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' POP DEVICES

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I. INTRODUCTION AND RELIEF REQUESTED

Until 2012, the Defendants made and sold transvaginal devices that were woven from plastic and implanted in a woman's body to treat pelvic organ prolapse. 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; urinary incontinence; and other urinary conditions. These risks are such that numerous countries have taken regulatory action in response to transvaginal mesh, ranging from requiring enhanced disclosures to limiting its use. In fact, in 2012, Defendants stopped selling their transvaginal mesh products for pelvic organ prolapse in the United States.

Women here in Washington have suffered as a result of Defendants' transvaginal mesh products. One Washington woman describes her complications from Defendants' Prolift mesh product 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.

Since 2003, Defendants have made a number of transvaginal mesh devices to treat pelvic organ prolapse in women. In the Instructions for Use (IFUs) that accompanied these devices for the entire relevant period, Defendants knowingly omitted serious, debilitating, and life-altering complications associated with the mesh devices. As Defendants acknowledge, the IFUs are a critical source of information for the doctors who will permanently implant Defendants' transvaginal mesh in women's bodies. Defendants knew that their transvaginal mesh devices could cause chronic, life-long pain and other adverse consequences but failed to disclose those risks and consequences in the IFUs.

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 the Consumer

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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.[1]

As a matter of law, Defendants' omissions in the IFUs for the Gynemesh PS, Prolift, Prolift+M, and Prosima devices were 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 for Defendants' IFUs for the POP transvaginal mesh devices from their release until they were taken off the market in 2012.

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 devices marketed for the treatment of POP; a companion motion addresses the SUI devices.[2] For the relevant period (2003-2012), Defendants' POP devices were sold and distributed in Washington through Defendant Ethicon, Inc. Declaration of Breena Roos in Support of State's (1) Motion for Summary Judgment on Liability as to Defendants' Instructions for Use for Defendants' TVT Devices and (2) Motion for Summary Judgment on Liability as to Defendants' Instructions for Use for Defendants' POP Devices ("Roos Decl."),[3] Ex. 3 (Defendants' Answer to Integratory No. 1). Defendant Johnson & Johnson has agreed to accept liability for the actions of its subsidiary, Ethicon, Inc. *Id.*; Dkt. 168.

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[1] Defendants' IFU omissions are part of a larger strategy that included doctor and patient marketing. This threshold motion relates only to certain omissions from Defendants' IFUs for the Gynemesh PS, Prolift, Prolift+M, and Prosima transvaginal 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.

[2] *See* State of Washington's Motion for Partial Summary Judgment on Liability as to Instructions for Use for Defendants' TVT Devices (the "TVT MSJ").

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

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A. Defendants' Devices for the Treatment of Pelvic Organ Prolapse

POP is a condition where the supportive muscles and tissues of the pelvis weaken, causing one or more of the pelvic organs (i.e., the vagina, cervix, uterus, bladder, urethra, and rectum) to prolapse or "drop" from their normal positions. Ex. 62. POP can be caused by labor/childbirth or aging. *Id.* POP can be treated non-surgically, through pelvic floor exercises or a pessary (a removable device inserted into the vagina), or surgically using native tissue or a synthetic mesh. *Id.* In 1998, Defendants introduced their TVT System for the treatment of SUI, discussed in the companion motion. *See* TVT MSJ, Section II.A.

In 2003, Defendants introduced Gynemesh PS, made from Prolene Soft mesh, for the treatment of POP. Ex. 4. Gynemesh PS was indicated for insertion through the vagina (i.e., transvaginally) or through the abdomen. *See* Ex. 2.A; Ex. 4. The Gynemesh PS device was the first transvaginal mesh device indicated for the treatment of POP, but was mostly used by surgeons when prior surgical measures were unsuccessful until Defendants' second transvaginal POP device, Prolift, came on the market in 2005. Ex. 36 (Dep. of Axel Arnaud ("Arnaud Dep.") (11/29/17)) at 46:9-19 ("Q. So before PROLIFT came on the market, all meshes, not just GYNEMESH, were not frequently used for primary repair?... THE WITNESS: One of the reasons is that before PROLIFT, you could hardly find in a textbook of surgery or in any source of medical information. You could hardly find a description of a technique using a mesh. So surgeons who were obliged to use this mesh repair had no guideline, no well-described procedure to repair the pelvic floor with a mesh.").

In 2005, Defendants began marketing and selling Prolift in Washington (even before it was cleared by the FDA), a pelvic floor repair "kit" for the treatment of POP. Ex. 2.G; Ex. 4; Ex. 5; Ex. 71. The Prolift included pre-cut Prolene Soft mesh, tools for implantation, and a specific surgical procedure for transvaginal implantation. Ex. 2.G; Ex. 4. In 2009, Defendants introduced Prolift+M (a kit using a different mesh made by Defendants (Ultrapro), with a delayed absorbable suture) and Prosima (a kit made from Prolene Soft mesh that included a

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vaginal support device that would remain in place for two to four weeks post-surgery, to allow for tissue ingrowth) in Washington. Ex. 4; 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' POP 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." *Id.* 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 that 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.*

In July 2011, the FDA issued a Safety Communication and "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Exs. 60 & 61. The target audience of this Safety Communication, like the 2008 FDA PHN before it, were health care providers implanting transvaginal mesh to treat POP and SUI, healthcare providers caring for patients implanted with transvaginal mesh, and patients. The FDA's Safety Communication informed readers "that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**," whereas the FDA's 2008 PHN stated otherwise. Ex. 61 (emphasis in original); *see also* Ex. 60 at 8, 11. The FDA's Safety Communication stated transvaginal POP repair "may expose patients to greater risks" when compared to traditional non-mesh repairs.

According to the FDA's 2011 Safety Communication "the most frequent complications

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reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization." Ex. 61 at 2. The FDA further stated:

> Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.
>
> In particular, these products are associated with serious adverse events, including vaginal mesh erosion (also called exposure, extrusion or protrusion), a complication which can require multiple surgeries to repair and may result in continued sequelae (e.g., pain) even after mesh removal. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.

Ex. 60 at 12. The FDA concluded that "[m]esh erosion can require multiple surgeries to repair and can be debilitating for some women," and that "[i]n some cases, even multiple surgeries will not resolve the complication." Ex. 61. More, the FDA found a "*previously unidentified risk* of transvaginal POP repair with mesh," that being "[m]esh contraction (shrinkage)." *Id.* (emphasis in original). The FDA stated the literature "associate[d] mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." *Id.* In this, the FDA concluded that "[b]oth mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse," and that "men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion." *Id.*

The FDA recommended that health care providers "be aware of the risks of surgical mesh," "[b]e vigilant for potential adverse events from the mesh, especially erosion and infection," "[i]nform patient that implantation of surgical mesh is permanent, and that some

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complications associated with implanted mesh may require additional surgery that may or may not correct the complication," "[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 using surgical mesh." Ex. 61. The FDA also recommend that healthcare providers consider that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications," that "[r]emoval of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life," that "[c]omplete removal of mesh may not be possible and may not result in complete resolution of complications, including pain." *Id.*

Less than one year later, in May 2012, Defendants removed the Prolift, Prolift+M, and Prosima products from the market. Ex. 74; Ex. 75. At the same time, Defendants changed the indication for Gynemesh PS so that it was no longer indicated for transvaginal implantation (i.e., it could only be implanted abdominally).[4] Ex. 38 (Dep. of Catherine Beath ("Beath Dep") (7/12/13)) at 518:9-20; Ex. 73.

From 2002 through 2012, Defendants sold 1,851 POP devices in Washington. Roos Decl., ¶ B.5, Ex. 5.

B. Defendants' Instructions for Use for the POP Devices

1. Each POP 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 POP devices shipped to Washington contained an IFU. Ex. 6 (CR 30(b)(6) Deposition of Eric Dunn ("Dunn 30(b)(6)

[4] The State does not seek a finding of liability for Defendants' marketing of the Gynemesh PS product after this transition.

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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" 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) Deposition of Susan Lin ("Lin 30(b)(6) Dep.") (3/13/13)) at 488:17-25. 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 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]

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[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:[redacted] 201:11-202:10 [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]

[redacted]

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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] (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]

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[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. 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. (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. [redacted] Ex. 49 (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. For the entire period of time relevant to this case, Defendants' POP transvaginal mesh device IFUs omitted numerous known adverse reactions associated with the devices

Consistent with the findings of the FDA, Defendants admit their POP transvaginal mesh devices are associated with certain adverse reactions. For example, the current IFU for

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Gynemesh PS—the only of Defendants' POP mesh devices still on the market—identifies the following adverse reactions:

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, bleeding including hemorrhage, or hematoma, urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction, acute and/or chronic pain, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.
- Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, GYNECARE GYNEMESH™ may potentiate an existing infection.
- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- These adverse reactions may require surgical treatment.
- As with any surgery, one or more revision surgeries may be necessary to treat these complications.
- GYNECARE GYNEMESH™ is a permanent implant that integrates into the tissue. In cases in which the GYNECARE GYNEMESH™ needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

Ex. 2.F. Defendants' IFUs did not disclose many of the above adverse reactions for each of the POP devices. *See* Appendix.[5] The below chart identifies the adverse reactions disclosed in Defendants' 2015 Gynemesh PS IFU, but not disclosed in the various IFUs for Prolift, Prolift+M, Prosima, or transvaginally-indicated Gynemesh PS.

[5] For the court's convenience, the Adverse Reactions sections of each of the POP IFUs are excerpted in an Appendix to this motion.

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Adverse Reactions Disclosed in Gynemesh PS 2015 IFU vs. IFUs at Issue[6]

Adverse Reaction	Gynemesh PS 2015-Present[7]	Gynemesh PS 2003-2006[8]	Gynemesh PS 2006-2012[9]	Prolift 2005-2009[10]	Prolift 2009-2012[11]	Prosima 2007-2012[12]	Prolift+M 2008-2012[13]
Punctures or lacerations of vessels, nerves, bladder, urethra, or bowel may occur … and may require surgical repair	✓			✓	✓	✓	✓
Infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion	✓	✓	✓	✓	✓	✓	✓
Scarring that results in implant contraction			✓	✓		✓	
Hemorrhage	✓						
Hematoma	✓				✓		✓
Urinary Incontinence	✓				✓		✓
Urge incontinence	✓						
Urinary frequency	✓						
Urinary retention/obstruction and/or ureteral/ureter obstruction	✓				✓		✓
Voiding dysfunction	✓				✓		✓
Pain					✓		✓
Acute and/or chronic pain	✓						
Wound dehiscence	✓				✓		✓
Nerve damage	✓				✓		✓
Recurrent prolapse	✓				✓		✓
Contracture	✓				✓		✓
Scarring	✓				✓		✓
Mesh exposure	✓				✓		✓
Foreign body response that could result in extrusion, erosion, exposure, fistula formation, and/or inflammation	✓						
Pelvic pain or pain with intercourse which…	✓				✓	✓	✓
may resolve with time/may be self-resolving over time					✓	✓	✓
in some patients may not resolve	✓						

[6] A ✓ indicates the adverse reaction was disclosed; the absence of a ✓ indicates the adverse reaction was not disclosed for the indicated product and time period.

[7] Ex. 2.F.

[8] Ex. 2.A

[9] Ex. 2.B-2.D.

[10] Ex. 2.G & 2.F.

[11] Ex. 2.I & 2.J.

[12] Ex. 2.M & 2.N.

[13] Ex. 2.K & 2.L.

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Adverse Reaction	Gynemesh PS 2015-Present[7]	Gynemesh PS 2003-2006[8]	Gynemesh PS 2006-2012[9]	Prolift 2005-2009[10]	Prolift 2009-2012[11]	Prosima 2007-2012[12]	Prolift+M 2008-2012[13]
Impaired normal voiding for a variable length of time	✓				✓	✓	✓
Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening	✓						
Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area	✓						
Adverse reactions may require surgical treatment/revision surgeries	✓						
Permanent implant	✓						
Seroma	✓						
Atypical vaginal discharge	✓						
Pain/discomfort to the patient's partner during intercourse from exposed mesh	✓						
Death	✓						

As demonstrated by the above chart, the first Gynemesh PS IFU only warned of the risk of infection potentiation, inflammation, adhesion formation, fistula formation, erosion, and extrusion. Ex. 2.A. Defendants later added "scarring that results in implant contraction," but did not warn of numerous serious risks during the relevant 2003-2012 period. Ex. 2.B-2.D. The Prosima IFUs added pain or pain with intercourse which "may be self-resolving over time," but still omitted chronic foreign body reaction/inflammatory response, chronic pain, pain with intercourse that may not resolve, and numerous urinary issues. Ex. 2.M & 2.N; *see also* Ex. 86 (explaining that chronic pain means something different from "pelvic pain or pain with intercourse"). The Prolift IFUs were similar to those for Prosima until 2009, when Defendants added numerous risks, but still omitted others, including chronic foreign body reaction/inflammatory response, chronic pain, pain with intercourse that may not resolve, and some urinary issues. *Compare* Ex. 2.G & 2.F, *with* Ex. 2.I & 2.J (warning of "pain" but not chronic pain). The Prolift+M IFUs similarly omitted chronic foreign body reaction/inflammatory response, chronic pain, pain with intercourse that may not resolve, and some urinary issues. Ex.

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2.K & 2.L.

As noted above, Defendants stopped selling the Prolift, Prolift+M, and Prosima in 2012. *See* Section III.A, *supra.* In March 2014, Health Canada (Canada's FDA counterpart) [redacted] Ex. 24 at ETH.MESH.16357665-6. [redacted] *Id.* [redacted]

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[14] Defendants' practice is to maintain the same IFU to be used worldwide; thus, the IFU used in the United States is also used in Europe, Australia, Japan, Canada, and numerous other countries. *E.g.*, 2.A.

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[redacted]

Ex. 86. Defendants [redacted]

Id. Ultimately in late 2015, Defendants updated the IFUs for the Gynemesh PS to reflect all of the adverse reactions [redacted], plus others. Ex. 26 & 27; *see also* Ex. 2.F; Ex. 28.

[redacted]

Defendants admit that all of the adverse reactions disclosed in the 2015 Gynemesh PS IFU are adverse reactions applicable to the other POP devices. Ex. 23 (Weisberg 30(b)(6) Dep. (11/12/15)) at 95:13-19 (Prolift); *see also* Ex. 49 (Hinoul 20(b)(6) Dep. (5/3/17)) at 500:5-15. Defendants admit [redacted] updated [redacted]

[redacted]

Ex. 45 (Dep. of Piet Hinoul ("Hinoul Dep.") (6/27/13)) at 507:20-25. Further, they admit they knew at launch of the Prolift of the adverse reactions and that [redacted]

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[redacted] Ex. 23 (Weisberg Dep. (11/12/15)) at 140:13-143:9, 144:23-146:5; *see also* Exs. 29 & 30.

Some of the most serious adverse reactions missing from the POP IFUs at various times include chronic foreign body response/inflammatory response, chronic pain, dyspareunia (pain with intercourse), and urinary problems. As discussed below, Defendants knew of these adverse reactions and knew that they were unique to, or heightened by, the mesh in their devices (in contrast to than non-mesh surgical techniques for POP repair). Further, Defendants knew that the difficulty of removing mesh once implanted would exponentially increase the impact of these adverse reactions.

Chronic Foreign Body Reaction/Inflammatory Response. Unlike native tissue surgery, which introduces no foreign material into the body, a mesh surgery involves the implantation of a material that will inevitably generate a chronic foreign body reaction and a chronic inflammatory response. Chronic foreign body reaction and inflammation can cause the mesh to "erode" (i.e., move or change positions) inside the body or extrude into or become exposed in the vaginal canal. 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. Defendants agree that [redacted] Ex. 7 (Hinoul 30(b)(6) Dep. (4/5/12)) at 150:13-151:17; Ex. 92 (Hinoul 30(b)(6) Dep. (4/6/12)) at 542:17-19; Ex. 47 (Hinoul 30(b)(6) Dep. (1/17/17)) at 55:4-18, 120:14-20, 121:1-9; Ex. 91. [redacted] 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 Dep. (5/24/12)) at 184:23-25.

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Defendants' internal documents and testimony establish [redacted] Ex. 87 at ETH.MESH.00870467 [redacted]; *see also* Ex. 89 at 8 [redacted]

Despite these admissions, Defendants' POP IFUs did not warn of a chronic foreign body response or chronic inflammatory response during the relevant period. *See* Appendix & Ex. 2. In fact, Defendants state in all but the Prolift+M IFUs that the mesh "elicits a minimum to slight inflammatory reaction, which is transient…" Exs. 2.A-2.J, 2.M-2.N. In 2015, Defendants updated the IFU for the Gynemesh PS to identify "Foreign body response that could result in extrusion, erosion, exposure, fistula formation, and/or inflammation" as an adverse reaction. *See* Ex. 2.F.

Chronic Pain. Dr. Hinoul (an Ethicon Medical Director) admitted [redacted] Ex. 8 (Hinoul 30(b)(6) Dep. (9/18/12)) at 737:16-25 [redacted] 738:1-12 [redacted] *see also id.* at 671:13-20; 675:1-9; Ex. 20 (Weisberg Dep. (5/24/12)) at 144:2-10 [redacted] Ex. 49 (Hinoul 30(b)(6) Dep. (5/3/17)) at 466:12-15, 493:23-494:4, 504:13-23

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[redacted]

505:7-13; Ex. 55 (Robinson Dep. (3/13/12)) at 311:2-312:12 [redacted]

Despite these admissions, Defendants' POP IFUs did not warn of chronic pain during the relevant period. *See* Appendix & Ex. 2. The Prolift+M, Prosima, and post-2009 Prolift IFUs warned of pelvic pain or pain with intercourse that "may resolve with time" or "may be self-resolving over time." Exs. 2.I, 2.J, 2.K, 2.L, 2.M, 2.N. In 2015, Defendants added "acute and/or chronic pain" and "pelvic pain or pain with intercourse, which in some patients may not resolve" to the Gynemesh PS IFU. Ex. 2.F.

Dyspareunia (Pain During Sexual Intercourse). Dr. Axel Arnaud, who led the development efforts for the Prolift, Ex. 36 (Arnaud Dep. (11/29/17)) at 20:13-16, testified that [redacted]

[redacted]

Ex. 37 (Arnaud Dep. (11/30/17)) at 56:7-16. Further, Defendants admit [redacted]

[redacted]a. 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, 286:11-287:2.

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In fact, on January 11, 2005, Dr. Axel Arnaud, Defendants' European Scientific Director, sought to add the following language to the Prolift IFU:

[redacted] Ex. 79. [redacted] *Id.*

Despite these admissions, Defendants' POP IFUs did not warn of persistent pain with intercourse during the relevant period. *See* Appendix & Ex. 2. The Prolift+M, Prosima, and post-2009 Prolift IFUs warned of pelvic pain or pain with intercourse that "may resolve with time" or "may be self-resolving over time." Exs. 2.I, 2.J, 2.K, 2.L, 2.M, 2.N. In 2015, Defendants added "Pelvic pain or pain with intercourse, which in some patients may not resolve" and "Pain/discomfort to the patient's partner during intercourse" to the 2105 Gynemesh PS IFU. Ex. 2.F.

Urinary Problems. Defendants have admitted [redacted] Ex. 23 (Weisberg Dep. (11/12/15)) at 140:13-143:9, 144:23-146:5; *see also* Exs. 29 & 30. Indeed, in 2005, [redacted] *Id.*

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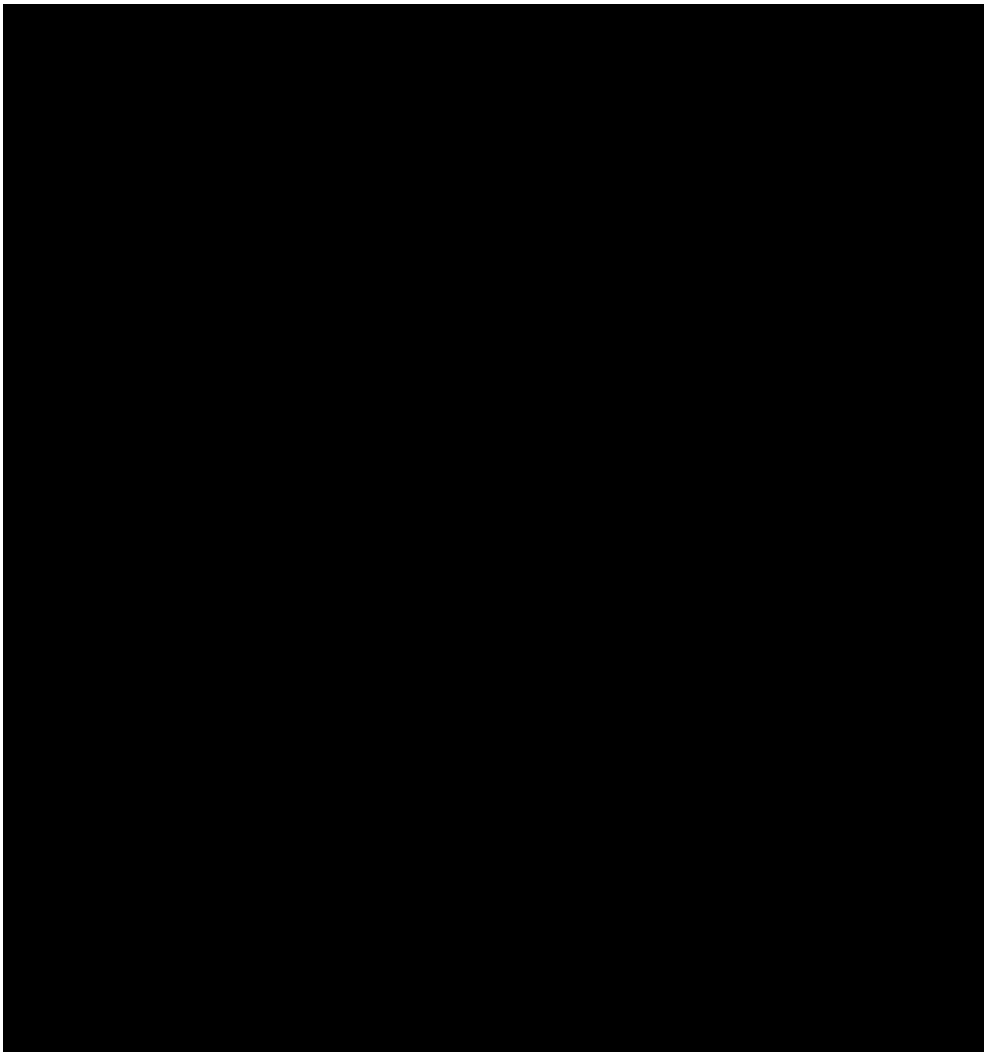

Despite these admissions, the POP IFUs did not warn of urinary frequency until the 2015 update to the Gynemesh PS IFU. *See* Appendix & Ex. 2. Urinary retention/obstruction and voiding dysfunction were not included in the Prosima and pre-2009 Prolift IFUs (they were included in the Prolift+M and post-2009 Prolift IFUs). *Id.*

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. [redacted]

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[redacted]. Ex. 52 (Holste Dep. (7/30/13)) at 298:7-14; Ex. 8 (Hinoul Dep. (9/18/12)) at 679:3-7; 680:6-682:3. [redacted] Ex. 90 at 14 [redacted]

Difficulty of Removal. All of the adverse reactions discussed above are exacerbated by the difficulty of removing the mesh once it is implanted in the body. Defendants have acknowledged that [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. 58 (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. Despite this, Defendants did not disclose the difficulty of removal.

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

Throughout the life of the POP devices, Defendants purposefully tried to obscure the complications associated with them. For example, [redacted]

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[redacted]

Ex. 77.

In January 2005, Dr. Arnaud [redacted]

[redacted]

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Ex. 79. Despite this request, [redacted]

[redacted]

Id. Not surprisingly, Defendants never updated the IFUs for its transvaginal POP devices to include Dr. Arnaud's suggested warning.

Further, individual physicians told Defendants [redacted]

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[redacted]

Ex. 82.

Numerous peer-reviewed articles regarding POP and other transvaginal mesh noted the lack of research regarding adverse reactions associated with the devices. Ex. 66 (2011, "The extent of impact of mesh-related complications on quality of life has so far not been investigated thoroughly."); Ex. 63 (2008, "Vaginal mesh kit procedures to correct pelvic organ prolapse have become increasingly popular, yet there is still a paucity of studies evaluating long-term outcomes and complications of these procedures."); *see also* 68 (2013, "Little is known about a possible relationship between mesh retraction and other major complications of POP surgery.").

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

In 2006, Jean Giallombardo (at the time, age 68), a Rochester, Washington resident, was diagnosed with POP and SUI and implanted with both the Prolift and Defendants' TVT-Obturator sling. Decl. of Jean Elizabeth Giallombardo ("Giallombardo Decl.") ¶ 3. Both devices

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were implanted by an Olympia, Washington urologist with no prior experience implanting a mesh device, with direction and oversight by Dr. Douglas Grier, a Seattle urologist. *Id.* ¶¶ 3, 5. At the time she received the device, the Prolift IFU did not warn about the risks of voiding dysfunction, urinary tract infections, recurrence of POP, or chronic lower back and leg pain; consistent with these omissions from the IFU that he was provided by Defendants, her doctor did not warn her of these potential adverse reactions. *See id.* ¶¶ 7, 14; *see also* Section II.B.2, *supra* (discussing omissions from Prolift IFU); TVT MSJ, Section II.C. 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. Giallombardo Decl. ¶¶ 8-13. As a result, she now (twelve 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 also wears a pessary device to support her pelvic floor due to recurrence of her prolapse. *Id.* ¶ 9. Ms. Giallombardo describes her circumstances as a "nightmare"; she is largely homebound and suffers from depression and loneliness. *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' knowing omissions of adverse reactions from the POP IFUs.

IV. EVIDENCE RELIED UPON

This Motion is based on the papers and pleadings on file and the Declaration of Breena Roos 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

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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 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. *State v. LA Inv'rs, LLC*, 2 Wn. App. at 538-39. Here, there is no disputed issue of material fact about the content of the Defendants' 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.

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

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

Defendants omitted known, serious risks and adverse consequences about their POP devices and affirmatively misrepresented the seriousness of adverse consequences in the IFUs for the POP devices. Defendants' omissions 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 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 over 12 years, Defendants knew that the POP devices could cause, among other things, chronic, lifelong pain; chronic infections; contracture/shrinkage; painful sexual intercourse for the woman and her partner; urinary incontinence; and other urinary conditions.

"'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 are deceptive, the State is not required to prove that any consumer (or physician with respect to IFUs) was actually deceived by Defendants' IFU

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omissions. "To prove that a practice is deceptive, neither 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*, *supra* (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 POP, 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 1,851 POP devices in Washington, each with an IFU. Exs. 2 & 5. As detailed above, Defendants purposefully failed to disclose numerous, known

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serious adverse events associated with their POP devices in the IFUs. This failure to disclose violated the FDA's regulations and Blue Book guidance (IFUs must include "**all adverse reactions reasonably associated with the device**"), both of which Defendants agree apply to medical device IFUs, should be followed, and would have required Defendants to disclose these known risks and adverse events. The FDA regulations and Blue Book guidance—which Defendants have adopted as their own standard—make no exception for Defendants' devices; nor do they allow Defendants to simply assume physicians already know of adverse reactions to get around these requirements.

Indeed, Defendants agree [redacted] Ex. 16 (O'Bryan 30(b)(6) Dep. (5/18/12)) at 106:16-107:2; Ex. 18 (Paine 30(b)(6) Dep. (9/27/12)) at 648:21-649:25, 650:20-651:3, 651:25-652:10, 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.

Defendants agree [redacted], which provide that "[a]n **adverse reaction is an undesirable effect, reasonably associated with the use of the device**, that may occur as part of the effect of the

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device or may be unpredictable in its occurrence," and that medical device IFUs must include "**all adverse reactions reasonably associated with the device**." Ex. 11 (Lin 30(b)(6) Dep. (3/13/13)) at 489:1-9, 489:22-490:1 (emphasis added). This point is further elaborated by the testimony of Defendants and numerous of their representatives. [redacted]

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

Defendants' omissions of the serious risks associated with their POP 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 surgical mesh, which is permanently implanted in women's bodies, surely is of material importance to the physicians implanting Defendants' POP devices.

Federal courts are in accord regarding materiality when interpreting the analogous FTC Act.[15] 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),

[15] 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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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 POP devices that was omitted from 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.

b. Defendants' omissions 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 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

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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 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 required the POP 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; Ex. 12. The Blue Book, adopted by Defendants, is intended to assure adequacy and consistency in IFUs. Ex. 12. Defendants and the FDA expected 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 POP devices. Ex. 58 (Robinson Dep. (9/11/13)) at 1046:1-8; s*ee* Physical Medicine Devices; Reclassification of Iontophoresis Device Intended for Any Other Purposes, 81 Fed. Reg. 48703-01 (July 26, 2016) (reclassifying 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").

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Defendants' failures to disclose—and in this case, knowing failures to disclose—adverse events associated with the POP devices in the IFUs is at least unscrupulous. It also offends 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' POP 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 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 POP devices. Defendants' omissions 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 POP devices and IFUs were sold and distributed by Defendants to health care providers in Washington. Ex. 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)

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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 were not isolated instances of misjudgment, but rather, the result of a pattern of deceptive behavior. Ex. 2. The State has met its burden as to the public interest impact.

I certify that this memorandum contains 10,123 words, in compliance with the Local Civil Rules.

DATED this 26th day of October, 2018.

ROBERT W. FERGUSON
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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.

/s/ Daena Temkova
DAENA TEMKOVA

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APPENDIX

Gynemesh PS

Gynemesh PS IFU 3/20/2003 — 3/30/2006, Roos Decl., Ex. 2.A

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, and extrusion.

Gynemesh PS IFU 3/31/2006 — 12/11/2008, Roos Decl., Ex. 2.B

ADVERSE REACTIONS

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

Gynemesh PS IFU 12/8/2008 — 4/14/2014, Roos Decl., Ex. 2.C

ADVERSE REACTIONS

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

Gynemesh PS IFU 12/18/2008 — 11/30/2010, Roos Decl., Ex. 2.D

ADVERSE REACTIONS

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

Gynemesh PS IFU 3/16/2013 — Present, Roos Decl., Ex. 2.E

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention or obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion, e.g., through vaginal epithelium.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

Gynemesh PS, cont'd

Gynemesh PS IFU 4/3/2015 — Present, Roos Decl., Ex. 2.F

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, bleeding including hemorrhage, or hematoma, urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction, acute and/or chronic pain, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.
- Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, GYNECARE GYNEMESH™ may potentiate an existing infection.
- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- These adverse reactions may require surgical treatment.
- As with any surgery, one or more revision surgeries may be necessary to treat these complications.
- GYNECARE GYNEMESH™ is a permanent implant that integrates into the tissue. In cases in which the GYNECARE GYNEMESH™ needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

Prolift

Prolift IFU 1/11/2005 — 12/13/2007, Roos Decl., Ex. 2.G

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

Prolift IFU 12/17/2007 — 9/24/2009, Roos Decl., Ex. 2.H

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

Prolift IFU 10/1/2009 — 5/7/2010, Roos Decl., Ex. 2.I

ADVERSE REACTIONS

- **Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureteral obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.**
- **Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.**
- **Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.**
- **Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.**

Prolift IFU 5/11/2010 — Discontinuance (8/15/2012), Roos Decl., Ex. 2.J

ADVERSE REACTIONS

- **Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureteral obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.**
- **Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.**
- **Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.**
- **Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.**

Prolift +M

Prolift +M IFU 12/12/2008 — 1/13/2011, Roos Decl., Ex. 2.K

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureter obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

Prolift +M IFU 2/4/2011 — Discontinuance (8/15/2012), Roos Decl., Ex. 2.L

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureter obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

Prosima

Prosima IFU 6/19/2007 — 5/17/2010, Roos Decl., Ex. 2.M

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that result in implant contraction.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pain with intercourse and pelvic pain. These may be self-resolving over time.
- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during dissection or mesh placement and may require surgical repair.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

Prosima IFU 6/18/2010 — Discontinuance (8/15/2012), Roos Decl., Ex. 2.N

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that result in implant contraction.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pain with intercourse and pelvic pain. These may be self-resolving over time.
- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during dissection or mesh placement and may require surgical repair.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.