 'deceptive' within the CPA." *Indoor Billboard/Wash., Inc. v. Integra Telecom of Wash., Inc.*, 162 Wn.2d 59, 75, 170 P.3d 10 (2007) (citation omitted). For 16 years, Defendants knew that the TVTs could cause, among other things, chronic, lifelong pain in the pelvis, legs, groin, and/or abdomen; chronic infections; contracture/shrinkage; painful sexual intercourse for the woman and/or her partner; recurrence of SUI; and a host of new urinary issues, including other forms of incontinence, voiding dysfunction, and urinary tract infections. Defendants also misrepresented the nature of other serious complications, including that the TVT could cause only transitory pain or transitory foreign body response/inflammation, when Defendants knew the pain and complications could be chronic.

"'Deception exists if there is a representation, omission, or practice that is likely to mislead a reasonable consumer.'" *Mandatory Poster Agency*, 199 Wn. App. at 518-19 (quoting *Rush v. Blackburn*, 190 Wn. App. 945, 963, 361 P.3d 217 (2015)). Even an accurate communication can be deceptive if the "net impression" it conveys is deceptive. *Panag*, 166 Wn.2d at 50 (citing *F.T.C. v. Cyberspace.com LLC*, 453 F.3d 1196, 1200 (9th Cir. 2006)). Further, where the defendant has a duty to disclose certain facts, the failure to comply with industry standards constitutes evidence of a deceptive act or practice. *Nguyen v. Doak Homes, Inc.*, 140 Wn. App. 726, 734, 167 P.3d 1162 (2007); *see also Testo v. Russ Dunmire Oldsmobile, Inc.*, 16 Wn. App. 39, 51, 554 P.2d 349 (1976) ("A party's failure to reveal something she is in good faith bound to disclose has the inherent capacity to deceive the other party.").

To prove that Defendants' omissions and misrepresentations are deceptive, the State is not required to prove that any consumer (or physician with respect to IFUs) was actually

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deceived by Defendants' IFU omissions and misrepresentations. "[N]either intent to deceive nor actual deception is required. The question is whether the conduct has the capacity to deceive a substantial portion of the public." *Stephens v. Omni Ins. Co,* 138 Wn. App. 157, 166, 159 P.3d 10 (2007), *aff'd sub nom. Panag*, 166 Wn.2d at 50 (citing *Hangman Ridge Training Stables v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 785-86, 719 P.2d 531 (1985)). The purpose of the capacity-to-deceive test is to deter deceptive conduct before injury occurs." *Hangman Ridge Training Stables v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 785, 719 P.2d 531 (1985).

Further, the State is not "required to quantify the exact number of consumers that were deceived." *LA Inv'rs*, 2 Wn. App. 2d at 542; *see also Behnke v. Ahrens*, 172 Wn. App. 281, 292, 294 P.3d 729 (2012) ("Washington courts have not tried to decide as a matter of law whether the potential victims of a deceptive act or practice are sufficiently numerous to qualify as a substantial portion of the public."). In deciding whether conduct has the capacity to deceive a substantial portion of the public, courts consider whether the conduct could be replicated. *See Burns v. McClinton*, 135 Wn. App. 285, 302-06, 143 P.3d 630 (2006) (accountant did not violate CPA by failing to inform client of fee increases when there was a unique relationship between accountant and client and no evidence that accountant failed to disclose fee increases to other clients).

In evaluating whether Defendants' IFUs had the capacity to deceive a substantial portion of physicians treating women for SUI, the court should look not to the most sophisticated physicians, but to the least. *Panag*, 166 Wn.2d at 50. A physician is a consumer of medical devices when he or she uses those devices to treat patients. *See Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 313, 858 P.2d 1054 (1993) (a physician had a CPA cause of action against a drug manufacturer that failed to warn of significant risks of drug prescribed to patient).

It is undisputed that Defendants sold 10,701 TVTs in Washington, each with an IFU. Ex. 5. As detailed above, Defendants purposefully failed to disclose numerous, known serious adverse

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events associated with their TVT devices in the IFUs. The failure to disclose violated FDA's regulations and the Blue Book (IFUs must include "**all adverse reactions reasonably associated with the device**"), both of which Defendants [redacted] FDA regulations and Blue Book guidance—which Defendants have adopted as their own standard—demonstrate public policy for medical device disclosures and make no exception for Defendants' devices; nor do they allow Defendants to assume physicians already know of adverse reactions. Nothing in the applicable FDA regulations or Blue Book allows for or excuses Defendants' failure to disclose in the IFUs known adverse reactions associated with the TVT devices.

Indeed, Defendants agree [redacted] Ex. 16 (O'Bryan 30(b)(6) Dep. (5/18/12)) at 106:16-107:2; Ex. 17 (Paine 30(b)(6) Dep. (9/27/12)) at 648:21-649:25, 650:20-651:3, 652:16-653:13; Ex. 20 (Weisberg 30(b)(6) Dep. (5/24/12)) at 131:11-20; Ex. 21 (Weisberg 30(b)(6) Dep. (5/31/13)) at 624:16-23. Further, Defendants recognize [redacted] Ex. 56 (Robinson Dep. (3/14/12)) at 488:11-18; Ex. 58 (Robinson Dep. (9/11/13)) at 1046:1-1047:8; Ex. 16 (O'Bryan 30(b)(6) Dep. (5/18/12)) at 165:18-166:14; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1207:18-1208:22. [redacted]

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[redacted] Ex. 14 (Lin 30(b)(6) Dep. (8/1/13)) at 1050:13-17.

Prior to the launch of the TVT-Classic in 1999 and each TVT device launched thereafter, Defendants knew of numerous and very serious risks and adverse reactions associated with the use of the TVT devices, which Defendants never disclosed in the respective IFUs until late 2015. [redacted] They omitted risks and adverse reactions that relate to profound matters of health and safety, and the failure to disclose these known adverse reactions dramatically impeded the very purposes and policies behind the IFUs: to fully inform healthcare providers so that patients can ultimately make fully informed and autonomous decisions about their own bodies and medical treatments. Defendants' admitted failure to disclose these known and associated risks in their IFUs therefore had the capacity to deceive as a matter of law.

Defendants' omissions of the serious risks associated with their TVT devices were material. The Washington Supreme Court has determined that information is material if it "could be of material importance to a consumer's decision to purchase" goods or services. *Indoor Billboard*, 162 Wn.2d at 78. In *Indoor Billboard*, a telephone company misrepresented that a $4.21 monthly charge was required by FCC regulations, when it actually was not a required charge. *Id.* at 68. The court held that the misrepresentation was material because whether the $4.21 was required, and therefore unavoidable, impacted the consumer's decision to purchase service from the defendant. *Id.* at 78. If the mandatory nature of a $4.21 monthly charge is of material importance to a consumer purchasing telephone service, then information about significant health risks and complications associated with TVT, which is permanently implanted in women's bodies, surely is of material importance to the physicians implanting the TVT.

Federal courts are in accord regarding materiality when interpreting the analogous FTC

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Act.[9] Federal courts have held that an omission or misrepresentation is "material" if it involves "information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product." *F.T.C. v. QT, Inc.*, 448 F. Supp. 2d 908, 960 (N.D. Ill. 2006), *amended on reconsideration in part*, 472 F. Supp. 2d 990 (N.D. Ill. 2007), *aff'd*, 512 F.3d 858 (7th Cir. 2008), *and aff'd*, 512 F.3d 858 (7th Cir. 2008). More specifically, misrepresentations or omissions that "significantly involve health, safety, or other issues that would concern reasonable customers" to be presumptively material. *Id.* at 960, 965-66 (advertising claims regarding bracelet's ability to relieve pain were medical, health-related claims and were material); *see also F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1191 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009) ("For purposes of this case, it is sufficient to state that when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) or any claims regarding the safety of the product can be presumed material."). Here, information about the severe risks and adverse consequences of the TVT that was omitted from, or misrepresented in, Defendants' IFUs is both important to the doctors implanting the devices permanently in women's bodies and involve significant health or safety issues that would concern reasonable doctors. Moreover, Defendants admit that adverse reactions associated with their devices are material. [redacted] Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1207:5-11.

Not only did Defendants omit material information from their IFUs, they also misrepresented the characteristics of the TVTs in the IFUs. Defendants' misrepresentations were material. In this motion, the State asks the Court to decide that Defendants made two deceptive statements in their IFUs.

[9] The Court properly can look to, but is not necessarily bound by, the decisions of federal courts interpreting and applying federal statues similar to the CPA. RCW 19.86.920; *Robinson*, 106 Wn. App. at 114.

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First, Defendants' TVT IFUs deceptively communicated that the mesh would elicit a "transitory foreign body response" and a "minimal" and "transient" inflammatory reaction in the tissue in which it was implanted. Defendants' own documents and testimony demonstrate that this was **false**—mesh creates a chronic foreign body response and chronic inflammation. *See* Section II.B.3.a, *supra*. Indeed, Defendants removed the description of the foreign body response as "transitory" from the IFUs for all TVT devices in late 2015; and Defendants removed their description of the inflammatory reaction as "transient" from the TVT-Classic in 2010 (and never had it in the IFUs for the TVT-Exact and TVT-Abbrevo). By making these changes, Defendants demonstrated they knew their earlier statements about the "transitory" nature of the complications were false and misleading. As Defendants' current IFUs now acknowledge, the foreign body response can result in extrusion, erosion, fistula formation, and inflammation—complications that themselves can cause numerous health issues. Appendix.

Second, in their IFUs for the TVT-Obturator and TVT-Abbrevo, Defendants stated that patients might experience "transitory" leg pain lasting 24-48 hours. However, Defendants knew that these devices were associated with chronic leg pain lasting far longer than two days. *See* Section II.B.3.d, *supra.*

Both misrepresentations are material because they affected health and safety. Therefore, Defendants' misrepresentations regarding material health consequences were deceptive as a matter of law.

b. Defendants' omissions and misrepresentations were unfair as a matter of law

In addition to being deceptive, Defendants' IFUs were unfair under the CPA. "[A]n act or practice can be unfair without being deceptive." *Klem v. Wash. Mut. Bank*, 176 Wn.2d 771, 787, 295 P.3d 1179 (2013). In *Klem*, the Supreme Court noted that, because the CPA does not define "unfair" or "deceptive," the court has "allowed the definitions to evolve through a gradual process of judicial inclusion and exclusion." *Id.* at 785. Further, "[g]iven that there is no limit to

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human inventiveness, courts … must be able to determine whether an act or practice is unfair or deceptive to fulfill the protective purposes of the CPA." *Id.* at 786.

To determine whether an act or practice is unfair, the court may examine "whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness." *Magney v. Lincoln Mut. Sav. Bank*, 34 Wn. App. 45, 57, 659 P.2d 537 (1983) (*quoting F.T.C. v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244, n.5, 92 S. Ct. 898, 31 L. Ed. 2d 170 (1972)); *see also Klem*, 176 Wn.2d at 785 (citing *Magney* with approval). The court may also examine whether the acts or practices are "immoral, unethical, oppressive, or unscrupulous." *Magney*, 34 Wn. App. at 57.

As detailed above, Defendants recognize that the TVT IFU represents [redacted] Ex. 16 (O'Bryan 30(b)(6) Dep. (5/18/12)) at 165:18-166:14. Defendants are [redacted] Ex. 19 (Smith 30(b)(6) Dep. (6/5/13)) at 1203:6-14; Ex. 9 (Hinoul 30(b)(6) Dep. (1/14/14)) at 1207:18-1208:22. Moreover, federal regulations, the FDA and industry standard Blue Book, and Defendants' own internal policies require the TVT IFUs to identify all known, associated adverse reactions. Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 489:1-9, 489:22-490:1. The Blue Book, adopted by Defendants, is intended to assure adequacy and consistency in IFUs. Ex. 12. Defendants and the FDA expect doctors would look at "Warnings" and "Adverse Reactions" and to rely in part on that information to learn of complications and warnings related to the TVT devices. Ex. 58 (Robinson Dep. (9/11/13)) at 1046:1-8; *see* Physical Medicine Devices; Reclassification of Iontophoresis Device Intended for Any Other Purposes, 81 Fed. Reg. 48703-01 (July 26, 2016) (reclassifying

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an unrelated device) (commenting that the purpose of 21 C.F.R. § 801.109(c) is to ensure that "clinicians will have access to and be aware of the warnings and precautions in the labeling [i.e., IFU], and as such, clinicians should be adequately informed of the risks associated with these devices").

Defendants' misrepresentations and failures to disclose—and in this case, knowing failures to disclose—adverse events associated with the TVT devices in the IFUs is at least unscrupulous. The omissions and misrepresentations also offend the public policy set forth in federal law and federal guidance/industry standard that are intended to ensure that doctors and patients are informed of the risks associated with Defendants' TVT devices. Moreover, Defendants' failure to disclose the adverse reactions violated their own internal policies. It is manifestly unfair to allow medical device manufacturers to knowingly withhold and misrepresent vital safety and risk information in the IFU. For the above reasons, Defendants' actions were unfair under the CPA as a matter of law.

There is no genuine issue of material fact that Defendants' IFUs omitted material information about risks and adverse consequences of the TVTs and made material misrepresentations about the TVTs. Defendants' omissions and misrepresentations are unfair and deceptive under the CPA as a matter of law and the State has met its burden on this element.

2. Defendants' actions occurred in trade and commerce

The CPA broadly defines "trade" and "commerce" to include "the sale of assets or services, and any commerce directly or indirectly affecting the people of the state of Washington." RCW 19.86.010(2). Additionally, it is the intent of the CPA "to bring within its reach *every* person who conducts unfair or deceptive acts or practices in *any* trade or commerce." *Michael v. Mosquera-Lacy*, 165 Wn.2d 595, 602, 200 P.3d 695 (2009) (citing *Short v. Demopolis*, 103 Wn.2d 52, 61, 691 P.2d 163 (1984)). There is no genuine issue of material fact that Defendants were engaged in for-profit trade and commerce; the TVT devices and IFUs were sold and distributed by Defendants to health care providers and consumers in Washington. Ex.

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5. Accordingly, the State has met its burden on this element.

3. Defendants' actions impacted the public interest

In determining whether the unfair or deceptive conduct affects the public interest, courts look to the following questions: (1) were the alleged acts committed in the course of defendants' business, (2) was there a pattern or generalized course of conduct, (3) were the acts repeated, (4) was there a real and substantial potential for repetition, and (5) if the act complained of involved a single transaction, were many consumers affected or likely to be affected by it. *Hangman Ridge*, 105 Wn.2d at 790. None of these factors is dispositive, nor must all of them be present to establish the public interest. *Id.* at 791; *see also* RCW 19.86.093.

Based on these factors, Defendants' distribution of IFUs unquestionably affected the public interest. There is no genuine issue of material fact that Defendants sold devices, accompanied by IFUs, into Washington as part of their general business practices. Ex. 5. It is also not disputed that Defendants' failure to disclose all of the risks in the IFUs and their misrepresentations were not isolated instances of misjudgment, but rather, the result of a pattern of deceptive behavior. Ex. 1. Indeed, [redacted] Ex. 39 (Chen Dep. (10/29/13)) at 120:15-122:4. The State has met its burden as to the public interest impact.

VI. CONCLUSION

Defendants admit their IFUs failed to disclose serious, known adverse reactions associated with the TVT devices, and misrepresented the nature and seriousness of other risks. Thus, the IFUs had the capacity to deceive and were unfair, and the State is entitled to summary judgment on liability for Defendants' IFUs circulated in Washington through 2015.

I certify that this memorandum contains 11,540 words, in compliance with the Local Civil Rules. A motion for overlength brief is pending.

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DATED this 26th day of October, 2018.

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CERTIFICATE OF SERVICE

I certify that I served a copy of the foregoing on the following party/parties via the following methods:

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I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

DATED this 26th day of October, 2018, at Seattle, Washington.

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APPENDIX

TVT-Classic

TVT IFU 9/8/2000 — 11/26/2003, Roos Decl., Ex. 1.A

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT IFU 12/22/2003 — 2/21/2005, Roos Decl., Ex. 1.B

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Classic, cont'd

TVT IFU 2/11/2005 — 4/7/2006, Roos Decl., Ex. 1.C

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT IFU 4/7/2006 — 10/7/2008, Roos Decl., Ex. 1.D

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Classic, cont'd

TVT IFU 10/13/2008 — 11/23/2010, Roos Decl., Ex. 1.E

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

TVT IFU 11/29/2010 — 11/26/2014, Roos Decl., Ex. 1.F

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

TVT-Classic, cont'd

TVT IFU 12/9/2014 — 8/31/2015, Roos Decl., Ex. 1.G

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

TVT-Classic, cont'd

TVT IFU 10/7/2015 —Present, Roos Decl., Ex. 1.H

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

TVT-Obturator

TVT-Obturator IFU 1/7/2004 — 3/4/2005, Roos Decl., Ex. 1.I

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator IFU 3/7/2005—5/19/2005, Roos Decl., Ex. 1.J

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator, cont'd

TVT-Obturator IFU 5/25/2005 — 4/29/2008, Roos Decl., Ex. 1.K

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator IFU 4/23/2008—5/7/2010, Roos Decl., Ex. 1.L

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator, cont'd

TVT-Obturator IFU 5/12/2010 — 11/27/2014, Roos Decl., Ex. 1.M

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator IFU 12/15/2014 — 9/16/2015, Roos Decl., Ex. 1.N

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Obturator, cont'd

TVT-Obturator IFU 9/22/2015 — Present, Roos Decl., Ex. 1.O

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- The plastic sheaths initially covering the PROLENE Mesh are designed to minimize the risk of contamination. Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

ORDERED NOT RELIED

TVT-Abbrevo

TVT-Abbrevo IFU 9/10/2010—11/27/2014, Roos Decl., Ex. 1.V

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over-correction, i.e., too much tension applied to the mesh implant, may cause temporary or permanent lower urinary tract obstruction.

TVT-Abbrevo IFU 7/1/2015 — 9/15/2015, Roos Decl., Ex. 1.W

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over-correction, i.e., too much tension applied to the mesh implant, may cause temporary or permanent lower urinary tract obstruction.

TVT Abbrevo, cont'd

TVT-Abbrevo IFU 9/24/2015 — Present, Roos Decl., Ex. 1.X

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over-correction, i.e., too much tension applied to the mesh implant, may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

TVT-Secur

TVT-Secur IFU 12/16/2005—Discontinuance (8/15/2012), Roos Decl., Ex. 1.P

ADVERSE REACTIONS

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies and surgical implants, PROLENE mesh and absorbable materials may potentiate or exacerbate an existing infection.
- Over-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence.

TVT-Exact

TVT-Exact IFU 5/4/2010 — 6/6/2013, Roos Decl., Ex. 1.Q

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the Implant may cause temporary or permanent lower urinary tract obstruction.

TVT-Exact IFU 8/5/2013 — 10/17/2013, Roos Decl., Ex. 1.R

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

TVT-Exact IFU 10/23/2013 — 11/26/2014, Roos Decl., Ex. 1.S

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the Implant may cause temporary or permanent lower urinary tract obstruction.

TVT-Exact, cont'd

TVT-Exact IFU 8/12/2014 — 9/9/2015, Roos Decl., Ex. 1.T

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the Implant may cause temporary or permanent lower urinary tract obstruction.

TVT-Exact IFU 9/8/2015 — Present, Roos Decl., Ex. 1.U

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the Implant may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death