SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN DIEGO, CENTRAL BRANCH

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, **v.** **JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation, and DOES 1 through 100, inclusive,** Defendants.	Case No. 37-2016-00017229-CU-MC-CTL **STATEMENT OF DECISION** Dept: C-67 Judge: The Honorable Eddie C. Sturgeon Trial Date: July 12, 2019 Action Filed: May 24, 2016

I. OVERVIEW

When a medical device manufacturer chooses to affirmatively advertise its products, California's Unfair Competition Law and False Advertising Law require that it do so truthfully, thereby deterring deceptive and misleading advertising. (Cf. *Barquis v. Merchants Collection Ass'n.* (1972) 7 Cal.3d 94, 110.) This is equally true whether the manufacturer targets doctors or patients. The Court concludes that the People of the State of California ("Plaintiff") have proven by a preponderance of the evidence that Defendants deceptively marketed their pelvic mesh products in the state of California and that their marketing was likely to deceive reasonable doctors and reasonable lay consumers, including potential patients and their friends and family, about the risks and dangers of these products. The Court therefore finds in favor for Plaintiff and awards civil penalties in the amount of $343,993,750. The Court would like the parties to file and serve supplemental briefs on the issue of injunctive relief by February 18, 2020.

II. PROCEDURAL BACKGROUND

A. The Pleadings

Plaintiff filed a complaint against Johnson & Johnson and Ethicon Inc. on May 24, 2016, and on November 21, 2016, filed an amended complaint against Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (collectively, "J&J" or "Defendants"). The first amended complaint claimed that J&J misrepresented the risks and complications of its pelvic mesh devices to doctors and patients in violation of the Unfair Competition Law (Bus. & Prof. Code, § 17200 et seq.) ("UCL") and the False Advertising Law (Bus. & Prof. Code, § 17500 et seq.) ("FAL"). Plaintiff requested an injunction pursuant to Business and Professions Code sections 17203 and 17535, and civil penalties pursuant to Business and Professions Code sections 17206 and 17536.

B. Stipulations by the Parties

Prior to the commencement of this action, the parties signed a tolling agreement with an effective date of October 17, 2012. (Defs.' Memo. P&A. ISO Mot. in Limine to Exclude Evid. Outside the Relevant Statutory Periods (#3 of 8), at p. 1 [filed 6/10/19]; Decl. of Stephen D. Brody ISO Mot. in Limine, Ex. 7 [parties' tolling agreement].) Accordingly, the People's UCL claims, which are subject to a four-year statute of limitations, were tolled to October 17, 2008.

(Bus. & Prof. Code, § 17208; *People v. Overstock.com, Inc.*, (2017) 12 Cal.App.5th 1064, 1077 [four-year statute of limitations for UCL claims].) The People's FAL claims, which are subject to a three-year statute of limitations, were tolled to October 17, 2009. (Cal. Code Civ. Proc., § 338(h); *Overstock.com, supra*, 12 Cal.App.5th at 1074, n. 8 [three-year statute of limitations for FAL claims].)

On August 3, 2018, the parties signed a stipulation and proposed order regarding Defendants' corporate structure and financial condition. (PX4835.) The Court signed the order on August 7, 2018. (*Ibid.*) Pursuant to the stipulation and order, any judgment by this Court applies equally to all three Defendants in this action. (*Id.* at ¶¶ 1, 2, 3.) Also pursuant to the stipulation and order, Defendants' financial condition "shall be represented as and limited to" the net worth of Johnson & Johnson, which is $70,418,000,000, and the net worth of Ethicon, Inc., which is $2,762,046,000. (*Id.* at ¶¶ 4, 14.)

On April 6, 2018, Plaintiff moved the Court to compel, among other things, further responses to their Special Interrogatory Nos. 4, 5, 7, and 8. (People's Memo. P&A. ISO Mot. to Compel Further Interrog. Responses [filed 11/15/17].) Those interrogatories and the relevant definitions requested that Defendants identify all of the brochures "distributed, published, or circulated by [Defendants]" to the public and all of the presentation materials that "accompan[ied] or supplement[ed] oral presentations" to the public regarding their pelvic mesh products. (Decl. of Daniel Osborn ISO Mot. to Compel Further Interrog. Responses, Ex. II [Special Interrog. Nos. 4, 5, 7, and 8; definitions of "BROCHURE" and "PRESENTATION MATERIALS"].) On April 16, 2018, the Court granted Plaintiff's motion to compel and ordered the parties to meet and confer to "designate which documents shall be relied upon as final drafts for trial purposes." Pursuant to this order, on June 19, 2019, the parties signed a stipulation identifying the "final versions for trial purposes" of Defendants' marketing communications regarding their pelvic mesh products. (PX4824.)

III. STATEMENT OF FACTS

A. The Pelvic Mesh Products

J&J's pelvic mesh products at issue in this case are the TVT family of slings used to treat stress urinary incontinence ("SUI") (i.e., the involuntary leakage of urine during physical activity such as coughing, sneezing, laughing, or exercise) and the Gynemesh, Prolift, Prolift+M, and Prosima devices used to treat pelvic organ prolapse ("POP") (i.e., a condition in which the pelvic floor muscles can no longer support pelvic organs, causing them to drop into and sometimes outside of the vagina.)

In 1974, J&J developed its heavyweight Prolene hernia mesh, which was knitted from Prolene polypropylene suture. (7/16/19 Tr. 69:6-25, 70:26-71:7 [Dr. Rosenzweig].) In 1998, J&J launched its first TVT sling product for SUI. (*Id.* at 67:4-6.) J&J subsequently launched four more iterations of the TVT sling over the next decade: TVT Obturator ("TVT-O") in 2004, TVT Secur in 2006, TVT Abbrevo in 2010, and TVT Exact in 2010. (*Id.* at 67:7-11.) All of the TVT devices included the same heavyweight mesh as the Prolene hernia mesh, just cut to a different sling shape. (*Id.* at 53:3-12, 69:6-25.)

In 2002, J&J launched the Gynemesh Prolene Soft ("Gynemesh") to treat POP. (7/16/19 Tr. 69:19-25 [Dr. Rosenzweig].)] J&J launched the Prolift,[1] Prolift +M, and the Prosima, also for POP, in 2005, 2008, and 2009, respectively. (*Id.* at 67:12-25, 69:19-25.) In the Gynemesh, Prolift, and Prosima devices, J&J used a different, lighter-weight mesh than in the TVT but which was still made from the same Prolene suture material. (*Id.* at 69:6-70:7.) The Prolift+M was knitted from a blend of Prolene and Monocryl. (*Id.* at 69:6-25, 70:8-10.)

B. Defendants Deceptively Marketed Their Mesh Despite Knowing the Serious Risks

SUI and POP are lifestyle conditions, which means that while they may have a varying degree of impact on a patient's lifestyle ranging from minor to significant, they are not life-

[1] J&J never sought the required 510(k) clearance from the FDA before it began marketing Prolift to the public. (8/8/19 Tr. 149:19-26 [Dr. Hinoul].) Rather, J&J sold Prolift for three years before the FDA found out Prolift was on the market in late 2007, at which point the FDA instructed the company that it may not market Prolift pending a retroactive 510(k) clearance. (JX10052.6.) J&J did not stop selling Prolift at any time. (8/8/19 Tr. 151:16-153:28 [Dr. Hinoul].)

threatening or debilitating. (7/16/19 Tr. 47:26-28, 58:16-59:5 [Dr. Rosenzweig].) There are a range of surgical and non-surgical treatment options available for both SUI and POP, all of which require trade-offs in terms of the risks, efficacy, and the convenience or lifestyle benefits of the treatment. For instance, insertable devices like pessaries are effective and have minimal risk but are inconvenient and undesirable from certain lifestyle perspectives. (*Id.* at 48:25-49-22, 59:6-60:3.) Other solutions like medication, injectables, and pelvic floor exercises have varying degrees of efficacy and are not one-time cures—they require repeat treatment or sustained commitment. (*Id.* at 48:22-50:15, 59:6-15.)

Prior to J&J's development and widespread marketing of its TVT slings, surgery for SUI was not an attractive or commonly selected treatment option because, except in the most severe cases, the lifestyle benefits were not worth the risks of a major, invasive, open surgery and the associated significant recovery period. (7/16/19 Tr. 53:13-24 [Dr. Rosenzweig].) According to J&J's its witnesses, J&J revolutionized this field by offering a solution to the lifestyle inconveniences of SUI that could be achieved through a "safe and effective," "minimally invasive" out-patient procedure with a speedy recovery. (8/8/19 Tr. 19:20-24, 24:28-25:22 [Dr. Hinoul]; 8/9/19 Tr. 27:12-28:6 [Dr. Hinoul]; 8/19/19 Tr. 158:1-2 [Dr. Nager]; 8/21 Tr. 47:17-48:2 [Dr. Kahn]; 9/17/19 Tr. 138:14-17 [Dr. Rosenblatt].) But, as discussed below, J&J marketed the benefits of its mesh products without fully and truthfully disclosing the accompanying risks and complications.

As Ethicon Medical Director Dr. Piet Hinoul testified, J&J knew from the time it launched TVT in 1998 that its mesh slings caused severe, long-term complications such as excessive contraction or shrinkage of the tissue surrounding the mesh; "debilitating" and "life-changing" chronic pain; pain to sexual partner; chronic or lifelong dyspareunia; and a whole range of urinary dysfunction complications. (See Section V.A on risks known to the company.) The company also knew that these complications could be so severe that mesh removal would be necessary but, unlike other implants, removal is difficult and harmful and can take multiple surgeries; J&J also knew that some of the most severe complications of mesh can be irreversible. (*Ibid.*)

J&J concealed its knowledge of the serious risks of mesh from the patients and doctors they

targeted with their marketing, circulating deceptively incomplete Instructions for Use ("IFU") warnings with each of their devices and propagating that deception throughout their marketing communications. (See Sections V.D-G on deception.) Defendants' marketing to both patients and doctors consistently and repeatedly touted mesh's benefits while misrepresenting, downplaying, and concealing its potential for serious, long-term complications. Defendants' patient-facing brochures, websites, presentations, and other materials consistently emphasized the speed, safety, and effectiveness of Defendants' mesh products (e.g., JX10201; JX10222; JX11599 at 11-12) and marketed mesh as providing significant lifestyle benefits to women by restoring their ability to have a fulfilling sex life and to engage in physical activity. (See, e.g., JX10210 at 3; JX11347 at 5; JX11599 at 12.) Defendants sold a similar message to doctors through in-person detailing by sales representatives armed with sales aids, in-person trainings and promotional seminars, and other tactics designed to assuage risk concerns and drive the widespread use of mesh implants.

1. Defendants Disseminated Their Deceptive Messages Through a Consistent, Nationwide Marketing Scheme

J&J marketed its mesh products directly to a potential patient population through "surround sound" marketing intended to "create consumer demand" for mesh among women who would not otherwise seek a surgical solution to their condition. (PX0447 at 3, 12, 22; PX0045 at 4; PX0150 at 2-6; PX0359 at 5, 9; see also 7/23/19 Tr. 26:25-27:3, 27:27-28:19 [key objective of Defendants' consumer marketing is to "[c]reate consumer demand and advocacy"; "We are creating the markets . . . one consumer/physician at a time"].)

This surround-sound approach to "creating a market" for their mesh included the dissemination of patient brochures and in-office patient counseling materials; a telephone hotline; a Find-A-Doctor directory service that would point women to doctors who implant J&J's products; internet advertising to drive traffic to the company's promotional website; and public relations events and advertising featuring Bonnie Blair, a respected Olympic medalist, as a spokesperson. (See, e.g., JX11089 at 6, 9-14, 18; PX0447 at 12; PX0045; 7/24/19 Tr. 80:8-25, 81:28-84:12, 86:4-8; 8/6/19 Tr. 96:7-12, 133:28-134:9; 8/22/19 Tr. 42:23-43:13.) J&J also partnered with physicians and hospitals to carry out "field marketing" efforts, which consisted of

hosting "education" or "awareness" events directed at patients and primary care physicians; supplying mailers and other content for patient outreach; and participating in community events such as health fairs. (See, e.g., 8/6/19 Tr. 27:1-17; PX4771 [10/4/18 Dep. Tr. of Jason Goodbody] at 31:13-33:18, 35:15-36:16, 191:5-17; PX0359.)

J&J also engaged in an aggressive campaign to create and grow its doctor market for mesh. The company deployed sales representatives, armed with sales aids and patient brochures, to doctors' offices and operating rooms. PX4632 at 15-16 [Defs.' Amended Response to Special Interrog. No. 205]; 8/14/19 Tr. 64:13-22 [Dr. Fugh-Berman].) The company paid preceptors to train and promote mesh to doctors across the country (PX4632 at 8-12, 16; 8/27/19 Tr. 67:11-68:10, 68:19-69:1 [Mr. Jones]; 8/22/19 Tr. 95:1-98:20 [Dr. Grier]; see also PX0171 at 5, 11-12, 17; PX0025 at 7-9, 15; 8/14/19 Tr. 135:1-136:25 [Dr. Fugh-Berman]), and recruited prominent doctors considered thought leaders within the community ("key opinion leaders" or "KOLs") to speak about mesh (8/27/19 Tr. 69:4-28; PX0228 at 167; see also 8/14/19 Tr. 63:19-64:12, 120:15-27, 133:25-134:15, 144:2-11 [Dr. Fugh-Berman]). As Dr. Nager described, manufacturers like Ethicon drove doctors' use of mesh products through "Marketing, Marketing, Marketing," including advertising, sales representatives, and training events by the company. (8/20/19 Tr. 167:22-168:10.)

J&J went to great lengths to make sure that this wide array of marketing activity delivered consistent messages to patient and physician audiences alike. Company control over the uniformity of mesh marketing messages started with the copy approval of all marketing materials at the national level. As Ethicon Medical Director Dr. Piet Hinoul, former Ethicon sales representative Michelle Garrison, and former Ethicon marketing product director Scott Jones all testified, all of J&J's sales training materials and outward-facing marketing materials about J&J's mesh products—including doctor-directed sales aids, professional education training materials, and patient-directed marketing materials—were copy approved at the national level by company medical, regulatory, and legal management before they could be disseminated. (8/7/19 Tr. 31:1-32-7 [Dr. Hinoul]; 7/24/19 Tr. 63:9-19 [Ms. Garrison]; PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 190:15-191:04; 8/27/19 Tr. 84:21-86:26 [Mr. Jones].) One of the copy review team's

functions was to ensure that the claims made in promotional marketing materials were consistent with pre-approved product claims developed by J&J's global marketing teams. (PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 257:11-258:11, 259:12-260:9.) The copy-approved marketing materials were then made available on a centralized online platform called Literature Depot. (7/24/19 Tr. 63:9-12, 65:14-66:19 [Ms. Garrison].) Sales representatives could order all doctor and patient-facing marketing materials through Literature Depot and used the same doctor-directed sales aids nationwide. (*Id.* at 62:14-16, 65:22-66:1.)

The testimony at trial from J&J witnesses confirmed the company's emphasis on ensuring consistency in their marketing and messaging surrounding mesh. Former sales representative, manager, and marketing product director Scott Jones testified that the company's "philosophy" for "doctor-directed marketing" revolved around "making sure there was a level of consistency in how we communicated brand," whether through sales representatives or professional education. (8/27/19 Tr. 63:14-64:4.) Mr. Jones testified that it was "important to Ethicon that sales reps consistently carried the same marketing messages into the field." (8/27/19 Tr. 151:28-152:3.)

To ensure consistent messaging to physicians, sales representatives nationwide received the same training and documents (7/24/19 Tr. 17:16-17, 19:8-13, 27:10-28:8, 62:4-16 [Ms. Garrison]), participated in the same marketing campaigns (8/27/19 Tr. 191:24-192:17, 193:20-194:8 [Mr. Jones]; see also PX4834 [Think Again video]), and were provided the same sales tools (8/27/19 Tr. 194:16-195:17, 197:2-13 [Mr. Jones]; see also PX4834). A significant part of sales representatives' in-person training focused on preparing sales representatives for "in-depth conversations with physicians" regarding Defendants' mesh devices. (7/24/19 Tr. 15:16-20.) That preparation included training on how to talk about device features and benefits with physicians (*Id.* at 15:11-15; 8/27/19 Tr. 151:16-24); training on how to discuss mesh risks and complications with physicians (7/24/19 Tr. 15:20-27); training on how to respond when physicians asked questions about complications or raised concerns about mesh products (*Id.* at 15:28-16:2, 17:21-26); and training on J&J's approved mesh marketing messages and how to communicate those messages to physicians (*Id.* at 16:3-27, 18:15-19:7; 8/27/19 Tr. 50:27-51:6, 151:3-7). The messages and product information taught to sales representatives matched the messages and

information contained in product sales aids. (7/24/19 Tr. 65:3-13; 8/27/19 Tr. 51:3-15, 151:8-15; PX4807 [9/5/17 Dep. Tr. of Scott Jones] at 172:15-174:2, 179:21-180:6, 196:13-197:01.) Having sales representatives practice messaging in this manner "help[ed] provide uniformity" and a "consistent message across the country," including in California. (7/24/19 Tr. 18:21-19:13; see also *id.* at 65:7-13; PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 260:10-261:13, 218:9-16 [Jones did not recall ever conveying product information not contained in a sales aid or IFU].)

This focus on consistency in messaging extended beyond print marketing materials and sales conversations. Defendants paid physician consultants and KOLs to deliver company marketing messages through company-approved training and promotional presentations to other physicians. (See, e.g., PX0848 [email furnishing paid presenter with copy-approved "Science of What's Left Behind" promotional presentation]; PX0125 at 3-4 [sales training presentation discussing the "what's left behind" marketing message].) Dr. Douglas Grier, an Ethicon-paid consultant and third-party fact witness called by Defendants, corroborated this with his testimony that the company provided him with the presentation slides and speaker notes that he presented to other doctors and approved all representations he made about its products. (8/22/19 Tr. 98:6-20, 101:21-23, 103:16-24.)

J&J also prioritized consistency in the marketing messages delivered to patients. As early as 2002, J&J described its "surround sound" approach to direct-to-consumer marketing as the "integrated executions of advertising, public relations, interactive marketing, in-physician office communication and education materials, local marketing events, etc." (PX0447 at 3; see also *id.* at 12.) Patient brochures were drafted with input from the same product marketing personnel responsible for developing pelvic mesh sales aids. (8/27/19 Tr. 83:2-20, 92:10-23.) Physicians who partnered with J&J to give promotional presentations to patients and primary care physicians through J&J's Field Marketing program were required to use Ethicon-approved visual aids and hand-outs, and were "guided to read directly from the presentation, the entirety of the presentation." (PX4771 [10/4/2018 Dep. Tr. of Jason Goodbody] at 65:1-67:6, 68:15-17; PX0467 [presenter agreement requiring use of Ethicon-approved materials].) Defendants even strategized about how to encourage their physician customers to use the same terms that Defendants used in

their patient brochures, such as "minimally invasive," "most common procedure," and "out-patient," when discussing TVT with patients, because those words were "optimally suited to convincing patients to accept the [TVT] sling procedure." (PX0039 at 24.)

C. Defendants' Marketing Concealed What They Knew About Mesh Risks and Downplayed FDA Warnings

The evidence at trial shows that rather than disclose what it knew about some of the severe risks of pelvic mesh in its labeling and marketing materials, J&J has instead taken active, willful measures for nearly twenty years to suppress information and conceal serious risk and complication information from physicians and patients.

J&J knew from the time of launch of TVT in 1998 that its mesh slings were associated with the following complications: (1) lifelong and recurring risk of vaginal exposure; (2) lifelong and recurring risk of erosion into organs; (3) excessive contraction or shrinkage of the tissue surrounding the mesh, which can cause acute and chronic pain and dyspareunia; (4) debilitating/ life-changing/chronic pain; (5) chronic groin pain; (6) pain to sexual partner; (7) chronic or lifelong dyspareunia; (8) neuromuscular problems, including acute and/or chronic pain in the groin, pelvic, and/or abdominal area; (9) urge incontinence; (10) urinary frequency; (11) urinary retention; (12) urinary obstruction; (13) voiding dysfunction; (14) need for mesh removal for serious complications like pain/dyspareunia/urinary dysfunction; and (15) removal can take multiple surgeries and require significant dissection and even after additional surgeries are performed, adverse reactions and their symptoms may not resolve. (See Section V.A. on risks known to the company.)

Despite that knowledge, in 2000, two years after the TVT launch, Defendants actively chose to conceal the fact that TVT mesh could cause complications so serious as to necessitate removal. J&J marketing personnel made the decision not to publicize or share information with customers regarding techniques for TVT mesh removal because they believed it would be bad for business. (PX1820.) Ethicon Marketing Director Laura Angelini argued that "if we, in any way, publish [information about the potential need for removal], we start giving reason to believe that explant of TVT may be needed in some circumstances. Frankly, I do not want to dig my own

grave!" (*Ibid.*; PX4781 [9/17/2013 Dep. Tr. of Laura Angelini] at 276:22-277:6.) Consistent with Ms. Angelini's concerns, J&J did not include the risk of or potential need for removal of pelvic mesh in its IFUs until 2015. (See Section V.D.1 and 2, Tables 2 [TVT IFUs] and 3 [POP Mesh IFUs].) Later, in 2005, Ms. Angelini again willfully hid harmful information about the company's devices, instructing an Ethicon marketing employee, Kimberly Hunsicker, to remove dyspareunia data from the abstract of a presentation about Prolift because including that information "IS GOING TO KILL US." (PX0841 [capitalization in original].) Ms. Hunsicker replied to Ms. Angelini that she would "remove the dyspareunia" from the abstract language. (*Ibid.*)

The evidence shows that J&J also declined internal requests to improve its IFU disclosures. Just prior to the launch of Prolift in 2005, Dr. Axel Arnaud, an Ethicon medical director responsible for pelvic mesh, suggested adding the following adverse reaction to the Prolift IFU: "WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse . . . This must be taken in consideration when the procedure is planned in a sexually active woman." (PX0854 at 2 [capitalization in original].) Scott Ciarrocca, a research and development employee who was project lead for Prolift (8/28/19 Tr. 28:16-29:2 [Mr. Ciarrocca]), replied that "[w]e have already printed launch stock," meaning that the company did not want to print off new copies because "these IFUs were already on a shelf someplace in Switzerland." (PX0854 at 2; 8/28/19 Tr. 50:26-51:22.) J&J never added warnings regarding retraction leading to distortion of the vagina or elevated risk to sexually active women to the Prolift IFUs. (See Section V.D.2, Table 3 [POP Mesh IFUs].)

The evidence at trial also revealed instances in which J&J chose to avoid learning negative information associated with its devices for fear of competitive disadvantage. In 2006, the Ethicon medical director responsible for pelvic mesh products, Dr. David Robinson, responded to a request from marketing employee Jonathan Meek about forming a registry (a type of study to collect data about outcomes or complications) to better understand the risks of the newly launched Prolift device—specifically, whether the company would face any "legal risk" if it

captured complications data. (PX1162.) Dr. Robinson explained that, although he could not opine on "legal risk," he was concerned about such a study capturing complications information that might be "reportable" to the FDA. (*Ibid.*) Specifically, he said, "if none of our competitors are keeping registries, our complication data may appear increasingly accurate but with decreasing appeal." (*Ibid.*)

In 2008, the FDA issued a Public Health Notification warning that both SUI and POP meshes can present "serious consequences." (DX7923.) The FDA thus advised that patients should be informed of "the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall," and that "complications associated with the implanted mesh may require additional surgery that may or may not correct the problem." (*Ibid.*) Rather than heeding the Public Health Notification to improve the IFUs and marketing materials to include the risks of mesh known to the company as listed above, Ethicon President Renee Selman instructed sales representatives that "they are not to proactively initiate conversations with customers about this notice." (PX1313 [Selman memo]; PX4814 [6/21/13 Dep. Tr. of Renee Selman] at 631:21-632:8, 633:2-5; PX0968 [email from marketing product director Scott Jones distributing Ms. Selman's instructions to the field sales team].) She further instructed sales staff to say, only if asked by a doctor, that "[t]he complications stated in the notification are known risks that can occur with surgical procedures of this type and they are included in the labeling for our products." (PX1313.) But this was not true; J&J's IFUs did not include such risks until 2015. (See Section V.D.1 and 2, Tables 2 [TVT IFUs] and 3 [POP Mesh IFUs].)

In late 2008 and early 2009, J&J disregarded another internal medical professional's request to improve IFU disclosures, just as it had in 2005. Dr. Meng Chen, associate medical director for Ethicon and the only medical doctor in charge of monitoring medical device complaints for Ethicon (7/31/19 Tr. 11:2-18 [Dr. Chen]) unsuccessfully urged the company to consider updating the IFU in light of the FDA's warning earlier that year. (*Id.* at 64:10-64:27.) Dr. Chen testified that she reviewed between 20,000 to 30,000 complaints regarding Ethicon products in her eight years with the company, and a full one-third of complaints—or

approximately 8,000 to 10,000—were related to pelvic mesh. (*Id.* at 21:20-22:9.)[2] Based on her extensive experience reviewing mesh complaints, Dr. Chen informed Defendants that "[o]ur post-market knowledge with these products are much more than what we have in the IFUs of all three types of TVTs," and suggested that "you may look into it from senior management perspective and to facilitate IFU update for all three TVTs, particularly in the area of 'Potential Adverse Reactions.'" (PX0898.) Recounting a case in which a patient felt that a consent based on the TVT IFU was not adequate, Dr. Chen explained that "[o]ne of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflect[] the current knowledge of the manufacturer[] on the potential adverse reactions." (*Ibid.*) One month later, in January 2009, Dr. Chen continued the conversation with a J&J regulatory employee, stating, "Pardon me again, from what I see each day, these patient experiences are not 'transitory' at all," as claimed in the IFUs. (PX0904.) As a result of these discussions, Dr. Chen organized a meeting to consider whether the TVT IFUs should be updated. (7/31/19 Tr. 48:25-28; PX1230 at 1 [Meeting Agenda, Section I, "Purpose of the Meeting"].)

In her meeting agenda, Dr. Chen reiterated that "[p]atients did not feel there were adequate pre-op consent or risk-benefit assessment" and listed a number of "[p]atient-specific concerns," including "[p]ost-operative dyspareunia and pain—affect quality of life and affect daily routine"; "re-operations—tape excision, removal, re-do sling procedure"; and "[t]ype and intensity of the post-operative complications disproportion to pre-operative consent-expectations." (PX1230 at 2.) Although Dr. Chen stressed at trial that it was not her responsibility or role to determine what material belongs in the IFU, she also stated that she was fulfilling her "duty" by informing the Ethicon medical directors whose specific job it was to ensure the accuracy of the IFUs of what she knew to be true of the risks and complications based on her experience monitoring complaints. (7/31/19 Tr. 57:13-58:12.) Despite Dr. Chen's efforts to raise concerns, J&J did not warn of the need for removal in its IFUs until 2015, and has never added a warning regarding

[2] Also of note, Dr. Chen testified that she was responsible for monitoring all 200-300 Ethicon products (7/31/19 Tr. 22:24-28), meaning Ethicon's nine pelvic mesh products disproportionately accounted for a full one-third of patient complaints received by Ethicon, indicating the significance of the complications pelvic mesh patients were experiencing.

dyspareunia and pain so severe that they can affect daily quality of life and routine. (See Section V.D.1, Table 2 [TVT IFUs].)

In 2010, Ethicon medical director Dr. Hinoul corresponded with a researcher, Dr. Daniel Altman, regarding an Ethicon-funded clinical study of POP meshes Dr. Altman conducted. (PX1643.) Specifically, Dr. Hinoul asked Dr. Altman to remove dyspareunia information from the abstract of a study that was to be published in the New England Journal of Medicine, explaining that dyspareunia information "somehow will be used by the mesh antagonists," and the abstract "will be the only thing most surgeons read." (*Id.* at 2.) When Dr. Altman published the article the following year, there was no mention of dyspareunia in the abstract. (PX1750 at 1.)

In 2011, the FDA issued a Safety Communication update to the 2008 Public Health Notification focused on "Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." (PX0787.) The FDA warned that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare.** This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh in all patients with POP and it may expose patients to greater risk." (*Ibid.* [emphasis in original].) Specifically, the FDA warned that "[m]esh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair," and recommended that patients be informed "that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication," and of "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." (*Id.* at 2.)

As with the 2008 Public Health Notice, however, J&J adopted a marketing strategy of downplaying the FDA's 2011 warning. First, a number of J&J's paid consultants authored an article entitled "Time to Rethink" to push back against the FDA's conclusions. (PX0812 [Time to Rethink article]; PX4822 [Ethicon paid authors Dr. Vincent Lucente $1,752,469.46, Dr. Howard Goldman $177,043.91, Dr. Miles Murphy $129,237.07, and Dr. Heather van Raalte $100,123.93

as consultants].) That article claimed that the FDA's warning that POP mesh "introduces risks not present in traditional non-mesh surgery for POP repair" is "not accurate and is misleading to the public" because mesh and non-mesh repairs have all of the same risks except erosion. (PX0812 at 5). But this directly contradicts what the company knew that the dangerous characteristics of mesh, such as foreign body response, shrinkage and contracture, and chronic inflammation, which are not present in non-mesh repairs, can lead to several serious and potentially debilitating complications. (See Section V.A. on risks known to the company.) Despite what the company knew, however, J&J trained sales representatives to share the Time to Rethink article with doctors to downplay the FDA's 2011 warning. (PX0403 at 9-12.) J&J also instructed sales representatives to say that the same risks raised in the 2011 FDA notice were included in the IFUs, when in fact they were not. (PX0826; see Section V.D.1 and 2, Tables 2 [TVT IFUs] and 3 [POP Mesh IFUs].)

In 2012, because of the safety concerns it was seeing, the FDA issued orders requiring Defendants to conduct postmarket surveillance studies on all of their POP devices (Gynemesh, Prolift, Prolift +M, and Prosima) and on TVT Secur. (8/5/19 Tr. 38:17-39:24, 88:2-6, 88:10-15 [Dr. Kessler].) Rather than conduct the FDA-ordered long-term safety studies, J&J chose to instead stop selling TVT Secur, Prolift, Prolift +M, and Prosima, and changed the indications for use of Gynemesh so that it was no longer indicated for transvaginal placement. (*Id.* at 39:14-24.)

In 2013, the FDA released another update regarding pelvic mesh, this time specifically regarding SUI meshes. (DX7621.) The FDA found that "[t]he safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year." (*Ibid.*) Importantly, however, the FDA declined to conclude that safety and efficacy of SUI slings was established beyond one year, noting, "[l]onger follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up." (*Ibid.*)

In 2015, at the behest of the Canadian health authority, Defendants updated their IFUs for the pelvic mesh products that still remained on the market (TVT, TVT-O, TVT Abbrevo and TVT Exact) to include a number of complications that had been missing since the original 1998 launch of TVT. (8/7/19 Tr. 166:20-167:24 [Dr. Hinoul].) The adverse events that were added to the TVT

IFUs at this time included: (1) acute and/or chronic pain; (2) neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area; (3) pain with intercourse which in some patients may not resolve; (4) exposed mesh may cause pain or discomfort to the patient's partner during intercourse; (5) voiding dysfunction; (6) urge incontinence; (7) urinary frequency; (8) urinary retention; (9) one or more revision surgeries may be necessary to treat these adverse reactions; and (10) in cases in which Prolene mesh needs to be removed in part or whole, significant dissection may be required. (See Section V.D.1, Table 2 [TVT IFUs].)

Dr. Weisberg, the medical director for the company, testified that these 2015 additions to the TVT IFUs were adverse events that the company knew to be reasonably associated with these devices from the time of launch in 1998, and that it would have been reasonable and feasible to include this adverse event information from the very beginning. (PX4808 [11/12/2015 Dep. Tr. of Dr. Weisberg] at 208:7-211:19, 211:4-213:2; PX4088 [complication Nos. 1, 2, 3, and 10, above]; PX4083 [complication Nos. 5, 6, 7, and 8, above].) That the company chose not to do so rendered the adverse event information in the IFUs misleadingly incomplete for seventeen years, from 1998 to 2015.

Importantly, however, even after the 2015 changes, the TVT IFUs still misleadingly omitted, and omit to this day, a number of risks associated with J&J's pelvic mesh products: (1) lifelong/recurring risk of vaginal erosion; (2) lifelong/recurring risk of erosion to organs; (3) contraction or shrinkage which can cause acute and chronic pain and dyspareunia; (4) debilitating/life changing pain; and (5) even after additional surgeries are performed, adverse reactions and their symptoms may not resolve. (See Section V.D.1, Table 2 [TVT IFUs].)

Earlier last year, in April 2019, the FDA banned all transvaginal POP mesh devices from the United States market because the FDA found that their safety and effectiveness had not been established. (PX2786.)

IV. STATEMENT OF APPLICABLE LAW

A. The UCL and FAL Focus on the Defendants' Conduct

A company that markets its products in California "must do so truthfully." (*Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 946.) California's UCL prohibits "unfair, deceptive, untrue, or misleading advertising and any act prohibited by [the FAL]." (Bus. & Prof. Code, § 17200 et seq.) The FAL prohibits any corporation from disseminating "any statement . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading[.]" (Bus. & Prof. Code. § 17500 et seq.) "Any violation of the [FAL] necessarily violates the UCL." (*Kasky, supra*, 27 Cal.4th at 950 [quotation omitted].) The shared goal of both laws is to enforce "the public's right to protection from fraud, deceit, and unlawful conduct." (*Hewlett v. Squaw Valley Ski Corp.* (1997) 54 Cal.App.4th 499, 519.)

Because the common goal of the UCL and FAL is public protection, the UCL and FAL focus on the defendant's conduct rather than the victim's deception; their requirements, therefore, differ substantially from common-law fraud and tort doctrines. Neither the UCL nor FAL require common-law fraud or tort elements such as causation, reliance, or damages. (*In re Tobacco II Cases* (2009) 46 Cal.4th 298, 312 [UCL does not require actual falsity, knowledge of falsity by perpetrator, reasonable reliance, or damages].) "Actual deception or confusion caused by misleading statements is not required," and "[n]o proof of direct harm from a defendant's unfair business practice need be shown." (*Day v. AT&T Corp.* (1998) 63 Cal.App.4th 325, 332.) Rather, "**the only requirement is that defendant's practice is unlawful, unfair, deceptive, untrue, or misleading**." (*Prata v. Superior Court* (2001) 91 Cal.App.4th 1128, 1144.) As the California Supreme Court has explained, this distinction between the common law and the UCL "reflects the UCL's focus on the defendant's conduct, rather than the plaintiff's damages, in service of the statute's larger purpose of protecting the general public against unscrupulous business practices." (*In re: Tobacco II Cases, supra*, 46 Cal.4th at 312, citing *Fletcher v. Security Pacific National Bank* (1979) 23 Cal.3d 442, 453.)

B. A UCL or FAL Violation Only Requires the Dissemination of Deceptive Marketing

Because the only requirement for a violation is the likelihood of the marketing to deceive, "the primary evidence in a false advertising case is the advertising itself." (*Overstock.com, supra*, 12 Cal.App.5th at 1080-1081, citing *Brockey v. Moore* (2003) 107 Cal.App.4th 86, 100.) The "[i]ntent of the disseminator and knowledge of the customer are both irrelevant" because "[t]he statute affords protection against the probability or likelihood . . . of deception or confusion." (*Id.* at 1079, citing *Chern v. Bank of America* (1976) 15 Cal.3d 866, 876.) Nor does the UCL or FAL require proof that the consumer read the deceptive statements. (*People v. Dollar Rent-a-Car Systems, Inc.* (1989) 211 Cal.App.3d 119, 131 [rejecting position that there is no violation if consumer does not read contract because "[s]uch an interpretation would defeat the purpose behind the statutes," which is to "protect against the *likelihood* of deception to the public, not just *actual* harm"].) A deceptive marketing violation is, therefore, complete with the dissemination of advertising that is likely to deceive because the inquiry ends there; that the consumer reads the material, is actually deceived, or relies on the advertising is not required for a violation of the UCL and FAL. (*Kasky, supra*, 27 Cal.4th at 951 ["it is necessary only to show that members of the public are likely to be deceived."]; *Day, supra*, 63 Cal.App.4th at 332 ["it is immaterial . . . whether a consumer has been actually misled by an advertiser's representations. It is enough that the language used is likely to deceive, mislead, or confuse"].)

C. Deceptive Marketing Includes False and Misleading Statements

The UCL and FAL prohibit a broad range of deception, including both outright false statements as well as misleadingly incomplete half-truths, because these statutes "are meant to protect the public from a wide spectrum of improper conduct in advertising." (*Day, supra*, 63 Cal.App.4th at 332.) "By their breadth, the statutes encompass not only those advertisements which have deceived or misled because they are untrue, but also those which may be accurate on some level, but will nonetheless tend to mislead or deceive." (*Ibid.*; see also *Kasky, supra*, 27 Cal.4th at 951.)

Whether a particular statement is likely to deceive and therefore violates the UCL and FAL is a question of fact. (*McKell v. Washington Mutual, Inc.* (2006) 142 Cal.App.4th 1457, 1472; see also *People v. McKale* (1979) 25 Cal.3d 626, 635 ["What constitutes 'unfair competition' or 'unfair or fraudulent business practice' under any given set of circumstances is a question of fact . . . the essential test being whether the public is likely to be deceived"].) If a statement is demonstrably false, it violates the statutes' unambiguous prohibitions on "untrue" statements and is therefore inherently likely to deceive. If a statement is half true or even "perfectly true" but is "couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information," it also violates both the UCL and FAL. (*Day, supra*, 63 Cal.App.4th 332-333.)

D. Determining Likelihood of Deception

A court must determine likelihood of deception from the standpoint of the targeted audience. (*Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 512-513 [holding that the question of whether advertising is misleading is viewed from the vantage point of a "reasonable consumer" within the targeted group].) "Consumers of all kinds are entitled to be credulous; the reasonableness standard does not require that targeted consumers be suspicious or wary or that they investigate the merits of advertising claims." (*Id.* at 505-506, 508.)

V. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Defendants Knew About the Risks and Dangers of Their Pelvic Mesh Devices

Substantial evidence at trial showed that J&J knew, from the time its products were launched on the market, that the dangerous properties of mesh can lead to serious, long-term complications—in other words, that these grave complications are specific to and result from the mesh itself. The testimony of company medical directors, such as Dr. Piet Hinoul and Dr. Martin Weisberg, and numerous internal documents all consistently demonstrated that J&J had knowledge of the mesh properties that can lead to serious and long-term complications in women.

Dr. Piet Hinoul, Ethicon Global Head for Medical, Clinical, and Preclinical Affairs, testified that the company knew about the following mesh properties and complications since the

time of launch (8/7/19 Tr. 45:9-12, 68:1-4;Tr.; see also PX4808 [11/12/15 Dep. Tr. of Dr. Martin Weisberg] at 140:13-23, 141:7-142:3, 142:14-143:9, 144:23-146:5; PX0158 [Ethicon Expert Meeting, Meshes for Pelvic Floor Repair, June 2, 2006, Norderstedt], PX4761 [11/16/12 Dep. Tr. of Dr. Axel Arnaud] at 447:9-449:16; PX4817 [11/30/17 Dep. Tr. of Axel Arnaud] at 36:14-38:2):

Table 1: Hinoul Testimony on Known Mesh Risks

TVT Complications	POP/Prolift Complications	Mesh Properties
• Vaginal exposure (lifelong/recurring) • Erosion to organs (lifelong/recurring) • Contracture causing pain • Removal for pain/dyspareunia • Debilitating/life changing pain • Chronic groin pain • Pain to partner • Chronic pain • Chronic dyspareunia (8/7/19 Tr. 38:12-39:14, 40:28-41:3, 41:21-42:15, 44:25-45:12 [Dr. Hinoul].)	• Same as "TVT Complications" • Risks to young, sexually active women • Incapacitating pelvic pain • Dyspareunia • Large scale erosion that are difficult to treat • Distortion of vaginal cavity interfering with intercourse • Shrinkage leading to pelvic pain and dyspareunia (8/7/19 Tr. 68:1-10, 70:2-11, 79:28-80:4, 81:15-82:8 [Dr. Hinoul].)	• Chronic foreign body reaction • Shrinkage/contraction • Infection/biofilm • Inflammation • Not inert (8/7/19 Tr. 79:28-80:4, 82:14-26, 83:21-23, 84:19-85:17 [Dr. Hinoul].)

Dr. Hinoul's testimony made clear that the company understood these risks to be specific to and resulting from the mesh device, as opposed to just being risks of the surgery. (8/7/19 Tr.38:26-39:1 [admitting that "there is a lifelong risk of erosion and vaginal exposure as a result of the TVT mesh"], 39:4-7 [admitting that "there is a recurrent risk of erosion and vaginal exposure as a result of the TVT mesh"], 39:8-14 [admitting that "[TVT mesh] can cause contracture" and "TVT mesh contracture [can] cause pain"]; 40:28-41:3 [admitting that "TVT

mesh can cause contracture leading to chronic pain"]; 42:4-15 [admitting that "chronic pain from the TVT mesh [] can be debilitating and life-changing," "chronic groin pain can result from TVT mesh," "TVT mesh can also cause chronic pain syndromes"]; 44:25-45:2 [admitting that "pain to partner is also another risk caused by the TVT"]; 45:4-7 [admitting that "chronic pelvic pain and chronic dyspareunia, those complications could result from the TVT mesh"]; 70:2-11 [admitting that "POP meshes could come with life-changing complications including incapacitating pelvic pain, dyspareunia, and large-scale erosions that can be exceedingly complex and not easily resolved"]; 79:28-80:4 [admitting that "retraction or the shrinkage of the mesh tissue can result in distortion of the vaginal cavity that can interfere with sexual intercourse"]; 81:23-82:8 [admitting that "shrinkage of the tissue around the foreign body results in pelvic pain" and "dyspareunia," and "[t]he [] are new morbidities or new complications related to the materials used"]; see also PX4820 [1/14/14 Dep. Tr. of Dr. Hinoul] at 1492:12-1495:6.)

Dr. Hinoul's testimony at trial further confirmed that these risks are specific to the mesh (as opposed to the inherent dangers of the procedure) by explaining how the dangerous properties of mesh listed in the column 3 of Table 1 above lead to the serious, long term complications listed in columns 1 and 2. He admitted that "the introduction of mesh has introduced a new kind of complications related to the materials used." (8/7/19 Tr. 81:3-19 [Dr. Hinoul]; PX0356 at 2.) Dr. Hinoul also testified about an internal memorandum dated 2009 that he authored with two other company medical directors, Dr. Aaron Kirkemo and Dr. David Robinson. (PX0356 at 2; 8/8/19 Tr. 115:12-116:24 [Dr. Hinoul].) This internal memorandum stated that "[t]he mesh induces an acute and chronic foreign body reaction, which can lead to both exposure and shrinkage," and explained that "[t]he most prevalent specific complications are mesh exposure and shrinkage of the tissue around the foreign body. This may then result in symptoms of pelvic pain and dyspareunia." (8/7/19 Tr. 81:23-82:26 [Dr. Hinoul].)

Dr. Hinoul's testimony also illuminated the link between the dangerous properties of biofilm/mesh infection and inflammation and the serious, long-term complications caused by mesh. He admitted that the propensity of the mesh to become infected and form a biofilm formation can lead to complications because "when the biofilm forms and the inflammatory

reaction is more intense, that can lead to enhanced contraction and shrinkage of the mesh," which in turn "can lead to more significant pain and dyspareunia." (PX4820, 9/18/12 Tr. 681:8-16.) Dr. Hinoul further explained that this chain reaction happens because an infected mesh or biofilm "can cause a more intense inflammatory reaction." (8/7/19 Tr. 84:26-85:1.)

In addition to Dr. Hinoul's testimony, numerous internal company documents demonstrated that the dangerous mesh properties and their resulting complications were well-known to J&J. For example, during an Ethicon Expert Meeting regarding "Meshes for Pelvic Floor Repair" in Norderstedt on June 2, 2006, several experts and Ethicon employees discussed "Unmet clinical needs" and memorialized the company's understanding of the current dangers of their mesh devices and the ways the materials need to be improved in order to avoid serious complications:

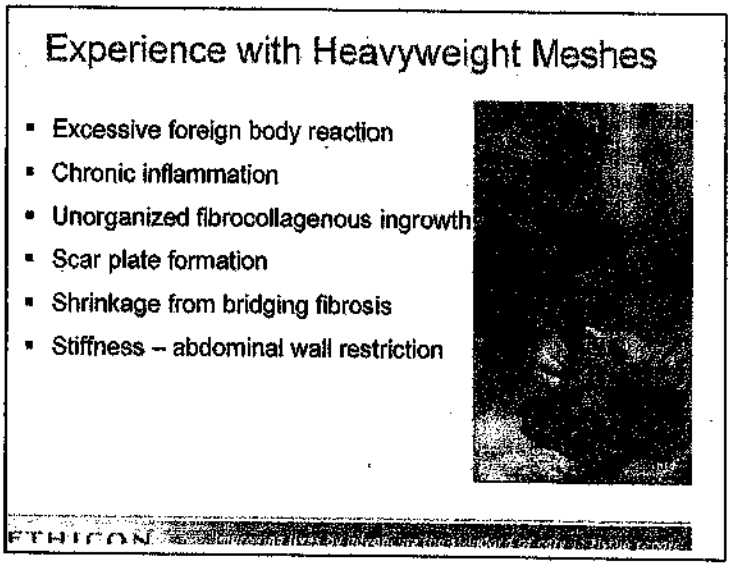
This is the summary of unmet needs:

Unmet clinical needs	**Priority (points)**
No shrinkage / no long-term contraction Fibrosis reduction Severe contraction → Dyspareunia → sexual function↓ *Tension response* ↓ = ↓ *Sexual pain?* *No folding of mesh* *No rigidity*	10
No vaginal distortion, normal vaginal wall, maintain sexual function, normal sexual function	8
Elasticity simulating physiology	5
No chronic pain Patient comfort *Less erosion* *Less vaginal mesh exposition*	4 2

(PX0158 at 5; PX4761 [11/16/12 Dep. Tr. of Axel Arnaud] at 447:9-449:19 [testifying that surgeons' "unmet clinical need . . . is to reduce the rate of complication"]; PX4817 [11/30/17 Dep. Tr. of Axel Arnaud] at 36:14-38:2; see also 7/16/19 Tr. 108:6-28, 109:22-110:25 [Dr. Rosenzweig].)

The following internal company documents further demonstrate J&J's knowledge of the ways in which the dangerous properties of mesh can cause complications:

- In an internal draft manuscript dated 2004 on the "TVM technique," which was the prototype for the Prolift, the inventors of the Prolift (known as the TVM Group) described the bacteria leading to biofilm formation in the mesh weave and stated that the resulting "[c]hronic infection is the actual problem associated with the placement of such prosthesis." (PX0046 at 8; see also 7/16/19 Tr. 120:14-122:15 [Dr. Rosenzweig].)
- In an "Interim report mesh explants pelvic floor repair" dated April 2008, Prof. B. Klosterhalfen, an expert consultant for Ethicon, also found that the presence of mesh inside the body can cause chronic pain: "Neuromas and neuronal proliferations are found often in the periphery of pelvic floor mesh implants"; "Neuromas and neuronal proliferations induce chronic pain." (PX0736; 7/17/19 Tr. 78:24-80:4 [Dr. Rosenzweig].)
- In a presentation given in 2007 by Boris Batke, an Ethicon scientist, he discussed some of the dangerous properties of "heavyweight meshes," including "Excessive foreign body reaction"; "Chronic inflammation"; "Scar plate formation"; "Shrinkage from bridging fibrosis"; and "Stiffness":



(PX0325 at 6.) And as Dr. Jorge Holste's deposition testimony confirmed, the TVT mesh is considered a heavyweight mesh. (7/16/19 Tr. 86:11-87:8 [Jorge Holste]; see also 7/16/19 Tr. 87:11-23 [Dr. Rosenzweig].)

- In an email string dated November 2002, Ethicon employees discussed the company's understanding of shrinkage of TVT mesh: "As we discussed the shrinkage rate is influenced

by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that [Ethicon Medical Director Dr.] Axel [Arnaud] was using 30% shrinkage as rule of thumb . . ." (PX1151; see also 7/16/19 Tr. 112:17-113:2, 113:10-15, 113:24-114:2, 114:17-24 [Dr. Rosenzweig].)

- In an internal document titled "LIGHTning Critical Strategy" dated September 2006, Ethicon acknowledged that mesh shrinkage and scar plate can lead to complications:

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

(PX0245; see also PX4761 [11/15/12 Dep. Tr. of Axel Arnaud] 284:18-285:19.)

In addition to the mesh-specific complications that Dr. Hinoul testified about at trial (see Table 1 above), Dr. Martin Weisberg, another medical director for Ethicon, testified that the company also knew from the time of launch about the following mesh-related complications for the TVT and/or the POP mesh products, which were not included in J&J's labeling until 2015: (1) neuromuscular problems, including acute and/or chronic pain in the groin, pelvic, and/or abdominal area; (2) urge incontinence and de novo urge incontinence; (3) urinary frequency and de novo urinary frequency; (4) de novo urinary retention; (5) de novo urinary obstruction; (6) de novo voiding dysfunction; (7) excessive contraction or shrinkage of the tissue surrounding the mesh; and (8) risk of needing multiple removal surgeries which may not resolve the adverse reactions from the mesh. (PX4808 [11/12-13/15 Dep. Tr.] at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9, 144:23-146:5, 207:1-19, 312:25-313:10, 320:16-321:19, 323:1-324:15.)

As Dr. Hinoul confirmed, a device manufacturer is in the best position to know about its device's properties and complications. (8/7/19 Tr. 147:20-148:9 ["Q. How, if at all, did Ethicon know or become aware of these mesh problems? A. Well, obviously, we are the mesh manufacturer . . ."].) Dr. Hinoul testified that the company's knowledge of mesh complications was based on knowledge from the research and development phase; post-market surveillance, including monitoring of adverse event reports from doctors and patients received by the company; deliberate surveys of the published medical literature as part of their business functions; internal

risk analyses; preclinical studies; and other internal work. (8/7/19 Tr. 35:6-9, 147:15-149:7.) Dr. Rosenzweig's testimony corroborates that J&J had these various sources of information for their pelvic mesh devices. (7/17/19 Tr. 118:12-119:23, 120:8-20.)

B. Expert Testimony Confirmed that the Dangerous Properties of Mesh Can Lead to Complications

Testimony from Plaintiff's expert witnesses Dr. Bruce Rosenzweig, Dr. Vladimir Iakovlev, and Dr. Michael Thomas Margolis also confirmed that the inherent properties of mesh are clinically significant because they can lead to serious, long-term complications.

1. Dr. Bruce Rosenzweig

Dr. Rosenzweig is a practicing urogynecologist. (7/16/19 Tr. 10:15-11:7.) His opinions in this case are based upon his medical experience, personal experience as a target of marketing by J&J, extensive review of the literature, review of internal company documents and company testimony, and review of J&J's marketing materials. (7/16/19 Tr. 44:26-45:12.)

Dr. Rosenzweig testified about the following dangerous properties of polypropylene meshes: (1) chronic foreign body and chronic inflammation; (2) shrinkage, contraction, bridging fibrosis; (3) deformation (*i.e.*, roping, fraying, curling, loss of pore size, particles); (4) bacterial adherence of mesh/subclinical infection; and (5) degradation. (7/16/19 Tr. 70:13-16, 71:2-13, 72:14-25, 74:2-6; 7/17/19 Tr. 37:9-22; 38:19-22.) He further testified that these dangerous properties of mesh can lead to complications, including erosion; pain; chronic/lifelong pain, including pelvic pain, vaginal pain, groin pain; pain with sexual intercourse (dyspareunia); chronic/lifelong dyspareunia; pain to partner; decrease in sexual function; vaginal stiffness, distortion and shortening of the vagina; chronic infection; urinary dysfunction; defecatory dysfunction, bowel dysfunction, the need for one or more removal surgeries to address mesh-specific complications.[3]

[3] See, e.g., 7/16/19 Tr. 77:5-79:28 [chronic foreign body reaction/inflammation leading to erosion, pain, chronic pain, dyspareunia, chronic dyspareunia], 110:14-25, 116:11-22 [mesh shrinkage/contraction leading to pain, dyspareunia, voiding dysfunction, and other harms], 119:13-25 [biofilm/subclinical infection of the mesh leading to erosion, urge incontinence, chronic/lifelong pain and dyspareunia, mesh shrinkage/contraction]; 7/17/19 Tr. 12:28-13:23 [particle loss leading to pain, dyspareunia, pain to partner, increased inflammation and chronic foreign body reaction], 13:27-16 [loss of pore size, including from stretched mesh, leading to bridging fibrosis, scar plate,

Additionally, based on his review of the literature, Dr. Rosenzweig testified about the significant rates of urinary dysfunction resulting from mesh, at rates of approximately 20 to 60 percent. (7/17/19 Tr. 66:7-71:4.) This means that "a woman stands a 20 to 60 percent chance of walking away with a different urinary problem than she went in with." (7/17/19, 66:17-21.) J&J's expert witness, Dr. Peter Rosenblatt, agreed that rates as high as 21.3% for new onset urge symptoms after implantation of the TVT were within the range of what he has seen in the literature. (9/19/19 Tr. 71:7-71:14.) He also agreed that the overall incidence of voiding dysfunction after TVT implantation could be as high as 20.2%. (9/19/19 Tr. 75:16-23.)

The Court gives weight to Dr. Rosenzweig's opinions because they are consistent with and corroborated by the internal company documents and company testimony discussed above, and consistent with and corroborated by the testimony of other expert witnesses, including Dr. Iakovlev's testimony based on his pathology studies of the tissue reactions to mesh, and Dr. Margolis's testimony from his extensive clinical experience removing mesh and treating complications. The Court therefore finds Dr. Rosenzweig's testimony credible.

2. Dr. Vladimir Iakovlev

Dr. Iakovlev is a pathologist. He routinely analyzes tissue samples, including mesh explant samples, and renders patient diagnoses. (8/1/19 Tr. 1:4-22, 8:2-9:6.) He also uses histological staining methods to see the relationship between the implant and its surrounding tissue. (8/1/19 Tr. 12:27-13:19.) Dr. Iakovlev's opinions in this case are based on his education, training, and experience, including his research and experience in examining over 500 mesh explants, review of the published literature, and review of internal company documents. (8/1/19 Tr. 22:17-22.)

Dr. Iakovlev testified about the types of mesh-tissue interactions that occur in the body, including foreign body type inflammation to mesh; scarring and bridging fibrosis; scar contraction resulting in mesh contraction; nerve growth around and through the mesh or into the

---

contraction, nerve injury, and degradation], 14:19-16:1 [mesh deformation leading to difficulty urinating, difficulty emptying bladder, urge incontinence, chronic dyspareunia], 25:20-26:2 [degradation leading to particle loss, increase chronic foreign body reaction/inflammation, chronic pain, chronic dyspareunia, urinary dysfunction], 58:3-63:4 [mesh shrinkage/contraction, inflammation, irritated nerves, and erosion leading to urinary dysfunction], 76:18-28 [serious complications that can impact quality of life that are from the property of the mesh itself], 123:6-22 [serious complications "caused by the mesh left behind"].

mesh; mesh erosion/exposure; mesh folding, balling and curling; and polypropylene degradation. (8/1/19 Tr. 31:14-32:13.) He also testified about the clinical significance of these mesh-tissue interactions in patients, explaining that "they all together lead in some patients to complications." (See, e.g., 8/1/19 Tr. 42:9-19, 46:5-10, 62:14-63:1, 74:17-26; 30:28-31:23; 179:26-180:1.)

As with Dr. Rosenzweig, the Court gives weight to Dr. Iakovlev's opinions because they are corroborated by internal company documents and company testimony, and therefore finds his testimony credible.

3. Dr. Michael Thomas Margolis

Dr. Margolis is a practicing California urogynecologist who specializes in treating mesh complications. (7/25/19 Tr. 94:6-14, 104:18-20, 120:9-26.) He has treated approximately 1,000 patients with mesh complications and performed mesh explant surgery in approximately 600 of those patients. (7/25/19 Tr. 117:24-118:4.) Approximately 95% of the patients he treats are California women. (7/29/19 Tr. 26:5-8.) Dr. Margolis's opinions in this case are based primarily on his extensive clinical experience treating women with mesh complications over the last 20 years, but he also relied on several other sources as well, such as his education and training, the medical literature, and company materials. (7/29/19 Tr. 10:17-11:5.)

Dr. Margolis testified about the mesh complications that he has observed in his practice, including urinary dysfunction; pain with sexual intercourse; severe and chronic pain, including pelvic, vaginal, leg, and groin pain; severe and multiple/recurrent/persistent erosions; infections, including late onset infections 5, 10, even 15 years after implantation of the mesh; injury to partner during intercourse; vaginal stiffening and/or distortion; dense scar tissue enveloping mesh; mesh shrinkage/contracture; bowel dysfunction; defecatory dysfunction; and fistulas. (7/29/19 Tr. 15:27-16:24.) Unlike other implants, Dr. Margolis testified about the fundamental difficulty of mesh removal (likening it to trying to remove rebar from the concrete while trying to do as little damage as possible to the sidewalk) and the "essential irreversibility of the mesh-related complications" even sometimes after several removal surgeries. (7/29/19 Tr. 16, 20-24, 31:12-33:3.)

Dr. Margolis also testified about the differential diagnosis he performs to determine whether the mesh is the cause of his patients' complications. (7/25/19 Tr. 121:27-123:2.) For example, Dr. Margolis explained that if he can "reproduce the pain" by pushing on the area where there is mesh, it helps him determine whether or not the mesh is the cause of his patients' pain. (7/25/19 Tr. 122:11-123:7.) He also explained that, upon physical examination, he can sometimes "feel [the mesh sling] fixed firm and rigid and scarred into place . . . literally choking up on the urethra" and causing obstruction of the urethra. (7/25/19 Tr. 123:20-124:3.)

The Court gives weight to Dr. Margolis's testimony about his clinical findings and observations regarding mesh complications and their source, and finds his testimony be credible. The Court notes that Dr. Margolis's testimony, based on his clinical experiences treating mesh complications, is consistent with the internal company documents and company testimony and corroborates Dr. Rosenzweig's opinion regarding the complications that are caused by the properties of the mesh.

C. The Weight of the Evidence Demonstrates the Severe, Long-Term Risks of Mesh

J&J offered the expert testimony of Dr. Peter Rosenblatt, Dr. Charles Nager, and Dr. Karyn Eilber for the proposition that mesh does not cause or pose additional dangers aside from vaginal exposure and erosion. The Court concludes that the greater weight of the evidence, including company knowledge as the manufacturer of the device, internal company documents, company testimony, pathology findings on mesh-tissue reactions, and the clinical experiences and observations from mesh removal specialists, indicates otherwise.

The opinions of J&J's medical experts are inconsistent with and contradicted by the company's own admissions and knowledge regarding their own products. As described above, there is substantial evidence from company documents and testimony confirming the dangerous properties of mesh and that these mesh properties can lead to multiple serious and long-term complications in addition to exposure and erosion. But neither Dr. Nager's nor Dr. Eilber's testimony referenced or explained the internal company documents that contradicted their positions or even mentioned that they considered internal company documents at all in forming

their opinions in this case. And Dr. Rosenblatt testified that he has "never heard that a chronic foreign body reaction . . . would lead to exposure or shrinkage" (9/19/19 Tr. 21:26-22:4), contradicting at least three Ethicon medical directors who wrote that "the mesh induces an acute and foreign body reaction, which can lead to both exposure and shrinkage." (PX0356).

The examination of these defense expert witnesses also revealed conflicts of interest that could bias their opinion of mesh dangers. Dr. Nager is a former preceptor for Ethicon and trained other doctors to implant the TVT. (8/20/19 Tr. 117:3-7.) He has implanted between 800 to 1600 slings over the course of his career and taught and encouraged hundreds of other doctors to use mesh devices. (8/20/19 Tr. 116:25-117:25.) As President of the American Urogynecologic Society (AUGS) in 2013-2014, he formed the midurethral sling task force "to defend the mesh sling" and led the efforts to develop a position statement supporting the use of the mesh sling on behalf of the Society. (8/20/19 Tr. 141:6-19, 151:8-13.) They did so to produce a document that would help "members," including doctors and mesh manufacturers, "to use this position statement at legal proceedings" when they were sued in mesh litigation. (8/20/19 Tr. 155:20-4, 156:17-21, 156:28-159:6.) He told J&J specifically that "I'm trying to help you guys and defend the best procedure ever developed for SUI . . ." (8/20/19 Tr. 160:18-162:5.) He even told the AUGS membership that "you're going to have to pry the midurethral sling from my cold, dead hands." (8/19/19 Tr. 188:23-189:6.)

Dr. Eilber has been a paid consultant for mesh manufacturers for over 16 years, including for AMS, Boston Scientific, and Coloplast. (9/24/19 Tr. 15:5-17, 16:28-17:5, 103:1-27, 105:1-15.) She has also served as a litigation expert witness for Boston Scientific in 20-25 cases in just the past 3 or 4 years. (9/24/19 Tr. 102:14-20.) Dr. Eilber has implanted "thousands" of mesh slings/POP mesh devices over the course of her career. (9/24/19 Tr. 8:19-24, 111:24-28.) Because of her professional investment in defending the sling, she has authored medico-legal studies that tried (but failed) to prove that mesh victims' negative thought patterns were related to their intention to sue the mesh manufacturer. (9/24/19 Tr. 162:11-21, 162:25-163:5.) She is also paid to sit on the advisory board for Boston Scientific, where she would "discuss how to deal with the bad publicity surrounding mesh." (9/24/19 Tr. 103:8-13, 104:13-16.) Dr. Eilber further admitted

that she has been "very active in trying to deal with the bad publicity surrounding mesh." (9/24/19 Tr. 104:23-26.) And when J&J wanted to recruit a California doctor to author a letter against the instant lawsuit, Dr. Eilber was one of the five doctors to which the company reached out. (8/21/19 Tr. 180:3-16 [Dr. Bruce Kahn].)

Dr. Rosenblatt has implanted over 3,000 mesh devices over the course of his career. (9/17/19 Tr. 108:6-15, 114:13-15.) He has also been a paid consultant for almost every U.S. mesh manufacturer for the past 18 years—Ethicon, Boston Scientific, Bard, AMS, Coloplast, Medtronic—and had licensing agreements with several of them. He has also taught cadaver labs, trained other doctors to implant the mesh manufacturer's devices, given talks, seminars and booth presentations about mesh to other doctors during conferences, over meals, and other events hosted by the industry. (9/18/19 Tr. 175:6-190:26; 9/19/19 Tr. 157:3-17.) Dr. Rosenblatt has made somewhere in the range of $2.2 million to $5.5 million from mesh manufacturers, inclusive of his compensation as a paid litigation expert.

D. Defendants Deceptively Marketed Their Pelvic Mesh Concealing Their Knowledge of Mesh-Specific Properties and Complications

The evidence at trial demonstrates that J&J deceptively marketed its TVT and POP mesh devices through a combination of false statements, misleading half-truths, and omissions that were likely to deceive doctors (1) regarding the full range of complications associated with mesh use; (2) the fact that these complications can be severe and long-term; (3) that the complications are specific to and come from the mesh itself, *i.e.*, the dangerous properties; and (4) that there is no exit strategy when it comes to mesh. The Court reaches the factual conclusion that these misrepresentations were likely to deceive doctors that mesh use carried a minimal risk of complications and would not introduce new or additional dangers to pelvic surgery aside from the risk of vaginal exposure or erosion.

1. Defendants' IFUs Misled Regarding the Full Range of Mesh-Related Complications

As summarized in Table 2 below, J&J misrepresented the full range of mesh-related complications by omitting known complications from the TVT IFUs until 2015 (and even after

2015), despite the fact that the company had knowledge of these risks starting from 1998. An examination of the TVT IFUs reveal that, consistent with J&J's marketing of the mesh sling as a virtually risk-free device, these labels did not even mention the possibility of pain, much less the debilitating chronic pain that the company knew the mesh could cause. Similarly, the TVT IFUs did not disclose the risk of dyspareunia or pain to partner, much less the chronic or lifelong dyspareunia that could be caused by mesh contraction that was known to the company.

Table 2: TVT IFUs

	1998-2015 TVT Family IFUs[4]	2015-Present TVT Family IFUs[5]	Company Knowledge From the Time of Launch[6]
Erosion/ Exposure	• "***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/or] inflammation" (Emphasis added.)	• "Mesh extrusion, exposure, or erosion into the vagina or other structures or organs"	• ***Chronic*** foreign body reaction (8/7/19 Tr. 82:14-26; PX0356.) • ***Lifelong/recurrent*** risk of vaginal exposures • ***Lifelong/recurrent*** risk of erosion into other organs (8/7/19 Tr. 38:20-22, 38:26-39:1, 39:4-7.)
Pain	• **NO** mention of pain • **NO** mention of chronic pain • "***Transient*** leg pain lasting 24-48 hours may [occasionally] occur and ***can usually be managed with mild analgesics***"[7]	• "Acute and/or chronic pain" • "Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area"	- ***Debilitating/life changing/chronic*** pain • ***Severe, chronic/persistent*** groin/leg pain (8/7/19 Tr. 42:4-15; 8/8/19 Tr. 161:16-19, 187:1-188:18.)

[4] JX10176 [TVT IFU in use 9/8/00-11/226/03]; JX10158 [TVT IFU in use 12/22/03-2/21/05]; JX10159 [TVT IFU in use 2/11/05-4/7/06]; JX10188 [TVT IFU in use 10/13/08-11/23/10]; JX10175 [TVT IFU in use 11/29/10-11/26/14]; JX10189 [TVT IFU in use 12/9/14-8/31/15]; JX10160 [TVT-Secur IFU in use 12/16/05-discontinuance]; JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10177 [TVT-Exact IFU in use 5/4/10-6/6/16]; JX10181 [TVT-Exact IFU in use 8/5/13-10/17/13]; JX10182 [TVT-Exact IFU in use 10/23/13-11/16/14]; JX10190 [TVT-Exact IFU in use 8/12/14-9/9/15]; JX10165 [TVT-Abbrevo IFU in use 9/10/10-11/27/14]; and JX10191 [TVT-Abbrevo IFU in use 7/1/15-9/15/15].

[5] JX10186 [TVT IFU in use 9/18/15-present]; JX10184 [TVT-O IFU in use 9/22/15-present]; JX10187 [TVT-Exact IFU in use 9/18/15-present]; and JX10193 [TVT-Abbrevo IFU in use 9/24/15-present].

[6] See Section V.A.

[7] JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10165 [TVT-Abbrevo IFU in use 9/10/10-11/27/14]; and JX10191 [TVT-Abbrevo IFU in use 7/1/15-9/15/15] (emphasis added).

	1998-2015 TVT Family IFUs[4]	2018-Present TVT Family IFUs[5]	Company Knowledge From the Time of Launch[6]
			• Neuromuscular problems, including acute and/or chronic pain in the groin, pelvic, and/or abdominal area (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 320:16-21)
Sexual Function	• **NO** mention of dyspareunia • **NO** mention of chronic dyspareunia • **NO** mention of mesh contraction • **NO** mention of pain to partner	• "Pain with intercourse which in some patients may not resolve" • "Exposed mesh may cause pain or discomfort to the patient's partner during intercourse" • **NO** mention of mesh contraction	• Contracture causing pain • Contracture causing chronic pain • Dyspareunia • Chronic dyspareunia • Pain to partner (8/7/19 Tr. at 39:8-14, 40:28-41:3, 41:21-25, 44:25-45:7.) • Excessive contraction or shrinkage of the tissue surrounding the mesh (PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg] at 207:01-207:19.)
Urinary Dysfunction	• "***Over correction***, i.e., too much tension applied to the [tape/Implant/mesh implant], ***may cause*** temporary or permanent lower urinary obstruction" • "***As with other incontinence procedures***, de novo detrusor instability may occur following [the TVT procedure]/[a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System/GYNECARE TVT ABBREVO device]. To minimize this risk, make sure to	• "Voiding dysfunction" • "Urge incontinence" • "Urinary frequency" • "Urinary retention"	• De novo urge incontinence • De novo urinary frequency • De novo urinary retention • De novo urinary obstruction • De novo voiding dysfunction (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 323:1-324:15)

	1998-2015 TVT Family IFUs[4]	2015-Present TVT Family IFUs[5]	Company Knowledge From the Time of Launch[6]
	place the tape tension free in the mid-urethral position"[8]		
Removal	• **NO** mention of removal • **NO** mention of serious complication that would require a significant removal • **NO** mention of irreversibility of complications	• "One or more revision surgeries may be necessary to treat these adverse reactions" • "In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required"	• Need for mesh removal for serious complications, including chronic pain or dyspareunia, which may be difficult (8/7/19 Tr. 41:21- 42:3.) • Multiple revision surgeries may be necessary to treat adverse reactions, and significant dissection may be required - Even after additional surgeries are performed, adverse reactions may not resolve (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 320:22:321:19.)

As seen in Table 2 above, J&J omitted from its TVT IFUs some of the most significant risks, including chronic foreign body response, the lifelong and recurrent risk of vaginal exposures and erosion into other organs, pain and lifelong/chronic pain, dyspareunia and lifelong/chronic dyspareunia, pain to partner, and the need for mesh removal which may not resolve the complications from mesh. (Similarly, Table 3 below sets forth the risks that the company knew about but omitted with regard to its mesh POP products.) By only disclosing an incomplete list of risks that only tells half the story—the benign half—J&J's IFUs misled consumers about the whole picture of possible mesh risks. Those misleading omissions and half-truths are violations of the UCL and FAL: "[A] perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable." (*People v. Overstock.com* (2017) 12 Cal. App. 5th 1064, 1079 [quotations and citations omitted].)

[8] Not included in JX10176 [TVT IFU in use 9/8/00-11/226/03].

The deceptiveness of the incomplete list is further heightened by the fact that physicians would expect the IFU to provide a complete list of all device-related risks. The evidence at trial has demonstrated that the manufacturer is expected to include all adverse reactions reasonably associated with the use of the device in the IFU. (PX2000 [1991 FDA Device Labeling Guidance]; 8/5/19 Tr. 35:20-36:1 [Dr. Kessler].) Testimony from company witnesses demonstrated that J&J knew and understood this—Dr. James Hart, Ethicon VP of Medical Affairs Worldwide, testified that the purpose of the IFU was to provide a complete statement of the warnings, precautions, and adverse reactions for the device. (PX4816 [12/20/13 Dep. Tr.] at 800:3-8 ["the purpose of the IFU is to provide a complete statement of what the company knows with regard to . . . the warnings, the precautions and the adverse reactions for the device"].) Dr. Martin Weisberg, Medical Director for Ethicon, confirmed that "if we're aware of a significant risk that might occur, it should be listed" in the IFU. (PX4850 [5/24/12 Dep. Tr.] at 131:11-20.) Dr. David Robinson, another Medical Director for Ethicon, testified that he expected doctors to rely upon the Prolift IFU to accurately represent what the company knew to be the risks at the time. (PX4804 [9/11/13 Dep. Tr.] at 488:11-18.)

By providing physician consumers with a partial, misleadingly incomplete list of complications in the IFU—a document that those physicians expected to provide a comprehensive set of risks reasonably associated with the device—J&J was likely to mislead doctors that any complications not listed were simply not associated with the device. (7/22/19 Tr. 12:19-23 [Dr. Rosenzweig]; 7/29/19 Tr. 93:23-28 [Dr. Margolis].)

2. Defendants' IFUs Misled Regarding the Severity and Duration of Mesh Complications

J&J's IFUs not only omitted complications, but also omitted or affirmatively downplayed information about the severity and long-term nature of these complications that would give a doctor or patient pause about choosing mesh as a treatment option. For instance, Dr. Hinoul testified that the company knew about the risk of "debilitating" and "chronic" pain and "incapacitating pelvic pain," but omitted that severity and duration information when they disclosed only "pain" in the Adverse Events section, as seen in Table 3 for the POP mesh IFUs

below. (8/7/19 Tr. 42:4-9, 68:1-4, 70:2-11.) Dr. Hinoul also testified that the company knew about the risk of "chronic" dyspareunia, but disclosed only "pain with intercourse" which "may resolve with time." (8/7/19 Tr. 45:4-45:7, 68:1-4; *see* Table 3 [POP Mesh IFUs].)

Table 3: POP Mesh IFUs

	2003-2012 Gynemesh PS, Prolift, Prolift+M, Prosima IFUs[9]	2015 Gynemesh PS IFU[10]	Company Knowledge From the Time of Launch
Erosion/ Exposure	• Erosion, extrusion	• "mesh extrusion, exposure, or erosion into the vagina or other structures or organs"	• ***Lifelong/recurrent*** risk of vaginal exposures • ***Lifelong/recurring*** risk of erosion into other organs • Large-scale erosions that are difficult to treat (8/7/19 Tr. 38:20-22, 38:26-39:1, 39:4-7, 68:1-4, 70:2-11.)
Pain	• Pain • Included in 2005-2012 Prolift IFUs and 2008-2012 Prolift+M IFUs: "***Transient*** leg pain may occur and can usually be managed with mild analgesics" (Emphasis added.)	• "Acute and/or chronic pain" • "Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area"	• Debilitating/life changing/chronic pain • Chronic groin/leg pain • Incapacitating pelvic pain (8/7/19 Tr. 42:4-15, 39:4-7, 68:1-4, 70:2-11; 8/8/19 Tr. 161:16-19.) • Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area (PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg] at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9.)

[9] JX10170 [Gynemesh PS IFU in use 3/20/03-3/30/06]; JX10173 [Gynemesh PS IFU in use 3/31/06-12/11/08]; JX10171 [Gynemesh PS IFU in use 12/8/08-4/14/14]; JX10172 [Gynemesh PS IFU in use 12/18/08-11/30/10]; JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10157 [Prolift IFU in use 10/1/09-5/7/10]; JX10169 [Prolift IFU in use 5/11/10-discontinuance]; JX10155 [Prosima IFU in use 6/19/07-5/17/10]; JX10166 [Prosima IFU in use 6/18/10-discontinuance]; JX10154 [Prolift +M in use 12/12/08-1/13/11; JX10174 [Prolift +M in use 2/4/11-discontinuance].

[10] JX10185 [Gynemesh PS IFU in use 4/3/15-present].

	2003-2012 Gynemesh PS, Prolift, Prolift+M, Prosima IFUs[9]	2015 Gynemesh PS IFU[10]	Company Knowledge From the Time of Launch
Sexual Function	- In 2009-2012 Prolift IFUs and 2008-2012 Prolift+M IFUs: "Potential adverse reactions are those typically associated with pelvic organ prolapse procedures, including pelvic pain or pain with intercourse. These may resolve with time" - **NO** mention of pain with intercourse in 2003-2012 Gynemesh PS IFUs, 2005-2009 Prolift IFUs, 2007-2012 Prosima IFUs - **NO** mention of pain to partner - "scarring that results in implant contraction"/ "contracture, scarring"	• "Potential adverse reactions are those typically associated with pelvic organ prolapse procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve" • "Exposed mesh may cause pain or discomfort to the patient's partner during intercourse" • "Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur"	• Shrinkage leading to pelvic pain and dyspareunia • Pain to partner • Chronic dyspareunia • Distortion of vaginal cavity interfering with intercourse • Risks to young, sexually active women (8/7/19 Tr. 39:8-14, 40:28-41:3, 44:25-45:7, 68:1-10, 79:28-80:4, 81:23-82:5, 83:21-23; PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg] at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9.)
Removal	• **NO** mention of removal • **NO** mention of serious complications that would require a significant removal	- "one or more revision surgeries may be necessary to treat these complications" - "In cases in which GYNECARE GYNEMESH needs to be removed in part or whole, significant dissection may be required"	- Need for mesh removal for serious complications, including chronic pain or dyspareunia, which may be difficult (8/7/19 Tr. 41:21- 42:3, 68:1-4.) - Multiple revision surgeries may be necessary to treat adverse reactions, and significant dissection may be required - Even after additional surgeries are performed, adverse reactions may not resolve (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 320:22:321:19.)

	2003-2012 Gynemesh PS, Prolift, Prolift+M, Prosima IFUs[9]	2015 Gynemesh PS IFU[10]	Company Knowledge From the Time of Launch
Urinary Dysfunction	• **NO** mention of urinary dysfunction in 2003-2012 Gynemesh PS IFUs, 2005-2009 Prolift IFUs, 2007-2012 Prosima IFUs	- "urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction"	- Urinary incontinence - Urge incontinence - Urinary frequency - Urinary retention - Urinary obstruction - Voiding dysfunction (PX4808 Tr. at 144:23-146:5.)

Compounding the deception, J&J *did* use language describing the severity and duration of pain complications when it served its purpose of downplaying a complication. For example, as seen in Table 3, some of J&J's POP mesh IFUs warned that "Transient leg pain may occur and can usually be managed with mild analgesics," without mentioning the accompanying risk of chronic or lifelong leg pain. (See, e.g., JX10169 [Prolift IFU in use from 5/11/10 until discontinuance].)[11] This was in spite of knowing, as Associated Medical Director Dr. Meng Chen said in 2009, that those complications "are not 'transitory' at all." (PX0904; 7/31/19 Tr. 44:18-23, 45:2-13 [Dr. Chen].)

The severity and duration of complications are medically significant and effect medical decision-making. As Dr. Hinoul testified, "[s]hort-term adverse events have different clinical significance than chronic adverse events." (8/8/19 Tr. 159:13-16.) Dr. Hinoul further admitted that, as a medical doctor, "the risk of chronic pain, for example, would affect [his] medical decision-making differently than the risk of a short-term pain." (8/8/19 Tr. 159:17-21.) Dr. Hinoul also acknowledged that describing a complication as "lasting 2 days" and "treated with over-the-counter pain medication" has an "obviously different" clinical significance compared to the "possibility of chronic leg pain." (8/8/19 Tr. 162:10-16.) Similarly, J&J's expert witness Dr. Nager testified that he and his colleagues "consider pain to be acute or chronic, and then along a spectrum of severity." (8/20/19 Tr. 71:4-16.) Selectively disclosing mild, short-term complications while concealing severe and long-term complications is precisely the sort of

[11] See also JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10157 [Prolift IFU in use 10/1/09-5/7/10]; JX10154 [Prolift +M in use 12/12/08-1/13/11]; and JX10174 [Prolift +M in use 2/4/11-discontinuance].

misleading half-truth the law prohibits. (See *People v. Overstock.com* (2017) 12 Cal.App.5th 1064, 1079.)

By downplaying the severity and duration of mesh complications, as seen in Table 2 for the TVT and Table 3 for POP meshes above, J&J presented physicians a deceptive and misleading picture of the possible risk profile of mesh and prevented doctors from factoring that into their patient counseling and treatment decisions. The Court finds that these misleading half-truths and omissions regarding the severity and duration of complications were likely to deceive physicians in violation of the UCL and FAL.

3. Defendants' IFUs Misled Regarding the Causation of Complications and the Dangerous Properties of Mesh

In addition to omitting risks and complications altogether and concealing and downplaying their potential severity and chronic/long-term nature, J&J also misleadingly attributed the complications they did disclose to pelvic surgery generally, rather than to the mesh itself. For example, J&J described "pain with intercourse" as a complication "typically associated with pelvic organ prolapse procedures" (see, e.g., JX10154 [Prolift+M IFU in use 12/12/08-1/13/11]) even though the company knew that the use of the POP mesh device carried with it a heightened risk of sexual dysfunction so great that it was a "main concern for sexually active women" and that mesh use could result in distortion of the vaginal cavity, including vaginal tightening and/or shortening. (8/7/19 Tr. 68:5-10, 79:28-80:4 [Dr. Hinoul].) Similarly, J&J describes urge incontinence associated with the TVT implant as a risk that occurs "[a]s with other incontinence procedures," and attributes the risk of lower urinary tract obstruction to "over correction, i.e., too much tension," even though these complications can be caused by the mesh itself. (See, e.g., JX10175 [TVT IFU in use 11/29/10-11/26/14]; PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 323:1-324:15.)

As Table 4 below summarizes, J&J also misrepresented and concealed the dangerous properties that would let a doctor know that the complications are coming from the mesh itself. By misrepresenting or omitting the dangerous properties of mesh, J&J does not allow doctors to factor that into their patient counseling and treatment decisions. For example, the propensity of

mesh to induce a chronic foreign body reaction is significant because, as the company knew, these properties can result complications. (8/7/19 Tr. 81:23-82:26 [Dr. Hinoul].) Despite the company's knowledge that mesh induces a chronic foreign body reaction, the IFUs for its TVT family of products informed doctors that a "transitory foreign body response may occur" and that Prolene mesh elicits only "a minimal inflammatory reaction in tissues, which is transient." (See, e.g., JX10188 [TVT IFU in use 10/13/08-11/23/10].) Similarly, in the IFUs for their POP mesh products, J&J claimed that its "mesh elicits a minimum to slight inflammatory reaction, which is transient." (See, e.g., JX10169 at 5 [Prolift IFU in use 5/11/10-discontinuance].) At the least, these communications are misleading because they present a "best case scenario" of a benign transitory foreign body reaction that fails to disclose that mesh induces a chronic foreign body reaction and chronic inflammation that can lead to complications. (PX0356 [Hinoul internal 2009 memorandum stating "[t]he mesh induces an acute and chronic foreign body reaction, which can lead to both exposure and shrinkage"]; PX0325 at 6 [Batke 2007 presentation regarding dangerous properties of heavyweight meshes].)

Table 4: Mesh Properties

Mesh Properties[12]	Mesh Properties Misrepresentations/Omissions			Company Knowledge From the Time of Launch
	TVT Family IFUs[13]	POP Mesh IFUs[14]	Doctor-Directed Marketing Materials[15]	
Chronic foreign body reaction and chronic inflammation	• "***transitory*** foreign body response"[16] • "***minimal*** inflammatory reaction" (Emphasis added)	• **NO** mention of chronic foreign body response • "***minimal*** inflammatory reaction"/ "minimum to mild inflammatory reaction"	• Histologically well tolerated, inert • Healthy tissue incorporation	• Chronic foreign body reaction • Inflammation • Not inert (8/7/19 Tr. 82:14-24, 85:5-17)

[12] See Section V.B, above, regarding expert testimony confirming that the dangerous properties of mesh can lead to complications.

[13] Footnotes 4 and 5, *supra*

[14] Footnote 9, *supra*

[15] See, e.g., JX11597 ("no tissue reaction"; "macroporous mesh fosters tissue incorporation"; "does not potentiate infection"); JX11622, JX11626 ("A pronounced reduction in inflammation and improved integration into surrounding tissue"; "Reduced foreign body response"; "Large pores increase tissue integration"; "more natural healing"; "Resists wound contraction (shrinkage)"; "softer, more supple vagina [or tissue]"; "Bi-directional properties").

[16] Not contained in post-2015 TVT Family IFUs.

Mesh Properties[12]	Mesh Properties Misrepresentations/Omissions			Company Knowledge From the Time of Launch
	TVT-Family IFUs[13]	POP Mesh IFUs[14]	Doctor-Directed Marketing Materials[15]	
		(Emphasis added)		
Shrinkage, contraction, bridging fibrosis	• Bi-directional elasticity[17] • **NO** mention of shrinkage/ contraction	• Bi-directional elasticity[18] • "mesh remains soft and pliable"	• "Resists wound contraction (shrinkage)" • Remains soft and supple in the body • Bi-directional elasticity	• Shrinkage/ contraction (8/7/19 Tr. 79:28-80:4, 82:21-23.)
Bacterial adherence of mesh/ subclinical infection	• "may potentiate an existing infection"	• **NO** mention of heightened risk of infection/ biofilm	• Resists infection	• Infection/ biofilm (8/7/19 Tr. 84:19-85:1.)

In addition, J&J further misrepresents both the severity and the causation of the mesh complications when it fails to disclose in its IFUs that mesh has no exit strategy. The company knew from the time TVT was launched that when severe complications arise, some patients may need to undergo multiple invasive surgeries to attempt to remove the mesh, and even with removal the complications may never be fully resolved. (PX4808 [Dep. Tr. of Martin Weisberg] at 320:22-321:19; see also Table 2 and Table 3, above.) By omitting the need for removal from the IFUs, as the company did before 2015, the company was concealing from doctors that mesh could cause complication so severe that an invasive surgical procedure might be needed to remove it.

Testimony at trial confirmed that doctors need to know whether the complications are from the mesh itself in order to make treatment decisions. As J&J's expert witness Dr. Eilber testified, if "one of [her] patients has a complication, [she'd] like to figure out where that complication came from," and that doing so was "important to her." (9/24/19 Tr. 116:7-12.) J&J's third-party fact witness Dr. Kahn similarly testified that "[a]nytime someone has a complication from surgery, any good surgeon, including myself—for my patients, I'm going to investigate it as thoroughly as I can to try to get to the bottom of it and, importantly, fix the problem." (8/21/19

[17] Not contained in post-November 2010 TVT Retropubic, TVT-Exact, and TVT-Abbrevo IFUs.
[18] Not contained in post-October 2009 Prolift IFU and 2008-2012 Prolift+M IFUs.

Tr. 145:24-146:2.) And as Dr. Rosenzweig testified, if doctors understand that their complications may be coming from the mesh itself, rather than their technique, this will impact not only what they tell their patients but also how they treat them. (7/17/19 Tr. 47:26-49:5, 49:20-50:2.) In other words, as Dr. Rosenzweig explained, "if you're dealing with a very debilitating condition, it might be worthwhile to switch the debilitating condition you are trying to treat with a debilitating outcome. But if you're dealing with a lifestyle issue and then you have the risk of a debilitating condition, you would consider that very strongly and make sure the patient considers that very strongly in the decision-making process and in the informed consent process." (7/17/19 Tr. at 48:25-49:5.)

Based on the above, the Court therefore concludes that all J&J's TVT IFUs from launch to the present and all transvaginal POP IFUs from launch to 2012, when they were removed from the market, violate the UCL and FAL. Each of them contained a misleadingly incomplete or half-true list of associated complications that was likely to deceive doctors about the full range, severity, and causation of risks as discussed above. (*People v. Overstock.com, supra,* 12 Cal.App.5th at 1079 [true statements can be"[likely to mislead or deceive the consumer" due to "failure to disclose other relevant information"].) To this day, the following risks and complications specific to and resulting from the TVT are still missing from the post-2015 TVT IFUs: (1) lifelong/recurrent risk of vaginal exposure; (2) lifelong/recurrent risk of erosion to organs; (3) contracture causing pain or chronic pain; (4) even after additional surgeries are performed, adverse reactions not resolve; (5) chronic foreign body reaction/not inert; (6) shrinkage/contraction; and (7) mesh infection/biofilm formation. (See Table 2 [TVT IFUs], Table 3 [POP Mesh IFUs], and Table 4 [Mesh Properties].)

The Court also concludes that J&J's IFUs contained false statements about mesh's properties. For instance, J&J falsely claimed in their TVT and POP IFUs that the mesh possessed a "bi-directional elastic property allow[ing] adaptation to various stresses encountered in the

body." (See, e.g., JX10184 [TVT-O IFU in use 9/22/15-present].)[19] J&J kept this statement in some of their IFUs even after admitting internally—and to the FDA—that "there is no data to support 'allows adaptation to various stresses encountered in the body.'" (PX0937.) Untrue statements are inherently deceptive because they are false, and thus violate the UCL and FAL. (*Day v. AT & T Corp.* (1998) 63 Cal.App.4th 325, 332; see also, *Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 951.)

E. Defendants' Doctor Marketing Materials Contained Similar Deceptive Messages

J&J's deceptive IFUs, which omit or misrepresent mesh properties and the full range of known serious, long-term mesh complications, are also the cornerstone of J&J's other printed marketing materials regarding its pelvic mesh products. Based on the Court's review of J&J's doctor-directed marketing materials admitted into evidence (see Violations Appendix), the Court concludes that J&J's marketing materials were deceptive and misleading because they either (1) excerpted or referred doctors to an incomplete list of risks from the IFU; and/or (2) otherwise failed to disclose the full range of the serious, long-term risks resulting from the mesh that the company knew about, as discussed above.

The attached Violations Appendix catalogs all the printed marketing materials entered into evidence[20] and identifies the specific ways in which these communications are deceptive, as set forth below:

---

[19] See also JX10170 [Gynemesh PS IFU in use 3/20/03-3/30/06]; JX10173 [Gynemesh PS IFU in use 3/31/06-12/11/08]; JX10171 [Gynemesh PS IFU in use 12/8/08-4/14/14]; JX10172 [Gynemesh PS IFU in use 12/18/08-11/30/10]; JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10155 [Prosima IFU in use 6/19/07-5/17/10]; JX10166 [Prosima IFU in use 6/18/10-discontinuance]; JX10176 [TVT IFU in use 11/29/10-11/26/14]; JX10158 [TVT IFU in use 12/22/03-2/21/05]; JX10159 [TVT IFU in use 2/11/05-4/7/06]; JX10195 [TVT IFU in use 4/7/06-10/7/08]; JX10188 [TVT IFU in use 10/13/08-11/23/10]; JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10160 [TVT-Secur IFU in use 12/16/05-discontinuance].

[20] In the Violations Appendix, marketing materials ordered by sales representative Jason Logan and shipped into California between 2008-2011 are marked with (*); materials identified in J&J's discovery responses as having been shipped into California at some point from January 2012 onward are marked with (**); and materials that were ordered by Jason Logan 2008-2011 *and* identified by J&J's post-2012 are marked with (***). (See Penalty Appendix for further explanation.)

(1) J&J's advertising sells the benefits of mesh—such as positive outcomes, high efficacy/cure rates, or improved quality of life—without disclosing (a) the dangerous properties of mesh known to the company, such as chronic foreign body reaction, infection/biofilm, and contracture (see Table 4 [Mesh Properties]); (b) the mesh-specific complications known to the company, such as chronic pain, chronic dyspareunia, and urinary dysfunction (see Table 2 [TVT IFUs], Table 3 [POP Mesh IFUs]); or (c) the possible need for mesh removal and the dangers of removal (see *id.*);

(2) Misrepresenting risks introduced by mesh; reprinting or excerpting the misleadingly incomplete "Adverse Events" section of the IFU;

(3) Stating, "See package insert for full prescribing information," or otherwise directing consumers to the misleadingly incomplete IFU;

(4) Advertising the alleged positive properties of mesh, without disclosing the dangerous properties of mesh that lead to complications, so as to mislead doctors about the source of risks:

(a.) Misleadingly stating that mesh resists infection or similar language without disclosing known risk of mesh infection/biofilm. (See PX4820, 9/18/12 Tr. 681:8-16 and 8/7/19 Tr. 84:26-85:1 [Dr. Hinoul testimony re: risk of biofilm and mesh infection])[21];

(b.) Misleadingly stating that mesh has healthy tissue incorporation or similar language without disclosing known risks of shrinkage and contracture. (See 8/7/19 Tr. 79:28-80:4, 81:23-82:8 [Dr. Hinoul testimony re: risks of shrinkage and contracture]);

(c.) Misleadingly stating that mesh has minimal or transitory foreign body response/ inflammation or is inert without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications (See 8/7/19 Tr. 81:23-82:1-8, 85:5-17 [Dr. Hinoul testimony re: chronic foreign body reaction and mesh is not inert]);[22]

---

[21] For example, JX10896, a doctor-directed marketing material for the Prolift, claimed that the mesh "does not potentiate infection" despite Ethicon's knowledge that the mesh itself can cause infection and the creation of a biofilm. (JX10896.1.)

[22] For example, JX11622 advertises "[a] pronounced reduction in inflammation and improved integration into surrounding tissue," "[r]educed foreign body response," and "[l]ess fibrosis than traditional grafts." (JX11622 at 4.) These are "best-case scenario" half-truths because the sales aid does not disclose that the mesh itself induces a chronic foreign body reaction and chronic inflammation, which can lead to a variety of complications.

(d.) Misleadingly stating that mesh is soft, elastic, or resists wound contraction without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening. (See PX4761 [11/15/12 Dep. Tr. of Axel Arnaud] at 287:24-288:5 [agreeing that it was known that "[t]he scar plate that forms with in-growth of tissue into the mesh can cause stiffness of the vagina that further impacts sexual function in a negative manner."].)[23]

(5) Using Ulmsten/Nilsson[24] studies to paint misleadingly positive picture of negligible risks without disclosing the significant risk of urinary complications (see 7/17/19 Tr. 66:7-71:4 [Dr. Rosenzweig]; 9/19/19 Tr. 71:7-71:14 [Dr. Rosenblatt]; 9/19/19 Tr. 75:16-23 [Dr. Rosenblatt]) and the risk of serious, long-term complications specific to or introduced by mesh. (See company known risks in Table 2 [TVT IFUs].)[25];

(6) Advertising sales benefits of TVT-O without disclosing known risk of severe, long-term leg pain (See 8/7/19 Tr. 42:10-12 and 8/8/19 Tr. 161:16-19, 187:1-188:18 [Dr. Hinoul testimony re: chronic groin/leg pain].)

While the Violations Appendix catalogs one or more ways in which the admitted marketing materials contained deceptive messages in violation of the UCL and FAL, just one form of misleading communication per piece of marketing is sufficient for that piece to be deceptive and violate the law. The Court finds that the common theme and central deception that runs through the materials in the appendix is the failure to communicate the mesh risks known to

---

[23] For example, JX11622, a doctor-directed marketing material for the Prolift+M, states that the mesh "[r]esists wound contraction (shrinkage)," exhibits "[i]mproved tissue integration," and allows for "[s]ofter, more supple tissue." (JX11622 at 5.) These are "best-case scenario" half-truths because sales aid does not disclose that mesh shrinkage and contraction can cause the mesh to contract and stiffen, causing pain and dyspareunia.

[24] Dr. Ulmsten, inventor of the TVT device, conducted a study of 131 women implanted with the TVT. A contract provision with J&J conditioned $400,000 on the study's positive outcome and Dr. Ulmsten's company made more than $20 million on the sale of the device to J&J. Dr. Nilsson, a paid consultant for the company, chose to follow up on only 90 out of the 131 women in the Ulmsten study in his series of 5, 7, 11, and 17 year follow-up studies. ("Ulmsten/Nilsson studies"). These Ulmsten/Nilsson follow-up studies that are prominently featured in most of the TVT advertising are of questionable scientific validity given the significant conflict of interest and the unexplained, cherry-picking of a subset of patients for follow up. (See, e.g., PX4761 [7/20/13 Dep. Tr. of Dr. Arnaud] at 496:16-498:11 [Dr. Arnaud agreeing that J&J conditioned $400,000 payout for TVT follow-up studies on favorable "safety and efficacy" results]; see also PX4781 [9/16/13 Dep. Tr. of Laura Angelini] at 198:22-199:20 [marketing VP Laura Angelini agreeing that Ethicon had consulting agreements with four of five authors of the "five-year follow-up study"]; PX3462 [agreement between J&J and Medscand/ Ulmsten].)

[25] For example, JX11597, a doctor-directed marketing material for the TVT family of products, used the Ulmsten/Nilsson studies to advertise a 97% overall success rate, a "strong heritage of success and safety," and negligible complications rates without disclosing any of the dangerous properties or the serious long-term risks caused by the mesh. (JX11597 at 2, 6.)

the company while selling the benefits of the mesh. Thus, the Court concludes each advertisement was likely to deceive doctors about the risks and complications associated with mesh devices and therefore violated California law.

F. Defendants' Patient Marketing Materials Contained Similar Deceptive Messages That Were Likely to Deceive

The Court finds that because J&J's deceptive marketing did not communicate risks to doctors about the complications associated with its mesh devices, this risk information was in turn likely to not reach patients as well. As Ethicon sales manager Michelle Garrison testified, "So not knowing proper complications – **if we're not communicating that to the doctor, the doctor may not be able to communicate that to the patient. The patient needs to have informed consent. The doctor needs to be properly informed.**" (7/25/19 Tr. 48: 8-19 [emphasis added].) Similarly, Dr. Eilber agreed that "mesh complications can be serious," and that "if a patient isn't counseled on the risk of future mesh complications, then she can't make an informed decision about whether to have mesh surgery." (9/24/19 Tr. 127:27-128:6.)

Yet J&J not only withheld from doctors the risk information necessary to counsel patients, it also directed deceptive marketing straight to the consumer that sold the lifestyle benefits of a quick, easy cure while concealing the serious, long-term risks. J&J painted an overwhelmingly positive picture of its mesh products, positioning mesh as "a quick, safe, and minimally invasive cure… superior to other possible alternatives for treating POP and SUI" that "will restore the patient's lifestyle – with minimal, if any, risks." (7/22/19 Tr. 49:13-24; 51:5-27.) J&J's brochures, websites, presentations, and other materials consistently emphasized the speed, safety, and effectiveness of J&J's products. (E.g., JX10201 ["One-time minimally invasive 30-minute procedure" "the only procedure of its type with 7 years of proven results—clinically proven, safe and effective"]; JX11599 at 12 ["With GYNECARE PROLIFT, pelvic floor repair can be completed in less than half the time of traditional surgery. Patients may go home the next day and may experience less pain and quicker recovery."]; JX10222 ["minimally invasive 30-minute outpatient procedure"]; PX4657 at 64 [TVT "is a lightweight mesh used in a minimally invasive, effective outpatient treatment for stress urinary incontinence (SUI)"].)

J&J also marketed mesh as providing significant lifestyle benefits to women by restoring their ability to have a fulfilling sex life and to engage in physical activity. (E.g., JX10210 at 3 ["Short recovery period and quick return to normal activities"]; JX11347 at 5 [SUI can affect … "Intimacy and social relationships"]; JX11599 at 4 ["Pelvic organ prolapse can affect a woman's daily life, limiting physical activity and sexual intimacy."] *id.* at 12 ["The procedure is designed to restore normal anatomy, which means patients can resume sexual intimacy [and] normal physical activity … "].) In many TVT advertisements, J&J would present the number of women treated with mesh slings—e.g., "over 1 million women treated"—next to study results from a different and much smaller group of women suggesting their overwhelming satisfaction with the products' effects—e.g., "97% of women surveyed … were still dry or had less leakage 11 years later [and] … were so satisfied with the treatment … they would recommend the procedure … to a friend." (E.g., JX10222 at 13; 7/22/19 Tr. 83:4-23; see also PX4668 ["over 2 million women treated… 93% of women surveyed … were still dry … 97% … would recommend the GYNECARE TVT procedure to a friend."].) Moreover, as described by Plaintiff's marketing expert Dr. Anthony Pratkanis, J&J employed various known and effective marketing tactics, like the use of vivid imagery, to deliver its message about mesh's benefits. (E.g., 07/22/2019 Tr. 84:8-89:1.)

However, while J&J's marketing vividly portrayed the benefits of the company's products, J&J misstated, downplayed, and omitted the known risks of its pelvic mesh products. J&J knew the grievous risks and also knew full well why they should have disclosed them: as Dr. Hinoul agreed, "the reason" TVT complications are described in a patient brochure "is so that patients would clearly understand these risks." (PX4820 [1/14/14 Dep. Tr.] 1493:3-1494:22.) But J&J's actual practice was different. J&J misrepresented the risks of its devices throughout its patient-directed marketing materials.

As illustrated below (and as further catalogued in the patient sections of the Violations Appendix), these misleading communications take three common forms: 1) misleadingly incomplete risks discussions; 2) misleadingly incomplete adverse events information excerpted from product IFUs; 3) referring to misleadingly incomplete IFUs for product and risk

information.[26] As with the doctor-directed marketing, the common, core deception that runs throughout all these materials is Defendant's failure to communicate all serious long-term risks that they know about to the women who might be hurt by these devices.

1. Misleading and Incomplete Risks Discussions

J&J's patient-directed marketing materials commonly contained a section or paragraph titled "What are the risks," which downplayed the risks of mesh. (E.g., JX10210 at 14; JX11599 at 14; JX4657 at 65, 72.) These sections misleadingly described the risks they listed as common to all pelvic surgeries and did not identify the risks specific to the mesh itself.

The lion's share of J&J's brochure risks sections that ask "What are the risks?" begin their answer with a variation of "all surgical procedures present some risks." (E.g., JX10210 at 14.) Language that follows continues to focus on the procedure: "Complications associated with the procedure include… ." (*Ibid.*) Some of J&J's materials provided even less indication that risks arise from the mesh, answering "What are the risks?" with "All medical procedures present risks. As with all procedures of this type, there's a risk of injury to the bladder and surrounding organs." (E.g., JX10210.)[27]

The Court heard credible testimony from Dr. Pratkanis that by emphasizing the risks of the implantation procedure, J&J's marketing minimizes the risks specific to the mesh implant itself.

---

[26] The Court heard testimony from J&J's expert witness Dr. Punam Keller that she could not conclude, from an academic marketing perspective, that J&J's marketing was likely to deceive reasonable consumers. The Court found Dr. Keller's perspective on deception irrelevant and unpersuasive on the question of whether consumers were likely to be deceived as defined by California law. For example, Dr. Keller testified that it is impossible to know if marketing is likely to deceive on its face; in her view, empirical testing is always required. (9/23/2019 Tr. 179:24-182:4; 186:28-187:20.) But California law is clear that "the primary evidence in a false advertising case is the advertising itself." (*People v. Overstock.com*, 12 Cal.App.5th at 1080; see also *Brockey v. Moore*,107 Cal.App.4th at 99 [Not "a single California case require[s] use of survey evidence in [UCL] cases"].) She also testified that, from her perspective, a consumer must actually hold a false belief for there to be a likelihood of deception. (9/23/2019 Tr. 180:25-181:7.) Again, California law is to the contrary: "[I]t is immaterial . . . whether a consumer has been actually misled by an advertiser's representations." (*Day v. AT&T Corp.*, 63 Cal.App.4th at 332; see also *Brockey v. Moore*, 107 Cal.App.4th at 99.) Dr. Keller also assumed that a "reasonable consumer" would be skeptical and questioning (9/23/2019 Tr. 237:23-28), while California law allows reasonable consumers to be credulous and does not require that consumers be suspicious or wary or that they investigate the merits of ad claims. (*Lavie v. Procter & Gamble Co.*,105 Cal.App.4th at 505-06, 508.)

[27] Dr. Pratkanis's testimony regarding discussion of risks in J&J's marketing materials involved detailed comments on four brochures that were representative of the variation in J&J's marketing materials more generally: JX10210, JX10222, JX11599 & JX11463. (7/22/2019 Tr. 89:7-103:8.) The Court found this testimony helpful and agrees that these brochures broadly represent the variation in J&J's printed marketing materials from 2008 through 2013. (See Violations Appendix.)

(7/22/2019 Tr. 96:8-17.) Moreover, the misleading nature of this language is apparent on its face. As discussed above, and as known to J&J, a pelvic mesh implant comes with risks specific to the device itself. J&J's marketing is likely to deceive because it gives the impression that the relevant risks are those of the procedure, not the mesh.[28]

Furthermore, the risk sections of J&J's patient marketing do not include the severe and potentially debilitating risks known to J&J and are thus misleading in this way as well. By purporting to provide information about the risks of its products but then leaving out significant risks specific to the mesh, J&J's communications were likely to deceive. For example, after focusing on the risks of the *procedure*, JX10222's discussion of risks mentions, "There is also a risk of mesh material becoming exposed. Exposure may require treatment." (JX10222.) A reasonable consumer would not understand from this statement that the risk of exposure is lifelong or that exposure could be recurrent—risks known to the J&J.[29] And beyond J&J's misleading characterization and downplaying of the risk of exposure, its marketing materials consistently omit entirely many of the most severe risks a reasonable consumer would want to know about—e.g., debilitating chronic pain, chronic or lifelong dyspareunia, excessive contraction or shrinkage of the tissue surrounding the mesh, urinary dysfunction brought about by the mesh. Nor would a consumer understand that mesh risks can have a delayed onset—that the risk is lifelong.

2. Referring to Misleadingly Incomplete Risk, Adverse Events, and Safety Information

The risk discussion in J&J's marketing materials frequently concluded by directing patients to refer to additional product information for "a complete description of risks." (See, e.g., JX10210 ["For a complete description of risks, see attached product information."]; JX10222

[28] A few of J&J's later materials broke this mold, answering "What are the risks?" with two separate sections titled "Risks Common to All Pelvic Surgeries" and "Complications Associated with Synthetic Mesh." (JX11463.6 [approved for use by J&J in February 2013].) Unlike the other formulations discussed above, this language would, in the words of Dr. Pratkanis, "give the consumer cues" that there are complications associated with the synthetic mesh product itself. (7/22/2019 Tr. 97:19-98:14.) But while materials like JX11463 gave some indication that mesh comes with its own specific risks, they are still misleadingly incomplete because they leave out many of the severe, chronic risks of mesh known to J&J.

[29] One particularly extreme example approved for use in 2008, JX10210, fails even to mention the risks of exposure. (JX2010.14.)

[same]; JX11621 [same]; JX11347 at 22 [patient education presentation telling consumers to "refer to [TVT] patient brochure for a complete list of benefits, drawbacks and risks associated with this procedure"]; PX4657 at 65, 69 [2010 webpage promising "[f]or a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information"]; PX4668 at 4, 5 [2013 webpage promising same].) In light of J&J's own admissions regarding the risks known to it when it launched its mesh products, the information provided was not "complete." That is, while the risks included in the referenced "product information" and "Adverse Reactions" descriptions shifted over time, none of the materials promising a "complete description of risks" actually led patients to the full set of risks known to J&J at the time of product launch. Accordingly, the Court finds J&J's frequent promise of "a complete description of risks" in their marketing to be literally false and misleading such that reasonable consumers are likely to be deceived.

3. Misleadingly Incomplete Adverse Events Information Excerpted from Product IFUs

Finally, J&J's patient-directed marketing directly excerpted adverse event and other risk information from the relevant product's IFU. (*E.g.*, PX4657 at 69, 75, 78 [website excepting "Indication," "Contraindication," "Warnings & Precautions," and "Adverse Reactions" sections of IFUs]; JX11599 at 15 [POP brochure excerpting same]; JX11347 at 24 [SUI Patient Education Presentation excerpting same].) These are the same sources of risk information that other sections of J&J's material referred to as "complete." Yet, as discussed above, J&J's IFUs left out many of the risks known to J&J from the time of product launch and were likely to deceive reasonable doctors. (See Sections V.D.1 & 2 *supra*.)[30] The reproduction of this same information in patient-directed materials was likewise misleadingly incomplete. This tactic of selective disclosure of risk information is found throughout J&J's patient marketing. (See Violations Appendix; 7/22/2019 Tr. 6:10-18.) The Court finds it was likely to deceive a reasonable consumer.

[30] Ethicon's own officers have confirmed that their IFUs were not complete. (PX4761 [7/19/13 Arnaud Dep. Tr.] 125:15-126:06 [testifying that "most of the risk, the risks that are significant, we knew them" at the time of launch]; PX4808, 11/13/15 Tr. 307:23-308:03 [Dr. Weisberg testifying it would have been "feasible" to issue complete risk warnings at time of launch].) And, of course, J&J's mesh IFUs could not have been complete before 2015 because their lists of adverse reactions were substantially expanded that year. (8/5/19 Tr., at 40:11-26.)

The testimony of Jo Huskey illustrates J&J's misleading marketing operates the way it was intended—to create interest and demand for a medical procedure in a woman who wasn't otherwise looking for a treatment. Ms. Huskey testified that a brochure in her doctors' office featuring Bonnie Blair piqued her interest in mesh as a treatment option; it made her believe that TVT did not "interfere with [Blair's] lifestyle" and thus "would be perfect" for stopping her stress urinary incontinence because Ms. Huskey too was athletic. (7/22/19 Tr. 115:10-116:5; JX10210). The brochure Ms. Huskey consulted directed patients to a "complete description of risks," extracted from the IFU, which included *only* complications related to surgery generally and surgical technique, not the device itself. (JX10210 ["Punctures or lacerations . . . may occur during instrument passage"; "improper placement of the TVT device may result in incomplete or no relief"].) When asked whether anything in the ad "gave [her] any concern or pause about the procedure," Ms. Huskey explained:

> No. Because like I said, one-time, minimally invasive 30-minute procedure. The rest sold me, okay, now I need to ask [my doctor] because she's going to be the one doing the job. (*Id.* at 115:26-116:5.)

As a result of J&J's deceptive brochure, she followed up with her doctor and had the mesh implanted. As a result, she suffered severe chronic pain and dyspareunia that cost her the ability to work, physical activity and her sex life. (07/22/2019 Tr. 121:2-122:11; 122:10-14; 122:15-18.) None of the complications Ms. Huskey experienced were disclosed in the ad (JX10210). She did not know this could happen to her when she took further steps to seek treatment. And neither would any woman who read this brochure—because this information isn't there. The Court therefore concludes that patient directed materials (catalogued in the Violations Appendix) that failed to provide the complete risks known to the company were similarly likely to deceive and therefore violates the UCL and FAL.

4. As a Matter of Law, J&J's Deceptive Marketing Cannot Be Cured By Patients' Discussions With Their Doctors

J&J contends that its marketing's presentation of risks is not misleading because its brochures directed patients to speak with their doctors and because patients must give informed consent before mesh is implanted. This defense fails as a matter of law.

Courts have consistently held that violations of the UCL or FAL cannot be undone by later disclosures or further explanation. (See, e.g., *Prata v. Superior Court* (2001) 91 Cal.App.4th 1128, 1134, 1145-46 [deceptiveness of bank's advertising that its interest-charging loan program was the "Same-As-Cash" was not negated by instruction to consumer to "ask for details"]; see also, *Chern v. Bank of America* (1976) 15 Cal.3d 866, 876 [bank violated the UCL and FAL by advertising loan as having interest calculated "per annum"; court held that later disclosure that bank used 360 day year instead of 365 day year did not cure the UCL violation"]; *Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159 [fine print stating serving size was two vitamins did not cure the UCL violation of deceptively naming and labeling vitamin "One A Day"]; *Chapman v. Skype Inc.* (2013) 220 Cal. App. 4th 217, 228 [same, where defendant advertised calling plan as "unlimited" and disclosed restrictions on "unlimited" plan in a separate policy].) Simply put, if a company cannot cure its own deception with further disclosures, it cannot rely on the mere possibility that a third-party doctor will do so.[31]

Moreover, as the California Court of Appeals has noted, lay Americans have learned to "rely not only upon their personal physicians and organizations like the American Medical Association, but on pharmaceutical companies whose closely regulated research, production, and merchandising have taken the place of expertise the average citizen is unable to develop." (*Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159.) Consumers expect responsible advice from the reputable companies "we entrust daily not just with goods and services but with our lives" (*Ibid.*), because under California law, "consumers of all kinds are entitled to be credulous; the reasonableness standard does not require that targeted consumers be suspicious or wary or that they investigate the merits of advertising claims." *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 505-506, 508.

---

[31] J&J's expert witness Dr. Keller testified that, from her academic marketing perspective, one must take into account what consumers may learn about a product from their doctors. (9/23/2019 Tr. 213:6-21; 215:6-25.) However, for the reasons above, the Court finds this testimony unpersuasive: California law does not allow a business to cure deception by way of later (third-party) disclosure. Indeed, the violation of the law is complete once the business has circulated the deceptive material. (*People v. JTH Tax* (2013) 212 Cal.App.4th 1219, 1255.) Finally, Dr. Keller admitted that she is not qualified to opine on what doctors tell patients about J&J's mesh products (9/23/2019 Tr. 217:9-12), and the evidence in this case has shown that doctors too were deceived about the risks of J&J's products.

And as discussed above, while patients must speak with their doctors before getting mesh implants, J&J's deceptive marketing, including their misleadingly incomplete IFUs, rendered it highly unlikely that doctors would be able to provide the information necessary to inform and counsel their patients. For instance, Ethicon Medical Director Dr. Meng Chen, raised concerns about the ability of doctors to adequately consent patients several times, including in December 2008, when she highlighted her concern that patients were receiving inadequate pre-operative consent (PX0898) and noted that:

> Our post-market knowledge with [the TVT products] are much more than what we have in the IFUs of all three types of TVT . . . . Thorough pre-operative consent is one of 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 [sic] the current knowledge . . . on the potential adverse reactions.

(*Id.* [emphasis added]; see also, 7/31/19 Tr. 41:23-42:3 ["Q: . . . [A]n up-to-date IFU is important for patient consent? A: Indirectly, yes."]) The Court therefore finds that there is neither a legal nor factual basis to accept J&J's argument that doctors would have cured J&J's patient-directed deceptive marketing. For the reasons set forth above, the Court finds Defendants' patient-directed materials likely to deceive reasonable lay consumers.

G. Defendants' Deceptive Marketing Messages Were Likely to Deceive Doctors

1. Doctors are Likely to be Deceived by the IFU and Other Manufacturer Marketing Materials

Based on the testimony presented, the Court concludes that doctors do read the IFU and use manufacturer marketing material as a source of information in making treatment decisions. For the below reasons, the Court therefore concludes that doctors were likely to be deceived by J&J's deceptive marketing, both in the IFUs and throughout their other marketing materials.

Testimony from J&J's witnesses support the Court's conclusion that J&J's marketing practices had the capacity to impact doctor decision-making. Dr. Nager testified that he gave a presentation to doctors that identified "Marketing, Marketing, Marketing" as driving the use of POP mesh kits among doctors. (8/20/19 Tr. 167:22-26.) He also described how the manufacturers influenced doctors' patient-care choices through their advertising practices, such as journal ads

and sales representatives who would market mesh kits. (8/20/19 Tr. 167:24-168:10 ["Q. Did you feel that industry marketing of pelvic floor mesh kits was driving the use among doctors? A. I do. Q. How so? A. There were advertisements about the available mesh kits to treat pelvic organ prolapse. It was, you know, present in our journals and was present by representatives that would go to physicians' offices and market the mesh kits."].)

The Court further concludes that the IFU played a central role in J&J's deceptive marketing. Contrary to J&J's trial position, the company testified prior to trial in their discovery responses that "[o]ne of Ethicon's primary means for distributing printed information about its medical devices was by including such information with or alongside the medical devices themselves. In particular, instructions for use ("IFUs") were included in the packaging of each Ethicon mesh product." (PX4594 [Response to Special Interrogatory No. 6].) Testimony from company witnesses confirmed that J&J expected doctors to read and rely on the IFU. Although Dr. Hinoul attempted to diminish the importance of the IFU at trial by testifying that they get thrown in the garbage can (8/8/19 Tr. 25:27-26:1), his prior company testimony, to which the Court lends more weight, established that J&J "expect[ed] that doctors will rely on the statement in the IFU as to warnings, complications, adverse events, and rely on that information in counseling patients." (PX4820 [1/14/14 Dep. Tr.] at 1207:5-1208:22 ["I am in full agreement, the surgeon should be able to solely rely on the IFU. Absolutely."].)

While the Court heard testimony from J&J's witnesses that the IFU is not a primary source of information for doctors and was largely thrown away, the Court did not find this evidence persuasive in light of the substantial evidence to the contrary. Dr. Weisberg, Ethicon's Medical Director, testified that he "read the IFU for every product he used," that he did so "to learn about the product," and to "understand the complications or adverse events so [he] could properly communicate and warn [his] patients." (PX4808 [8/09/13 Dep. Tr.] at 664:5-9 667:13-17.) The Plaintiff's expert witness, Dr. Rosenzweig, testified that he reviewed the IFUs during Ethicon's trainings on the Prolift, TVT, and TVT-O. (7/22/9 Tr. 19:20-20:20.) The People's expert witness, Dr. Margolis, testified that he reviews IFUs in his practice and teaches his residents, fellows, and colleagues to do the same. (7/29/19 Tr. 91:14-93:8.) J&J's expert witness, Dr. Nager, testified

that he likely has reviewed IFUs in the past, including the adverse events section, and believes that some doctors do read the adverse events section of the IFU while others do not. (8/20/19 Tr. 109:11-18; 112:15-19.) Dr. Kahn, a third-party fact witness called by J&J, testified that he kept the TVT "package insert" and three other documents which contained adverse reactions information from the IFU in his file and used all four of these documents to learn about the TVT. (8/21/19 Tr. 148:25-149:4, 149:18-24, 152:24-153:1, 154:6-20, 155:18-156:8, 156:20-157:3; 160:19-161:19, 165:8-166:6, 166:17-18; PX4692 [TVT Package Insert in Dr. Kahn's TVT folder]; PX4688, PX4689, and PX4696 [Gynecare TVT brochure, 1999 Ulmsten article, and 1999 Olsson article, respectively, in Dr. Kahn's TVT folder with excerpted adverse events from IFU].) Dr. Douglas Grier, another third-party fact witness called by J&J and a paid preceptor for J&J for over 15 years on their pelvic mesh devices, testified that he has talked to and trained other doctors, including California doctors, on adverse events from the TVT IFU. (8/22/19 Tr. 4:23-5:2, 22:4-10, 116:13-18, 118:12-28, 159:3-160:10, 162:13-27.)

Based on the above and other evidence at trial, the Court therefore concludes that doctors are likely to read and be deceived by the IFU. The Court also notes that the IFU information is not limited to just the printed version of the IFU that is included in every device box, but also available on J&J's website and distributed through sales representatives who were also trained to discuss IFUs with physicians. (See 7/24/19 Tr. 11:7-18 [sales reps are trained on IFUs and IFUs can be downloaded from the Ethicon website], 12:25-13:7 [sales reps were trained to "direct physicians to the IFU for information about risks and complications"]; PX4807 [9/6/17 Dep. Tr. of Scott Jones] 387:07-388:10 [IFU was "available on our website"]; 437:04-438:02 [sales reps "could have pointed [physicians] to whatever risks, warnings, precautions we had" in the IFU labeling].)

2. *Denstply* Does Not Apply

The Court concludes that doctors were likely to be deceived by J&J's deceptive marketing, despite J&J's reliance on *Patricia A. Murray Dental Corporation v. Dentsply International* (2018) 19 Cal.App.5th 258.

Dentsply involved two dentists who alleged that the dental scaler device at issue was falsely marketed as suitable for "[p]eriodontal debridement for all types of periodontal diseases" because it emitted a non-sterile stream of water. (*Id.* at p. 261.) The question before the court in *Dentsply* was straightforward: whether dentists knew or should have known that a device hooked up to their office waterlines (which are not sterile) would not emit sterile water. While simple common sense alone would have been sufficient to provide the answer that everyone, not just dentists, are aware that tap water that comes out of their faucets is not sterile, the court was also able to point to a "vast amount of evidence" showing that the dental profession had known for years that waterlines could pose an infection risk; it also found "not credible" the plaintiffs' testimony that they believed the scaler emitted sterile water. (*Id.* at pp. 266-67, 273-74). Unlike in *Dentsply*, there is no basis to conclude that mesh-specific risks are generally known to the gynecologists, urologists and urogynecologists that J&J targeted with their marketing. As discussed below, the evidence at trial has shown that (1) highly qualified doctors testified that they do not know the mesh-specific risks that the company knew about from launch; (2) the biomaterial properties of polypropylene mesh and how they lead to complications are not within the baseline medical knowledge of reasonable doctors; and (3) there is no uniform source of information on device-specific risks except from the manufacturer's IFU.

3. Mesh-Specific Risks Are Not Generally Known or Obvious to Doctors

The Court rejects J&J's argument that it cannot be liable for hiding serious and long-term mesh risks in its IFUs and marketing materials because doctors already knew these risks. First of all, as discussed above in Section V.D.1, J&J knew that it was required to include all risks reasonably associated with the device in the IFUs, whether already known to doctors or not. In 2017, Dr. Hinoul also gave sworn testimony on behalf of the company that J&J did not decide to leave out complications in the IFU just because they felt it was known to doctors. (PX4820 [5/13/17 Dep. Tr.] at 601:11-18.) Dr. Robinson agreed that "a complication . . . should go in the IFU even if it's well-known" if that complication "doesn't occur without the product" and if "its frequency and severity have implications for risk benefit and unique to the product[.]" (PX4819

[10/12/17 Dep. Tr.] 241:9-19.) Dr. Weisberg testified that the company, in writing an IFU, did not assume that a doctor would figure out the risks of their products on their own. (PX4850 [11/13/15 Dep. Tr.] at 131:11-131:20 ["Q. Is it your understanding that in the IFU that if there's a potential significant risk to a patient, that if you assume that a physician would figure that out on their own, there's no need to mention it in the IFU? Is that your understanding in terms of how the IFU is prepared? A. No. If we're aware of a significant risk that might occur, it should be listed."]) Thus, the evidence demonstrates that J&J did not base their omission of mesh-related risks from the IFU and other marketing materials on the assumption that doctors already know.

Second, the testimony in this case clearly establishes that many reasonable doctors, in California and elsewhere, did not know the risks associated with J&J's mesh devices. The Court heard from several not just reasonable, but highly qualified doctors whose testimony established that they did not know that serious long-term risks such as chronic pain, dyspareunia, chronic groin pain were specific to or resulted from the mesh, despite the fact that these risks were well-known to the company from launch. Dr. Charles Nager, a Female Pelvic Medicine and Reconstructive Surgery (FPMRS) specialist (i.e., urogynecologist) who teaches and practices at the University of California, San Diego, testified that he understands that the only risks specific to the mesh, as opposed to the risks of the surgical procedure itself, are erosion and exposure. (8/20/19 Tr. 122:8-11 [Dr. Nager].) J&J's third-party witnesses Dr. Bruce Kahn, a urogynecologist at Scripps La Jolla, and Dr. Felicia Lane, a FPMRS specialist and OB/GYN at UC Irvine, each testified that they had a similar understanding of mesh risks:

> Q. You testified yesterday that the specific risks related to the mesh itself, as opposed to the procedure, are mesh exposure and mesh erosion, correct?
> A. That's correct.
> (8/20/19 Tr. 122:8-11 [Dr. Nager].)

> Q. Now, as opposed to the risks that come from the pelvic surgery, the risks that are specific to the mesh itself are erosion and exposure, correct?
> [. . .]
> A. So erosion, extrusion, exposure, mesh-related complications, yes.
> Q. And that's it, right?
> A. That's correct.
> (8/26/19 Tr. 164:21-165:3 [Dr. Lane].)

> Q. And so for the risks that are specific to the mesh itself, it's your understanding that those are erosion and exposure only, correct?

A. I believe that that's what I testified in my deposition. And I stand by that statement.
Q. And that applies to mesh slings, right?
A. Yes.
Q. And POP mesh kits?
A. Yes.
(8/21/19 Tr. 146:5-13 [Dr. Kahn].)

These California physicians—Dr. Nager, Dr. Kahn, and Dr. Lane—also testified that they in turn have taught hundreds of other doctors that the specific risks associated with pelvic mesh devices consist only of exposure and erosion. (8/20/19 Tr. 122:12-23 [Dr. Nager]; 8/21/19 Tr. 18:4-12, 17:27-18:3 [Dr. Kahn]; 8/26/19 Tr. 128:2-18, 130:2-8, 152:17-22 [Dr. Lane].)

Out of the three groups of doctors to whom J&J marketed its pelvic mesh devices—gynecologists, urologists, and urogynecologists/ FPMRS specialists—the urogynecologists are usually the most highly trained and specialized. Witnesses at trial—both Plaintiff's and J&J's—testified that doctors who completed a fellowship in FPMRS generally have a higher level of training and knowledge compared to general OB/GYNs and urologists. (7/25/19 Tr. 102:16-103:22 [Dr. Margolis]; 8/20/19 Tr. 120:7-121:1 [Dr. Nager]; 9/18/19 Tr. 154:21-155:9 [Dr. Rosenblatt].) Dr. Felicia Lane, who has taught OB/GYNs and FPMRS fellows, agreed that FPMRS specialists "will have additional expertise" with regard to "the risks and complications of mesh surgery" as compared to a generalist OB/GYN. (8/26/19 Tr. 168:24-169:17.) Therefore, based on the testimony of these witnesses, the evidence at trial showed that reasonable doctors—even those with a higher level of training—did not know the full range of risks and complications specific to J&J's pelvic mesh devices and were likely to be deceived by J&J's deceptive marketing.

Third, there was substantial evidence presented at trial that just because an article is in the published literature doesn't mean all doctors read it. In other words, like medical education, the literature is a variable source of information, meaning that what any practicing doctor knows depends on what and how many articles they make time to read while conducting a busy practice. There is no uniform or universal requirement as to which articles OB/GYNs must read (7/29/19 Tr. 124:5-13 [Dr. Margolis]), and J&J offered no evidence to the contrary. Moreover, an internal company document demonstrates J&J's knowledge of an obvious point—that doctors "are very

busy people—it can be difficult for them to stay current with all of the new literature that is published." (PX0191, at 15.)[32]

J&J's expert witnesses also confirmed that just because something is published doesn't mean all reasonable doctors have read it. As Dr. Rosenblatt—a veteran consultant/preceptor for many mesh manufacturers—testified, he did not become aware of a medical text on mesh complications co-authored by Dr. Shlomo Raz, a renowned specialist in treating mesh complications and in the field of urology and urogynecology (7/25/19 Tr. 120:27-121:15 [Dr. Margolis]), until more than four years after it was published. (9/19/19 Tr. 13:5-10.) Finally, Dr. Eilber agreed that "the vast majority of mesh studies on PubMed were not relevant to outcomes and complications of transvaginal mesh for POP and SUI." (9/24/19 Tr. 154:23-27.) She further agreed that "**as a result of there not being enough large scale, high-quality studies, the true complication rate after transvaginal mesh insertion is unknown.**" (9/24/19 Tr. 158:15-158:23 [emphasis added].)

4. Reasonable Doctors Depended on Defendants to Provide the Full Range of Mesh-Related Complications

The evidence at trial confirmed that reasonable doctors depended on J&J to provide comprehensive risks and complications information associated with their devices. J&J's TVT and Prolift devices were considered novel when they were launched on the market in the late 1990s and mid-2000s. J&J presented testimony that before the company introduced the TVT to the market in 1998, only a very few specialists were performing pelvic floor surgeries using mesh. (8/8/19 Tr. 25:8-10; 8/12/19 Tr. 18:26-19:16.)

As a result, the majority of the doctor witnesses who practice pelvic floor surgery did not learn how to implant J&J's pelvic mesh devices during medical school or residency and depended on the company to teach them about the mesh devices and how to implant them. (7/16/19 Tr.

[32] The People's expert witnesses, Dr. Rosenzweig and Dr. Margolis, also testified that reasonable doctors would not necessarily read all of the literature in their own field, and would have no reason to review literature that is outside their field, such as literature about hernias and on biomaterial sciences, or in journals they do not subscribe to. (7/22/19 Tr. 25:24-27:3 [Dr. Rosenzweig]; 7/29/19 Tr. 124:14-16, 124:22-125:17 [Dr. Margolis]; 7/30/19 Tr. 163:22-164:18 [Dr. Margolis].) And as several witnesses testified, most of the developed literature on mesh complications was in hernia literature. (7/18/19 Tr. 73:7-17 [Dr. Rosenzweig]; 8/1/19 Tr. 18:20-19:2 [Dr. Iakovlev]; PX4761, 11/15/12 Tr. 58:2-14 [Dr. Arnaud].)

35:11-24, 36:23-37:22 [Dr. Rosenzweig]; 7/22/19 Tr. 19:20-20:20 [Dr. Rosenzweig]; 7/29/19 Tr. 77:24-78:4 [Dr. Margolis]; 8/20/19 Tr. 29:2-4 [Dr. Nager]; 8/21/19 Tr. 30:2-17 [Dr. Kahn]; 8/22/19 Tr. 115:2-16 [Dr. Grier; 9/17/19 Tr. 73:6-16, 106:16-107:14 [Dr. Rosenblatt].) The Court infers that the same is likely true of many physicians practicing today. Three of J&J's witnesses—Dr. Nager, Dr. Grier, and Dr. Rosenblatt—were also paid preceptors for J&J who trained other doctors on how to implant J&J's pelvic mesh products, and used J&J slides and talking points when presenting to other doctors. (8/20/19 Tr. 117:3-10 [Dr. Nager]; 8/22/19 Tr. 21:2-18, 22:4-10, 98:6-20, 101:8-28 [Dr. Grier]; 9/18/19 Tr. 178:18-24, 179:21-180:3, 181:9-16 [Dr. Rosenblatt].)

Moreover, a comprehensive understanding of the biomaterial properties of mesh and their associated risks is not within a reasonable doctor's baseline medical education and training. As Dr. Margolis testified, the study of biomaterial sciences is the study of how certain materials behave in the body, and is different than the study of medicine, which focuses on anatomy, physiology, the diseased state, and treatment. (7/29/19 Tr. 73:28-75:18.) For this reason, as Dr. Margolis explained, doctors rely on the manufacturer's knowledge of the biomaterial properties of the device. (7/29/19 Tr. 76:23-77:18.) In the Moalli article on the "Tensile properties of five commonly used mid-urethral slings relative to the TVT" that Dr. Rosenblatt, J&J's expert relied on as a basis for his opinions (9/19/19 Tr. 112:9-19), the authors described doctors' state of knowledge regarding mesh properties as follows:

> The quality of the host tissue and the technique of sling placement also contribute to these complications; however, these factors are well known to most surgeons. **It is knowledge of the properties of the sling material that surgeons have the greatest knowledge deficit and consequently are completely dependent on the mesh information supplied by a representative of the vendor.** Even more problematic is that many of the representatives have little knowledge of biomechanical factors that may be relevant and tend to focus on aspects of the sling which facilitate the operation for the surgeon."

(9/19/19 Tr. 112:9-25, 113:24-114:1, 114:11-115:7 [Dr. Rosenblatt] [emphasis added].)

While J&J's witnesses testified about the various sources of information available to doctors other than the manufacturer, the testimony at trial confirmed, that the degree to which these sources actually inform them of mesh risks and complications varies from doctor to doctor.

(See, e.g., Tr. 9/24/19 Tr. 135:9-16 [Dr. Eilber].) For example, J&J's expert Dr. Eilber testified that residents get "the majority" of information about the risks of medical devices from their professors; that what they are taught "will depend on the knowledge of the professor;" that the surgical procedures they learn will depend on their mentors; and that the mesh complications they learn will depend on, to a degree, what their professors teach them. (9/24/19 Tr. 116:20-116:28, 118:19-118:22, 135:9-16.) As Dr. Eilber explained, the ACGME medical curriculum for educating urology residents does not include a requirement to teach residents about any particular mesh sling or POP mesh complications. (9/24/19 Tr. 133:8-135:8.)

Based on the weight of the evidence described above, the Court concludes not all doctors know the risks of mesh and *Dentsply* does not apply to the facts of this case. To the contrary, the weight of the evidence establishes that deceptive serious and long-term risks caused by the mesh were not obvious or widely-known among doctors. For the above reasons, the Court concludes that J&J's deceptive marketing was, therefore, likely to deceive reasonable California doctors.

5. Defendants Aggressively Promoted Their Pelvic Mesh Products To Doctors

The evidence at trial also showed that even if doctors may have ultimately learned of some mesh risks over time, it is reasonable to infer that J&J's aggressive marketing had the effect of nullifying those warnings and having a deceptive impact on doctors. The California Supreme Court has acknowledged that "an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given." *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65.) J&J engaged in many of the "overpromotion" tactics that the Stevens court describes, including "'watering down' its warnings" (see Section V.D.1-3 [IFU discussion], *supra*); placing journal advertisements that "constantly reminded physicians of the alleged effectiveness . . . without mentioning its dangers" (see e.g., JX10764 [TVT Secur journal advertisement]); "numerous personal visits to physicians by salesmen" and "encourag[ing] salesmen to counter allegations by physicians concerned over the dangers of the drug" (see, e.g., 7/24/19 Tr. 17:21-25 [Garrison testifying that sales representatives were trained on "objection

handling"]; PX2937 [TVT Abbrevo sales video]; PX4834 [Think Again video].) (*Stevens*, 9 Cal.3d at 66-67.) This is precisely the type of aggressive marketing J&J engaged in to promote their mesh products and override physician concerns, sufficient to overcome the incomplete warnings that J&J did provide to doctors.

Indeed, the evidence at trial showed that while some mesh-specific complications started coming to light as a result of the 2008 and 2011 FDA notices, J&J's marketing efforts focused on downplaying and rebutting the FDA's notices and assuaging doctors' concerns about using J&J's mesh products. For example, in the wake of the 2008 FDA notice, preceptors for J&J—including Dr. Rosenblatt and Dr. Grier—delivered presentations to doctors that communicated the message that the FDA notices did not apply to J&J's meshes. (PX4848; PX0848; JX11608; 8/22/19 Tr. 54:15-24, 60:13-22 [Dr. Grier testifying the purpose of JX11608 was to show "there's differentiation between these different products"]; 8/14/19 Tr. 128:22-129:7 [Dr. Fugh-Berman].) Internal company documents show that J&J trained sales representatives to "tell the mesh differentiation story." (PX0125; 7/24/19 Tr. 116:3-19, 117:4-118:6 [Michelle Irvin Garrison]; see also PX0968 [internal email instructing sales representatives not to initiate discussions with doctors about 2008 FDA notice and, if asked, to say that the risks are included in the IFUs]; PX0826 [internal email instructing sales representatives to say in response to 2011 FDA notice that risks are included in the IFUs].) After the 2011 FDA notice, J&J trained sales representatives to distribute to doctors an article entitled "Time to Rethink," authored in part by J&J's paid consultants, that challenged the FDA's 2011 concerns about POP mesh despite the company's internal knowledge about dangerous properties of mesh that can lead to severe and long-term complications. (PX0403, PX0812; 8/14/19 Tr at 106:11-28, 107:11-108:12, 109:8-24 [Dr. Fugh-Berman]; see also PX0355 [internal talking points on the 2011 FDA notice touting Nilsson and Altman studies as showing safety and efficacy of J&J's mesh].) Moreover, J&J's expert witness Dr. Eilber admitted that the 2008 FDA notice, which discussed both mesh slings and POP mesh, did not get as much attention as the 2011 FDA notice, which was only about POP mesh. (9/24/19 Tr. 147:27-149:27.) In fact, as Dr. Eilber testified, mesh use actually increased, rather than decreased, following the 2008 FDA notice. (9/24/19 Tr. 147:27-149:8.)

Based on the above, the Court concludes that J&J engaged in aggressive overpromotion tactics that downplayed the risks of mesh, nullifying negative information, and likely deceiving reasonable California doctors.

H. Defendants' Pelvic Mesh Degrades, Contrary to Their IFU Claims

J&J has known, since at least 1992, that the polypropylene material that comprises its Prolene and Prolene Soft meshes can degrade after implantation. In 1992, Ethicon scientists investigated Prolene sutures that had been implanted in dog hearts for seven years and concluded that the surface cracking on the explanted sutures was due to degradation of the polypropylene material in vivo. (DX7474 at 2.)

Based on internal company studies, Ethicon scientist and designated corporate representative Thomas Barbolt testified on behalf of the company that Ethicon knew at least since 1992 that surface cracking was the result of in vivo degradation of their polypropylene mesh. (PX4823 [1/8/14 Dep. Tr. of Thomas Barbolt] at 407:19-409:13.) Importantly, J&J knew of this surface degradation six years before the 1998 launch of their first TVT product but nevertheless has claimed from 1998 to the present, its polypropylene mesh is not "subject to degradation or weakening by the action of tissue enzymes" in all of the IFUs for its pelvic mesh products. (See Footnotes 4, 5 and 9, *supra*, listing all TVT IFUs and POP Mesh IFUs.)

In addition to the company's own knowledge and admission, the testimony of P's degradation expert, Dr. Vladimir Iakovlev, further demonstrates in vivo degradation of the Prolene material. Dr. Iakovlev, a pathologist, conducted histological studies of explanted Prolene mesh by looking at cross-sections of the mesh at high magnification under a microscope. (8/1/19 Tr. 19:25-21:10.) Dr. Iakovlev's histological studies revealed a visible cracked layer ringing the edge of the suture, which he confirmed to be degraded polypropylene because (1) the cracked layer was visible under polarized light, whereas biological material is not (*id.* at 66:26-68:27); and (2) blue dye granules were present within the cracked layer, confirming that it was dyed Prolene rather than biological material (*id.* at 70:20-72:14). Notably, Dr. Iakovlev's findings are corroborated by histological studies independently conducted by Ethicon scientists who concluded, for the same reasons and using the same methodology as Dr. Iakovlev, that the ringed

cracked layer was degraded Prolene. (*Id.* at 77:20-82:8; PX0434 at 2, 4, 27, 31 [polarized light]; PX0434 at 27, 28, 31 [presence of blue dye granules].)

Dr. Stephen MacLean, an expert for J&J, testified that he found no evidence of degradation when he used a novel cleaning method designed to strip the cracked layer away from the mesh. (9/16/19 Tr. 54:16-56:28.) The Court notes that this novel method was created by Dr. Shelby Thames, who developed it as a paid litigation expert defending J&J in cases involving pelvic mesh. (*Id.* at 161:20-163:11.) Dr. MacLean further testified that no published studies, other than Dr. Thames's own study, uses that method (*id.* at 140:9-15, 163:12-18), whereas the weight of the scientific literature on this subject uses different methodologies and concludes that mesh does degrade. (*Id.* at 18:25-35:3.)

For all these reasons, the Court credits the combined weight of the company's own internal studies, the company's own testimony, the weight of scientific literature, and Dr. Iakovlev's testimony over the lesser weight of Dr. MacLean's stand alone testimony and concludes that J&J's Prolene mesh degrades, in contradiction to IFU claims that it does not. The Court concludes that Defendants' false statements regarding degradation in the IFUs were likely to deceive and therefore violated the UCL and FAL.

VI. STATUTORY PENALTY COUNTS

In a UCL and FAL case, it is up to the Court to "determine what constitutes a violation" for the purpose of calculating penalties. (*People ex rel. Kennedy v. Beaumont Investment, Ltd.* (2003) 111 Cal.App.4th 102, 127.) There is no test or method of counting violations "applicable to all situations" (*id.* at 129); rather, "[w]hat constitutes a violation" for penalty purposes "depends on the circumstances of the case, including the type of violations, the number of victims, and the repetition of the conduct constituting the violation." (*People ex rel. Harris v. Sarpas* (2014) 225 Cal.App.4th 1539, 1566; see also *People v. JTH Tax, Inc.* (2013) 212 Cal.App.4th 1219, 1250-52 [discussing and endorsing a "case-by-case approach" to counting violations for UCL and FAL penalties].)

Regardless of the precise method the Court uses, the number of violations should be "reasonably related to the gain or the opportunity for gain by dissemination of the untruthful or

deceptive advertisement." (*People v. Sup. Ct. (Olson)* (1979) 96 Cal.App.3d 181, 198.) Examples of violation counts that have been held reasonable in other cases include the number of persons solicited by door-to-door salesmen (*People v. Sup. Ct. (Jayhill)* (1973) 9 Cal.3d 283, 288-289); the number of newspaper subscribers likely to read, respond to, or make a purchase of a good or service advertised in a newspaper advertisement (*Olson*, 96 Cal.App.3d at 198); the number of persons who spoke to a telemarketing representative (*Sarpas*, 225 Cal.App.4th at 1567); the number of persons who received deceptive marketing materials (*ibid*); and Nielsen estimates of the number of impressions associated with a television commercial (*JTH Tax*, 212 Cal.App.4th at 1254). In each case, the violation count reasonably captured the dissemination of deceptive information from which J&J stood to gain in some way.

In the present case, the Court finds it appropriate to include in the violation counts all quantifiable instances of circulation or dissemination of deceptive marketing material reasonably related to the use or sale of pelvic mesh. Notably, to the extent J&J targeted the same person repeatedly with deceptive marketing, each separate deceptive communication constitutes its own violation. (See *Beaumont Investments, supra,* 111 Cal.App.4th at 129 [rejecting the position that penalties "must always be calculated on a per victim rather than a per act basis" because "in a proper case, a *single* act in violation of regulations may constitute an unlawful business practice —a '*violation*' for which a penalty of up to $2,500 may be imposed" [emphasis original; internal quotations and citations omitted]].) Individualized proof of each violation is not required; instead, the Court may draw reasonable inferences about the number of violations committed based on the evidence presented at trial. (*Sarpas,* 225 Cal.App.4th at 1567; *see also Olson,* 96 Cal.App.3d at 198 [Noting that the number of violations may be proven by expert and circumstantial evidence, and to "require individualized proof of viewership" would be "so onerous as to undermine the effectiveness of the civil monetary penalty as an enforcement tool"].)

In the present case, the Court finds it appropriate to include in the violation counts quantifiable instances of J&J's circulation or dissemination of deceptive messages through the following means: (1) circulating IFUs; (2) circulating print marketing materials for doctors and patients; (3) hosting and driving traffic to patient-directed websites; (4) training doctors to

implant devices through professional education events; (5) deploying sales representatives to detail physicians; (6) providing to meals to physicians (both as a backdrop for physician presentations and for one-on-one conversations with sales representatives); and (7) community outreach to patients and primary care physicians, known as field marketing.

The Court concludes that each of these activities was related to either the sale or future sales of J&J's mesh devices. The print-marketing, websites, doctor trainings, sales rep detailing, and community outreach were all designed to drive future sales of the product, and thus relate to J&J's opportunity for gain. In-box IFUs were related not only to the gain from the sale of their accompanying device, but also to an opportunity for gain through future sales of the device by repeat customers.

While the evidence shows that J&J engaged in other marketing activities in addition to the above, Plaintiff presented proposed counts and requested penalties only for the subset of marketing activities for which their expert, forensic accountant Travis Armstrong, had evidence on which to base an estimated violation count. (8/6/19 Tr. 91:27-94:6 [in-box IFUs]; 74:28-75:6 [print-marketing shipments]; 146:4-147:3, 152:28-155:19, 159:7-12, 160:24-164:1 [website visits]; 80:15-24 [professional education]; 104:20-105:20, 107:20-108:12 [sales conversations]; 87:2-7 [meals]; 32:20-23, 33:7-10, 33:24-34:1, 34:15-24, 35:9-13 [field marketing].) *see also, e.g., id.* at 21:4-28, 27:24-29:5, 35:28-36:13, 47:4-52:17, 77:17-26, 83:6-83:24, 89:7-12, 96:16-98:1, 103:16-104:5, 132:14-28, 142:18-144:13, 147:4-148:26 [Mr. Armstrong discussing available and unavailable data].) The Court finds that for each of these categories, Mr. Armstrong relied on J&J's available data and evidence to draw reasonable inferences and extrapolations, make assumptions, and produce reasonable estimates or calculations of the circulation or dissemination of J&J's deceptive marketing messages. In doing so, for some of the categories, Mr. Armstrong conservatively omitted from his count certain gaps of time where the evidence shows that J&J was engaged in deceptive marketing conduct, but the incompleteness of J&J's data did not permit a calculation or estimate. (*See, e.g.*, 8/6/19 Tr. 147:4-148:26, 177:14-179:11.) The Court credits Mr. Armstrong's methodology, extrapolations, estimates and calculations and

finds that they have produced reasonable quantifications of the number of times J&J circulated its marketing materials.

As discussed above and as catalogued in the Violation Appendix, the Court concludes that J&J's IFUs and marketing materials, including websites and professional education, consistently and pervasively misled consumers about the risks of mesh devices. Though most of the untrue and misleading statements and omissions may vary across individual materials, the common theme that runs throughout all of J&J's marketing is that the company concealed from consumers the most serious and long-term risks resulting from the device. (See Violations Appendix.) The IFUs and marketing materials were all likely to deceive consumers.

The Court has also heard evidence at trial regarding the company-wide consistency of the marketing message across printed sales materials, professional education, and the content of sales representatives' verbal messaging to doctors. J&J's sales representatives, who were trained and coached to deliver the same consistent messages that pervade the company's print materials and IFUs (7/24/2019 Tr.65:3-13; PX4807 [9/5/2017 Dep. Tr. of Scott Jones]172:15-174:2, 179:21-180:6, 196:13-197:01; 8/27/19 Tr.51:3-15, 151:8-15), delivered verbal messages to doctors and other healthcare providers that were similarly deceptive as the print materials (i.e. because they failed to disclose the known serious long term risks of the device while selling the benefits). This evidence establishes that J&J's sales representatives were trained to and did convey deceptive or misleading information to the healthcare professional customers they detailed in the field, such that this Court can reasonably infer that mesh-related sales conversation gave rise to a violation. The Court also finds that J&J's mesh-related field marketing activities—which consisted of health fairs, public relations, primary care physician outreach, patient outreach, and patient education events—disseminated the same deceptive marketing messages that pervade J&J's other marketing materials, and therefore violated the UCL and FAL.

The Court finds that each circulation of J&J marketing as summed up below constitutes a violation of the UCL and FAL and warrants penalties. Additional explanations of Mr. Armstrong's methodology, the Court's reasoning, available evidence regarding violations counts, and alternate counts for UCL and FAL violations are collected in the Penalty Count Appendix.

A. In-Box Instructions for Use Circulated in California

Based on Mr. Armstrong's calculations drawn from J&J's discovery responses (PX4118-021, -022 & Ex.1), the Court finds that J&J circulated the following numbers of in-box IFUs in California during the statutory period, which violated the UCL and FAL and are subject to penalties (See Penalty Count Appendix)[33]:

- POP IFUs Distributed from Approx. Oct. 17, 2008-2012: **3,163 UCL Violations**[34]
- POP IFUs Distributed from Approx. Oct. 17, 2009-2012: **2,323 FAL Violations**[35]
- SUI IFUs Distributed from Approx. Oct. 17, 2008-Sept. 2015: **32,180 UCL Violations**[36]
- SUI IFUs Distributed from Approx. Oct. 17, 2009-Sept. 2015: **28,677 FAL Violations**[37]
- **Total: 66,343 UCL and FAL Violations**

B. Print Marketing Materials

1. Materials Sent into California from January 2012 Through February 2017

With respect to materials sent to California from January 2012 through September 2015, identifying the number of UCL and FAL violations is relatively straightforward. J&J's discovery responses (which were admitted into evidence) directly identify 8,166 materials, of which only 8,108 were marketing materials (as opposed to reprints of studies) sent into California from the beginning of 2012 onward. (PX4614 at 021-027 [Exhibit 1 to J&J's Response to the People's Special Interrogatory 6]; 8/6/19 Tr. 49:5-15.) The Court therefore finds that J&J sent 8,108

---

[33] J&J's device sales figures capture only annual sales numbers, so in order to account only for devices and IFUs sold in the last two months of the year, the Court will divide the total sales for 2008 (in the case of the UCL) and 2009 (in the case of the FAL) by six. (*Cf.* 8/6/2019 Tr. 94:7-14 [forensic accountant's testimony that one could estimate the last three months of the year by dividing by four].)

[34] Based on J&J's discovery responses, Mr. Armstrong testified to the following POP IFU circulation numbers for 2008 to 2012: 942 (2008), 820 (2009), 850 (2010), 935 (2011), 401 (2012). (8/6/19 Tr. 93:20-94:6.) The Court reached its total violation count as follows: (942 / 6) + 820 + 850 + 935 + 401 = 3,163.

[35] The Court reached its total violation count as follows: (820/6)+850+935+401=2,323.

[36] Based on J&J's discovery responses, Mr. Armstrong testified to the following SUI IFU circulation numbers for 2008 to 2015: 3,644 (2008), 3,475 (2009), 3,180 (2010), 4,512 (2011), 4,026 (2012), 3,685 (2013), 3,156 (2014), 2,832 (2015), 3,088 (2016), 3,183 (2017), 436 (2018). (8/6/2019 Tr. 92:12-93:19.) The Court reached its total violation count as follows: (3,644/6) + 3,475 + 3,180 + 4,512 + 4,026 + 3,685 + 3,156 + 2,832 + 3,088 + 3,183 + 436 = 32,180.

[37] The Court reached its total violation count as follows: (3,475/6) + 3,180 + 4,512 + 4,026 + 3,685 + 3,156 + 2,832 + 3,088 + 3,183 + 436 = 28,677.

deceptive printed materials into California between January 2012 and September 2015, which violated the FAL and UCL and are subject to penalties.

- **Printed Marketing Materials Sent to California for Distribution Jan. 2012-Sept. 2015:**
  - 8,108 UCL Violations
  - 8,108 FAL Violations
  - **Total: 16,216 UCL and FAL Violations**

2. Materials Sent into California from 2008 through 2011

To construct an estimate of the number of print materials shipped into the state of California, Plaintiff's expert Mr. Armstrong had to extrapolate sales representative Jason Logan's ordering patterns to other California sales representatives by averaging his periodic orders out into a monthly rate and calculating the total orders that would have been placed by other full-time sales representatives if they ordered at the same average pace. (8/6/19 Tr. 52:5-25, 59:26-2, 62:18-63:4, 66:1-25.) The materials ordered by Mr. Logan are identified in the Violations Appendix with one (*) or (***) asterisks. (See Penalty Count Appendix.)

The Court adopts Mr. Armstrong's estimate that California sales representatives ordered the following numbers of printed marketing materials shipped into California during the statutory period (8/6/2019 Tr. 74:28-75:6), which violated the UCL and FAL and are subject to penalties:

Print Marketing Materials Violations From 2008 to 2011										
Year	**Post-Oct. 17, 2008**		**Post-Oct. 17, 2009**		**2009**		**2010**		**2011**	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	579[38]	-	-	2717[39]	16,300	-	6,992	6,992	9,298	9,298
Total	**52,176 UCL and FAL Violations**									

C. Telephone Orders of Print Materials

In addition to the print marketing materials Defendants disseminated through their California sales representatives, Defendants also sent pelvic mesh brochures directly to California

[38] The Court divided by six Mr. Armstrong's estimate of California sales representatives' total 2008 orders (3,473) to reach the UCL violations count (3,473 / 6 = 579). (8/6/2019 Tr. 74:28-75:6; *cf.* 8/6/2019 Tr. 94:7-14.)

[39] The Court divided by six Mr. Armstrong's estimate of California sales representatives' total 2009 orders (16,300) by six to reach the FAL violations count (16,300 / 6 = 2,717). (8/6/2019 Tr. 74:28-75:6; *cf.* 8/6/2019 Tr. 94:7-14.)

healthcare providers who requested them through the 1-888-GYNECARE hotline. (8/6 Tr. 96:7-99:4; see also PX0003 [redacted copy of Defendants' 1-888-GYNECARE call logs]; PX0004 [additional redacted 1-888-GYNECARE call logs].) Defendants' call logs only sometimes indicated the number of brochures ordered by and sent to California healthcare providers. (8/6 Tr. 97:27-98:3.) The call logs directly identified the number of brochures requested in five orders during the statutory period totaling 1,075. (8/6 Tr. 99:5-100:7.) Those orders, in which the number of brochures were specified, are as follows:

- 2009 Orders:
  - **100 brochures** (100 Prolift brochures, PX0003-036 & -041 [first row indicates number of brochures ordered]) ordered on 09/03/2009 by Ms. [Redacted] Physician Assistant at "UCSF STANFORD HLTH CARE" (*See* PX0003 [complete data for this call contained in first row of pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046].)[40]
  - **200 brochures** (200 TVT brochures, PX0003-137 & -150 [forth row from the bottom indicates number of brochures ordered]) ordered on 09/23/2009 by Ms. [Redacted] Physician Assistant at Kaiser Stockton Hammertown West OB/GYN (*See* PX0003 [complete data for this call contained in the fourth row from the bottom on pages -059, -072, -085, -098, -111, -124, -137, -150, & -163].)[41]
- 2010 Order:

[40] Because Defendants housed their call logs in large spreadsheets, when redacted and printed, the columns with various information about a single call (caller's name, institution, brochure orders, etc.) spread across several pages. However, the consistent ordering of these documents' pages makes it straightforward to reconstruct the details of each call, even from the redacted copies. In order to recreate the spreadsheet, one would line up from left to right pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046. Then, by looking at the first row of that paper "spreadsheet," one would see all of the relevant data for that first call. The second row would provide the relevant data for the second call and so forth. Complete data for the next set of calls appears in the following pages of PX0003, again, aligned left to right: -002, -007, -012, -017, -022, -027, -032, -037, -042, & -047. This five-page pattern repeats until page -050.

[41] PX0003 pages -051 through -167 contain data for additional calls arranged similarly but in groups of 13 pages, rather than five pages. Thus, data for the calls initially listed in page -051 corresponds to additional columns on pages -064, -077, -090, -103, -116, -129, -142, and -155. The same repeated pattern holds for calls initially appearing on pages -052 through -063.

- **400 brochures** (300 English and 100 Spanish TVT brochures, PX0003-036 & -041 [ninth row indicates number of brochures ordered]) ordered on 12/07/2010 by Ms. [Redacted] Other at Urogynecology Consultants in Sacramento (*See* PX0003 [complete data for this call contained in ninth row of pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046].)

•2011 Orders:

- **175 brochures** (150 English and 25 Spanish TVT brochures, PX0004-011 & -013 [sixteenth row indicates number of brochures ordered]) ordered on 10/18/2011 by Ms. [Redacted] INQ-LPN at Mercy Medical Group in Sacramento (see PX0004 [complete data for this call contained in sixteenth row of pages -0001, -003, -005, -007, -009, -011, -013, & -015].)[42]
- **200 brochures** (100 English and 100 Spanish TVT brochures, PX0004-011 & -013 [sixth row indicates number of brochures ordered, *id.* at -007 [sixth row indicates TVT product]) ordered on 04/20/2011 by Ms. [Redacted] Other at Woodland Healthcare (see PX0004 [call data contained in sixth row of pages -0001, -003, -005, -007, -009, -011, -013, & -015].)

Mr. Armstrong used those five orders along with another earlier order to estimate the number of brochures requested and sent for calls in which the number of pelvic mesh brochures was not stated explicitly. (8/6 Tr. 98:11-100:16 [describing method for arriving at estimate of 196 brochures per order when specific number ordered not stated in call logs].) The resulting additional estimated orders for 2009-2011 are 979 in 2009, 1,175 in 2010, and 1,563 in 2011. (8/6/2019 Tr. 101:6-18.)

Because Defendants' pelvic mesh brochures contained the same pervasive misrepresentations, each brochure sent to California healthcare providers via the 1-888-

[42] PX0004 is a shorter document with only two pages per set of columns. To recreate this spreadsheet, one would line up from left to right pages -001, -003, -005, -007, -009, -011, -013, and -015. Then under those pages, one would line up left-to-right pages -002, -004, -006, -008, -010, -012, -014, and -016.

GYNECARE hotline constitutes an additional violation of the UCL and FAL. The Court finds the following violations: [43]

- **1-888-GYNECARE Brochure Orders UCL Violations 2009-2011**
  - **2009: 1,279 UCL Violations**[44]
  - **2010: 1,575 UCL Violations**[45]
  - **2011: 1,938 UCL Violations**[46]
- **1-888-GYNECARE Brochure Orders FAL Violations 2010-2011**
  - **2010: 1,575 FAL Violations**[47]
  - **2011: 1,938 FAL Violations**[48]
- **Total: 8,305 UCL and FAL Violations**

D. Online Advertising and Website Visits

In order to estimate the number of visits to mesh-related PelvicHealthSolutions.com subpages by California consumers, Mr. Armstrong used "click-through" data from J&J's online advertising campaigns to estimate the percentage of overall PelvicHealthSolutions.com visitors that viewed mesh-related content.[49] He then used two different approaches to further estimate the

---

[43] While Defendants' call logs reflect brochure orders in 2008 and 2009, in order to ensure compliance with the statute of limitations, People only ask to count as violations of the UCL brochures ordered via 1-888-GYNECARE from 2009 through 2011. Similarly, the People only ask to count as violations of the FAL brochures ordered via 1-888-GYNECARE in 2010 and 2011.

At trial, Mr. Armstrong testified that that total number of brochures sent to California via 1-888-GYNECARE, including both estimates and known order quantities, was 4,992. (8/6 Tr. 101:15-18, see also *id.* 99:23-100:7 [identifying 1,075 brochures in known-quantity orders], 101:6-18 [estimating 3,917 additional brochures, which sums with 1,075 to equal 4,992].) The People's violation counts are lower because they exclude a single 2008 order in the case of the UCL and 2008 & 2009 orders in the case of the FAL. Moreover, at trial Mr. Armstrong provided an estimate of 1,563 for the number of brochure orders in 2011 for which the actual number was unstated in Defendants' call logs. (8/6 Tr. 101:6-18.) Mr. Armstrong's other testimony (additional estimates and the total of all estimates) indicate the 2011 number was in fact 1,567. (*Ibid.*) Nevertheless, the People rely conservatively on the lower of these two numbers.

[44] The Court's math is as follows: 300 brochures identified in call logs (see PX0003-036, -041, -137 & -150) + 979 additional brochures estimated by Mr. Armstrong (8/6/2019 Tr. 101:6-18) = 1,279 violations.

[45] The Court's math is as follows: 400 brochures identified in call logs (see PX0003-036 & -041) + 1,175 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,575 violations.

[46] The Court's math is as follows: 375 brochures identified in call logs (see PX0004-011 & -013) + 1,563 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,938 violations.

[47] The Court's math is as follows: 400 brochures identified in call logs (see PX0003-036 & -041) + 1,175 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,575 violations.

[48] The Court's math is as follows: 375 brochures identified in call logs (see PX0004-011 & -013) + 1,563 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,938 violations.

[49] (8/6/19 Tr. 144:28-145:9, 145:17-146:3, 151:1-153:19, 153:28-154:10.)

number of those visitors located in California: one relying on California's share of the national population, and the other based on California's share of Defendant's total national sales of mesh products. (8/6 Tr. 144:28-145:16.) While the Court finds that these are both reasonable methodological choices, the absence of any evidence suggesting that SUI or POP disease rates are different in California than in other parts of the country militates in favor of the population analysis. The Court therefore adopts Mr. Armstrong's population-based estimate that 29,011 California-based visitors viewed the mesh-related subpages of PelvicHealthSolutions.com during the statutory period. (8/6/2019 Tr. 146:13-27.) (See Penalty Count Appendix.)

Relying on Mr. Armstrong's estimates based on California's proportional share of the national population, the Court finds the following numbers of visits by California consumers to mesh-related PelvicHealthSolutions.com subpages, which violated the UCL and FAL and are subject to penalties:

PelvicHealthSolutions.com Violations Based on Population Method										
Year	**Post-Oct. 17, 2009**		**2009**		**2010**		**2011**		**2012**	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	-	1,434[50]	8,606	-	6,994	6,994	5,973	5,973	7,438	7,438
Total	**29,011 UCL Violations** (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.) **21,839 FAL Violations** (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.)									

- **Total: 50,850 UCL and FAL Violations**

E. Professional Education and Training

J&J produced an admittedly incomplete list of professional education events held in California, and that list has been entered into evidence. (See PX4596.8, .18 [Response to Amended Special Interrogatory No. 9, including Exhibit 1] (March 20, 2017); 8/6/19 Tr. 77:17-78:14].) While the incompleteness of J&J's list means that it undercounts the true number of California doctors likely to be deceived by J&J's professional education and training

[50] The Court divided the 2009 visits (8,606) by six to reach the FAL violations count (8,606 / 6 = 1,434). (*cf.* 8/6/2019 Tr. 94:7-14.)

presentations, the number of attendees listed (8/6/2019 Tr. 80:15-24) provides a reasonable lower-bound of the number of violations of the UCL and FAL committed by J&J at these events:

Professional Education and Training Violations										
Year	Post-Oct. 17, 2008		Post-Oct. 17, 2009		2009		2010		2011	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	2[51]	-	-	4[52]	13	-	31	31	15	15
Total	**61 UCL Violations, 50 FAL Violations**									

- **Total: 111 UCL and FAL Violations**

F. Sales Representative Detailing

Mr. Armstrong based his estimate of 5 sales-detailing conversations per week on a sample weekly itinerary for Michelle Garrison (PX0871; 8/6/19 Tr. 103:24-105:20), J&J's designated witness on the role of sales representatives and their communications with physicians (7/24/19 Tr. 8:7-9:16), who testified in her PMQ deposition that the itinerary was "fairly representative" of sales representatives' detailing schedules. (7/24/19 Tr. 41:10-42:23, 45:11-26, 47:12-15.)[53] Mr. Armstrong further assumed that each full-time sales representative would interact with customers for 46 weeks each year, leaving six weeks for illness, vacation and other duties. (8/6/19 Tr. 104:20-105:20.) The Court finds that the 5 conversations-per-week average is reasonable and supported by the available evidence, as is the modest assumption that sales representatives worked for 46 weeks each year. (See Penalty Count Appendix.)

The Court adopts Mr. Armstrong's estimate that the following numbers of deceptive sales conversations took place between October 17, 2008 and 2015, which violated the UCL and FAL and are subject to penalties:

[51] PX4596.20 shows 1 event with 2 attendees occurred on 10/23/2008.

[52] PX4596.20 shows 2 events with 4 total attendees occurred on 12/17 and 12/29 of 2009.

[53] Ms. Garrison attempted to walk back her testimony at trial and paint the itinerary as not at all representative (7/25/19 Tr. 20:13-21:6), but the Court gives her trial testimony little weight. *See* the Penalty Count Appendix for further discussion.

Sales Representative Detailing Violations		
Year	UCL Violations	FAL Violations
Post-Oct. 17, 2008	312[54]	-
Post-Oct. 17, 2009	-	362[55]
2009	2,175	-
2010	2,594	2,594
2011	1,842	1,842
2012	1,268	1,268
Total	**8,191 UCL Violations**	**6,066 FAL Violations**

- **Total: 14,257 UCL and FAL violations**

G. Meals Provided to Healthcare Providers

Based on the information available in the expense report data produced by J&J, Mr. Armstrong calculated the number of meals (during presentations or one-on-ones with sales representatives) that were provided to doctors by J&J's employees who sold or marketed mesh. (8/6/19 Tr. 87:2-7.) Plaintiff acknowledges, J&J's meal expense data does not indicate which meals involved their pelvic mesh products as opposed to other products in the Women's Health portfolio. The Court concludes that corporate witness Michelle Garrison's testimony provides a benchmark to estimate the portion of sales representatives' meals provided to health care professionals. Two-thirds of the meetings listed in Ms. Garrison's "fairly representative" sales representative itinerary involved J&J's pelvic mesh products as opposed to the other products in the Women's Health portfolio. (PX0871.) Accordingly, the Court applies the two-thirds benchmark provided by Ms. Garrison's itinerary to the meal numbers identified in Mr. Armstrong's testimony and J&J's expense data. (*See* 8/6/19 Tr. 84:12-19, 87:2-7; PX0001.) This yields the following estimates of UCL and FAL violations occurring over meals at which J&J's employees were more likely than not to deliver the misleading communications about pelvic mesh they had been trained to provide (See Penalty Count Appendix):

[54] The Court divides Mr. Armstrong's 2008 estimate (1,873) by six (1,873 / 6 = 312) to limit the count to the last two months of the year.

[55] The Court divides Mr. Armstrong's 2009 estimate (2,175) by six (2,175 / 6 = 362 to limit the count to the last two months of the year.

Misleading Statements over Meals UCL Violations Oct. 17, 2008-2015[56]		
Year	UCL Violations	FAL Violations
Post Oct. 17, 2008	377 (3,430)[57]	-
Post Oct. 17, 2009	-	359 (3,260)[58]
2009	2,152 (3,260)[59]	-
2010	1,857 (2,813)	1,857 (2,813)
2011	1,162 (1,760)	1,162 (1,760)
2012	532 (806)	532 (806)
2013	822 (1,246)	822 (1,246)
2014	1,003 (1,520)	1,003 (1,520)
2015	294 (446)	294 (446)
Total	**8,199 UCL Violations**	**6,029 FAL Violations**

- **Total: 14,228 UCL and FAL violations**

H. Field Marketing

J&J themselves recorded attendee and impression figures for their field marketing activities, and relied on those figures in making business decisions related to their marketing activities. (8/6/19 at Tr. 28:21-29:27; PX4771 [10/4/18 Dep. Tr. Of Jason Goodbody] 279:22-280:05; PX0358; PX0299.) Their data regarding the number of attendees or impressions generated by each mesh-related field marketing activity is therefore a reasonable basis for counting violations for penalty purposes. (PX0358; PX0299.) The Court adopts as reasonable the following tallies and estimates of attendees and/or impressions associated with each category of field marketing, which violated the UCL and FAL and are subject to penalties[60]:

[56] Each of these counts, other than those that were further reduced to account for statutory cutoffs, is two-thirds of the total number of meals identified in Mr. Armstrong's testimony and J&J's expense data. For each count, the unreduced amount is identified parenthetically.

[57] The Court's math is as follows: (3,430 / 6) * .66 = 377. (*Cf.* 8/6/2019 Tr. 94:7-14.)

[58] The Court's math is as follows: (3,260 / 6) * .66 = 359. (*Cf.* 8/6/2019 Tr. 94:7-14.)

[59] The Court's math is as follows: 3,260 * .66 = 2,152.

[60] (8/6/2019 Tr. 32:20-23, 32:24-34:1, 33:7-10, 34:15-18, 35:9-13; PX0358 [2009 figures]; PX0299 [2010 and 2011 figures].)

Violation	UCL	FAL
Health Fairs	2,575	2,505[61]
Patient Education	593	433
Patient Outreach	500	500
Public Relations	22,500	22,500
Primary Care	309	294
Total	52,709	

VII. STATUTORY PENALTY FACTORS

For an action brought by the Attorney General on behalf of the People, both the UCL and FAL instruct the Court to impose a civil monetary penalty of up to $2,500 per violation of each statute. (Bus & Prof. Code, §§ 17206(a), 17536(a).) The penalties assessed under each statute are cumulative, meaning any single act that violates both the UCL and FAL may be subject to a total civil monetary penalty of up to $5,000. (Bus. & Prof. Code, § 17205; *Dollar Rent-A-Car Systems, supra*, 211 Cal.App.3d at 132.)

The Court's "duty to impose a penalty for each violation [of the UCL and FAL] is mandatory." (*People v. Custom Craft Carpets, Inc.* (1984) 159 Cal.App.3d 676, 686 [internal quotation and citation omitted].) "The amount of each penalty, however, lies within the court's discretion." (*Ibid.*) In exercising that discretion, the Court must take into account a non-exhaustive list of factors set out in identical sections of both the UCL and FAL:

> In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth.

(Bus. & Prof. Code, §§ 17206(b), 17536(b).) Civil penalties are important to UCL and FAL enforcement because "some deterrent beyond that of being subject to an injunction and being

[61] The Court reaches this number by tabulating the California-based events that occurred in 2009 as listed in the "Tracking" tab of PX0358.

required to return such ill-gotten gains is deemed necessary to deter fraudulent business practices." (*People v. Bestline Products, Inc.* (1976) 61 Cal.App.3d 879, 924.)

As discussed below, the Court considered each of the factors described in sections 17206(b) and 17536(b) and determines a penalty amount of $343,993,750 reflecting a penalty of $1,250 each for 153,351 UCL violations and 121,844 FAL violations committed starting October 17, 2008 or October 17, 2009, respectively, is both reasonable and supported by the evidence presented at trial and in light of the penalty factors listed in sections 17206(b) and 17536(b). J&J engaged in serious, knowing, and willful misconduct over a period of close to twenty years, and likely committed far more violations in California during the statutory period than are captured in those figures. (See Section VI, on penalty counts; see also Penalty Counts Appendix.) The amount also represents less than one percent of J&J's $70.4 billion total net worth and is not unconstitutionally excessive or disproportionate. (PX4835, ¶¶ 4, 14 [financial condition stipulation by the parties].)

A. The Nature and Seriousness of the Misconduct Weighs in Favor of Significant Penalties

First, the nature and seriousness of the misconduct were grave. Pelvic mesh products are meant to be permanently implanted in the human body for life and carry the potential to cause debilitating, chronic pain and destroy patients' sexual, urinary, and defecatory functions — consequences that go to the very core of personal identity, dignity, and quality of daily life. Despite having this knowledge from launch, J&J chose, willfully and knowingly, to withhold this crucial information from physicians and patients and to deceive them about the balance of risks and benefits associated with pelvic mesh. (See Sections V.D-F on deception.)

J&J's deception had real consequences for real people. California resident and TVT Abbrevo patient Colleen Perry testified that "there are many times that I, myself, feel like damaged goods; that because of the mesh surgery and because of the vaginal pain and the painful sex that a decision that I made ruined everything . . . it is devastating." (PX4748, 2/4/15 Tr. 2727:3-13.) Ms. Perry's husband, Patrick Perry, further testified about how the mesh

complications affected their marriage, explaining, "it kills me because I—I don't what know to do for her . . . we were such a great couple." (PX4749, 2/9/15 Tr. 2994:25-2995:27.)

Illinois resident and TVT Obturator patient Jo Huskey also testified that she used to lead an active personal life full of outdoor activity with her husband while holding down a physically demanding job as a physical therapy assistant. (7/22/19 Tr. 106:15-109:7, 109:15-110:17.) After her surgery, however, she began experiencing chronic pain and chronic dyspareunia so severe that she could not work, engage in physical activity, or have intercourse. (*Id.* at 121:2-122:11 [forced to cease physical activity due to pain], 122:10-14 [forced to resign her job], 122:15-18 [forced to cease sexual intercourse].) And as the Court addressed in Section V.F.3, Defendants deceptively piqued her interest in a TVT sling by featuring both an athletic female role model, Olympic speed skater Bonnie Blair, and a description of risks that purported to be complete but in reality disclosed none of mesh's most serious complications.

Testimony by Dr. Margolis corroborates the testimony by Ms. Perry, Ms. Huskey, and their husbands regarding the grave and serious nature of potential mesh complications and the fact that mesh complications are sometimes permanent and irreversible. Dr. Margolis, a California urogynecologist who specializes in treating mesh complications, has treated approximately 1,000 patients with mesh complications and explanted mesh from about 600 of them. (7/25/19 Tr. 94:6-14, 104:18-20, 120:9-26.) Approximately 95% of Dr. Margolis's patients are Californians. (7/29/19 Tr. 26:5-8.) Dr. Margolis has treated women with mesh complications suffering dyspareunia to the point where "[they] cannot engage in intercourse with [their] partner," it "caused [their] partner to leave," and "essentially ruined [their] life of intimacy." (*Id.* at 12:27-13:8.) He has treated women suffering urinary dysfunction caused by mesh to the point where they are forced to "intermittently self-catheterize [] throughout the day in order to empty [their] bladder," they "have to stay close to the bathroom at all times," "they won't go out to social events . . . for fear that they're going to leak urine all over the place," and "[i]t affects their work." (*Id.* at 17:15-18:11, 18:17-19:10.) He has also treated women with pain caused by mesh that "is often times chronic, permanent, irreversible and severe," to the point where they ended up in wheelchairs and suffered "pain that may be worse with activity, but may also be present even at

rest." (*Id.* at 22:1-21.) He described phenomenon that doctors call "chandelier" pain where a patient suffers "really severe pain" such that "when you touch or push on the area of pain [] they jump off the table and hang off chandeliers." (*Id.* at 25:2-28.) Dr. Karyn Eilber, J&J's medical expert, further corroborated Dr. Margolis's testimony, confirming on cross-examination that women with mesh complications may need to "redefine their personal health and identity" and to transition to a "new normal" that includes "being unable to have sex with their husband or partner ever again without feeling pain." (9/24/19 Tr. 166:27-167:15.)

The Court concludes that the nature of the deceptive marketing conduct is egregious and that penalties are warranted to vindicate the public wrong that has been done within the State of California. More than 53,000 women in the State of California had mesh devices implanted in their bodies (see Penalty Count Appendix) without being told by the company of the life-changing risks of these devices. Defendants' misconduct put mesh in the hands of California doctors more than 53,000 times without fully disclosing to them the grave risks known by the company.

B. Defendants' Willfulness and Persistence, and the Length of Time Over Which the Misconduct Occurred, Weighs in Favor of Significant Penalties

J&J persisted in its deceptive conduct for seventeen years even in the face of internal and external calls for change, amounting to hundreds of thousands of knowing, illegal statements targeted at California consumers.[62] Internal communications presented at trial show that J&J intentionally concealed and misrepresented risk information that would undermine the rosy picture it was selling to physicians and patients in its marketing materials. For instance, Laura Angelini, a marketing director, opted to bury clinical study participants' reports of dyspareunia because it would "kill us" to disclose them in study results. (PX0841.) The same marketing director earlier determined that the company would not want to provide physician customers with information regarding TVT mesh removal techniques because it would be "dig[ging] her own grave" to reveal to customers that mesh might ever need to be removed. (PX1820.) The company

[62] As discussed in further detail in Section VI, this is likely a significant undercounting of the actual number of violations because the People only requested counts on marketing activity for which there was enough data to either definitely establish or reasonably infer particular violations occurred.

also ignored internal calls for IFU changes that would have led to better disclosure of sexual function, pain, and quality-of-life risks, such as those raised by Medical Director Dr. Arnaud in 2005 and by Associate Medical Director Dr. Meng Chen in 2009. (PX0854 [Dr. Arnaud email re: inadequate IFU warnings]; PX1230 [Dr. Chen meeting agenda re: insufficient IFU warnings]; 7/31/19 Tr. 53:25-54:7 [Dr. Chen testimony that purpose of meeting was to consider whether IFU update was necessary].)

Instead of heeding the FDA's 2008 and 2011 warnings to increase consumer awareness of these dangers, Defendants chose to bury the warnings by instructing sales representatives that "they are not to proactively initiate conversations with customers about this [2008] notice" (PX1313 [Selman memo]), and to actively refute and undermine the FDA's warnings by circulating an article authored by paid consultants that disagreed with the FDA's 2011 warning (PX0812 [Time to Rethink article]; PX4822 [consultant payments]; see Section III.D regarding intentional concealment.)

As our Court of Appeal has noted, consumers place their trust in reputable health companies with years of brand recognition like Johnson & Johnson "whose closely regulated research, production, and merchandising have taken the place of expertise the average citizen is unable to develop." (*Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159.) Consumers expect "responsible entrepreneurism" from such companies, entrusting them "daily not just with goods and services but with our lives." (*Ibid.*) J&J knowingly and willfully abused that trust, depriving physicians of the ability to properly counsel their patients about the risks and benefits of undergoing surgery to have a synthetic product permanently implanted in their bodies, and depriving patients of the ability to make informed decisions about their own care.

This abuse of trust is particularly egregious when it comes to selling a permanent implant with no exit strategy while hiding its risks. Dr. Margolis testified about both the "essential irreversibility" of mesh complications and the collateral damage to surrounding tissue caused by removal surgery. (7/29/19 Tr. 16:9-24.) In other words, there is no safe way to remove mesh "[o]nce the mesh is scarred into place, once the cement is secured over that rebar in the sidewalk." (*Id.* at 31:12-32:8.) Consequently, patients who were deprived of the ability to make

an informed decision in the first place will not get a second chance. Consumers like Colleen Perry, Jo Huskey, and the nearly one thousand California women treated by Dr. Margolis have therefore suffered a harm that literally cannot be undone.

The Court further finds that it is likely that Defendants, through their deceptive marketing, convinced many doctors to implant mesh slings and POP mesh devices. The Court has heard testimony from several doctors, some of them preeminent specialists, that they have implanted hundreds, if not thousands, of slings over the course of their career while being under the impression that they pose minimal risks and do not cause the type of debilitating and long-term risks and complications that the company admits to knowing about. (8/20/19 Tr. 122:8-11 [Dr. Nager]; 8/26/19 Tr. 164:21-165:3 [Dr. Lane]; 8/21/19 Tr. 146:5-13 [Dr. Kahn].) And when severe, long-term complications started surfacing, Defendants' campaign of deceptive marketing likely worked to convince those doctors that any complications they were seeing were coming from the risks of the surgery or unusual patient reactions as opposed to the foreign body they were implanting. (See Section V.G on the likelihood of doctor deception.)

The Court finds in 2015, Defendants updated their IFUs for the pelvic mesh products that still remained on the market to include a number of complications that had been missing since the original 1998 launch of TVT. While the added adverse events that were added to the TVT IFUs better informed doctors and patients, it still omitted significant additional risks.

The Court therefore finds the nature and willfulness of Defendants' marketing conduct to warrant the penalties under statute: $1,250 per violation, per statute, for a total of $2,500 per violation.[63] (*Dollar Rent-A-Car Systems, supra*, 211 Cal.App.3d at 132 [penalties are cumulative].)

///

///

///

[63] Additionally, a Court may appropriately increase the penalty amount where the restitution provided for by the UCL and FAL is otherwise impossible to calculate and therefore unavailable for recovery. (*People v. Overstock.com, Inc.* (2017) 12 Cal.App.5th 1064, 1088 [noting that it was appropriate for the trial court to increase penalty value because restitution was unavailable to harmed consumers].)

VIII. INJUNCTIVE RELIEF

The People seek a permanent injunction under Business and Professions Code sections 17203 and 17535 that would bar Defendants from making false, misleading, or deceptive claims regarding transvaginal mesh products.

"Injunctive relief is one of the principal remedies available for violations of [the UCL] and [FAL]." (*Colgan v. Leatherman Tool Group, Inc.* (2006) 135 Cal.App.4th 663, 701 [quotation and citation omitted].) Section 17203 of the UCL states:

> Any person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction. The court may make such orders or judgments, including the appointment of a receiver, as may be necessary to prevent the use or employment by any person of any practice which constitutes unfair competition, as defined in this chapter, or as may be necessary to restore to any person in interest any money or property, real or personal, which may have been acquired by means of such unfair competition.

(Bus. & Prof. Code § 17203.) Section 17535 of the FAL is substantially identical.

The Legislature intended this broad, sweeping language to give courts the power "to enjoin ongoing wrongful business conduct in whatever context such activity might occur." (*Barquis v. Merchants Collection Assn.* (1972) 7 Cal.3d 94, 111.) That includes the power to require affirmative statements, such as the addition of warnings to product labeling. (*Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy* (1992) 4 Cal.App.4th 963, 972.)

Injunctions are not necessary where there is no threat of misconduct being repeated in the future. (*Colgan, supra*, 135 Cal.App.4th at 702.) "Injunctive relief will be denied if, at the time of the order of judgment, there is no reasonable probability that the past acts complained of will recur, i.e., where the defendant voluntarily discontinues the wrongful conduct." (*California Service Station etc. Assn. v. Union Oil Co.* (1991) 232 Cal.App.3d 44, 57.)

Voluntary discontinuation of wrongful conduct requires more than simply showing that past wrongful conduct has stopped: a defendant must show that it chose to discontinue the wrongful conduct *in good faith*. (*Phipps v. Saddleback Valley Unified School Dist.* (1988) 204 Cal.App.3d 1110, 1118 [citing *Mallon v. City of Long Beach* (1958) 164 Cal.App.2d 178, 190].) In *Mallon*, the Court of Appeal recognized a defendant's demonstration of good faith where it had amended

its answer to admit the wrongful conduct alleged, asserting that it would discontinue the practice and disavowing any intent to resume it in the future. (*Mallon, supra*, 164 Cal.App.2d at 180.) The court later contrasted that showing of good faith with the stance taken by the defendant in *Phipps*, which waited until it was enjoined by a preliminary injunction to change its policies and then at trial "held fast to its earlier position" that its conduct had not been wrongful in the first place. (*Phipps, supra*, 204 Cal.App.3d at 1118-1119.) And, as the court stated in *California Service Station*, a defendant's "statement at trial that it did not intend to violate [the relevant statute] and that it will pursue a lawful policy in the future" does not amount to a display of good faith sufficient to render an injunction unnecessary. (*California Service Station, supra*, 232 Cal.App.3d at 57.) Contrary to J&J's arguments, therefore, litigation conduct is highly relevant in determining whether defendants have voluntarily and in good faith discontinued their wrongful conduct.

Here, the People provided evidence that J&J's deceptive marketing of its mesh products is ongoing and may recur absent an injunction. J&J, which still markets its TVT mesh products, persists in its practice of omitting known, serious risks from the IFUs, namely, that the products carry a lifelong and recurring risk of exposure and erosion, tissue contracture causing chronic pain, debilitating and life-changing pain, chronic foreign body reaction, shrinkage or contracture, and infection or biofilm formation, as well as the fact that the mesh is not inert. (See Section V.D.1-3).

J&J has not demonstrated a good-faith discontinuation of its deceptive marketing conduct that would render an injunction unnecessary. Although the company wound down some of its active patient-marketing functions in January 2015, it did so for commercial reasons rather than out of a good-faith recognition that its marketing was false, misleading, and deceptive. (8/22/19 Tr. 183:26-186:2 [Mr. Horton].) Importantly, however, the company still distributes brochures to doctors upon request and makes them available on its website, and has continued to generate new marketing materials. (*Id.* at 188:13-19, 194:9-15.) Nothing prevents J&J from ramping up its deceptive marketing again if it finds that it is once again commercially appealing to do so.

This possibility is compounded by the fact that J&J has not acknowledged or disavowed any of its deceptive marketing practices; rather, as did the defendant in *Phipps*, it has staunchly

defended them. At trial, J&J's current medical director defended the company's inclusion of patently false and misleading representations in patient-facing brochures on the basis that patients could obtain accurate information elsewhere and would not understand the information disclosed to them in brochures anyway. (8/7/19 Tr. 50:17-53:4 [Dr. Hinoul]; see also Defs.' Mot. for Judgment at pp. 46-48 [filed 8/9/19] [arguing that brochure content is not significant because brochures are just a "jumping off point" for discussion with a doctor].)

The Court finds there is a reasonable probability that J&J could market its transvaginal mesh products deceptively in the future absent an injunction barring it from doing so. Injunctive terms prohibiting J&J from making deceptive or misleading claims regarding any SUI or POP mesh product is therefore warranted and necessary.

Furthermore, injunctive terms affirmatively requiring J&J to disclose significant risks and complications associated with its pelvic mesh products are necessary to alleviate the deception and confusion caused by J&J's years of untrue, misleading, and incomplete marketing statements. (See *Consumers Union*, *supra*, 4 Cal.App.4th at 973.) "To allow consumers to continue to buy the product on the strength of the impression built up by prior advertising—an impression which is now known to be false—would be unfair and deceptive." (*Ibid.* [quoting *Warner-Lambert Co v. FTC* (D.C. Cir. 1977) 562 F.2d 749, 761].) As discussed above, the evidence shows that Defendants have been deceiving physicians—including their own witnesses—for years, with the result that physicians have been unable to adequately counsel patients regarding the risks and benefits of pelvic mesh implants. It is within this Court's discretion to require Defendants to begin "correct[ing] the consequences" of that past misconduct by affirmatively disclosing significant risks in their communications going forward. (*Ibid.*)

For reasons set forth above, and throughout this Statement of Decision, the Court is requesting further briefing on the issue of an Injunctive Order.[64]

[64] The People filed a Proposed Injunction Order concurrently with its Proposed Statement of Decision and the Defendants filed a response.

IX. AFFIRMATIVE DEFENSES

A. Safe Harbor

The Court concludes that Defendants have not met their burden of proving that the 510(k) clearance process granted them a safe harbor for the deceptive statements and omission of risk information in their IFUs and other marketing. As the California Supreme Court has recognized, safe harbor is a narrow doctrine that can only be applied when the law (1) clearly permits the defendants' conduct, or (2) imposes an absolute bar against suing the defendant for the conduct at issue. (*Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company* (1999) 20 Cal.4th 163, 182-183 ["[t]o forestall an action under the unfair competition law, another provision must actually 'bar' the action or clearly permit the conduct"].)

The FDA's 510(k) clearance process is "a limited form of review" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 478) that is inherently insufficient to create a safe harbor for the same reasons it does not preempt state consumer protection law. (*Id.* at 494 [holding that 510(k) clearance does not bar state-law consumer protection action]; *Cabrera v. Fifth Generation, Inc.* (S.D.Cal. Nov. 20, 2015) No. 14-02990, 2015 WL 7444223 at *5 [stating that federal regulator's actions create safe harbor only under the same circumstances required for preemption].) The FDA's 510(k) clearance of J&J's mesh devices did not specifically approve the devices' labels or determine that they were not false or misleading, as would be required for J&J to be shielded from liability for its deceptive marketing claims. *(In re Bard IVC Filters Products Liability Litigation* (D. Ariz., Nov. 22, 2017) No. MDL 15-02641, 2017 WL5625547 at *2-3 [distinguishing between 510(k) clearance and approval]; 9/23/19 Tr. 77:9-13 [Mr. Ulatowski]; 8/5/19 Tr. 27:26-28:14, 37:14-22 [Dr. Kessler].) Moreover, the FDA's clearance letters explicitly informed Defendants that while they may market the device pursuant to the clearance, they remain,

> subject to the general controls provisions of the [FDCA] [. . . which] include requirements for . . . labeling, and prohibitions against misbranding . . . Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

> requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: . . . labeling.

(JX10021 [TVT Obturator]; JX10027 [TVT Secur], JX10029 [TVT Exact], JX10032 [TVT Abbrevo], JX10037 [Gynemesh], JX1044 [Prosima], JX10060 [Prolift and Prolift +M]; see also JX10019 [TVT clearance letter with substantially similar language].) In doing so, the FDA explicitly informed Defendants that they remain responsible for ensuring that their labeling is lawful and non-misleading (8/5/19 Tr. 29:8-30:5 [Dr. Kessler]) and that the FDA had made no determination on whether their labeling were truthful—in other words, that the clearance did not create a safe harbor for deceptive marketing.

Even if the 510(k) process could give rise to a safe harbor, Defendants have introduced no evidence, and so have not met their burden of proof, that the FDA explicitly authorized omission of the specific sample adverse events that Dr. Kessler testified about (for the TVT products: pain, chronic pain, dyspareunia, chronic dyspareunia, neuromuscular problems, recurrence of incontinence, potential necessity for one or more revision surgeries, pain to partner during intercourse, and death; for the POP mesh products: chronic pain, chronic dyspareunia, vaginal tightening and/or shortening, neuromuscular problems, pain to partner during intercourse, and death.) Neither has the FDA explicitly authorized the omission or misrepresentation of serious long-term complications or of dangerous mesh properties known to the company (see Section V.A, Table 1 [Hinoul Testimony on Known Mesh Risks]) that form the basis of the People's claims. As Dr. Kessler testified and as demonstrated by the 510(k) clearance files and communications entered into evidence, J&J never raised to or discussed with the FDA, and the FDA did not specifically authorize, the misrepresentations or omissions that the People allege are deceptive during the 510(k) clearance process for these devices. (8/5/19 Tr. 47:8-13, 48:20-23, 49:13; JX10001-JX10152 [510(k) files and communications between FDA and J&J].) As Dr. Kessler testified, if the FDA had granted express authorization for specific statements or omissions in the IFU, it would be documented in the 510(k) communications. (8/5/19 Tr. 49:17-28.) Therefore, the Court finds that Defendants have not established that the FDA "clearly

permit[ted]" the misrepresentations and omissions at issue in this case. (*Cel-Tech Communications, supra*, 20 Cal.4th at 182-183.)[65]

B. Learned Intermediary Doctrine

The Court concludes under the facts presented and given Plaintiff's enforcement role that the learned intermediary doctrine ("LID") does not shield from liability under the UCL and FAL where a manufacturer directs false or misleading communications to lay consumers. The LID is a common-law tort defense that holds that "if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed." (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65, citing *Love v. Wolf* (1964) 226 Cal.App.2d 378, 395.) This case is neither a tort case nor does it involve allegations that Defendants should have affirmatively reached out to the lay consumer population to communicate the risks; therefore, this doctrine has no applicability.

The UCL and FAL prohibit Defendants from deceiving any consumers to whom they direct their marketing—in this case, both doctors and patients. "[T]he only requirement [to demonstrate a violation] is that defendant's practice is unlawful, unfair, deceptive, untrue, or misleading" (*Prata, supra*, 91 Cal.App.4th at 1144), because the goal of California consumer protection law is to enforce "the public's right to protection from fraud, deceit, and unlawful conduct." (*Hewlett, supra*, 54 Cal.App.4th at 519.) While the likelihood of deception will be gauged by the reasonable member of the group who is targeted by the advertising (*Lavie, supra*, 105 Cal.App.4th 496, 512), nothing in consumer protection law shields manufacturers when they communicate deceptively to a potential patient population. In other words, a company cannot lie to consumers in California just because they are selling a medical product that requires a medical prescription, especially

///

///

///

[65] Defendants have also introduced no facts, and so have not met their burden, in support of their equitable affirmative defenses of unclean hands, estoppel, laches, and waiver. Accordingly, these affirmative defenses also fail.

when the UCL and FAL expressly prohibit such conduct. No California court has ever taken the extreme step of applying this doctrine to a law enforcement UCL and FAL action and this Court declines to be the first to do so.[66]

Dated: January 30, 2020

Eddie C. Sturgeon
EDDIE C. STURGEON
Judge of the Superior Court

[66] Even if the learned intermediary doctrine could reach UCL and FAL claims, it still would not shield Defendants here because it does not apply when the doctors themselves did not have "adequate warning" to enable them to pass that knowledge on to patients. (*Stevens, supra*, 9 Cal.3d at 65). As set forth above, the Court concludes that J&J also deceptively marketed to the doctor audience.

Penalty Counts
Appendix

Penalty Count Appendix

I. Instructions for Use

1. The Court finds that Defendants gained from every instance of a dissemination of an IFU, including the IFUs inside the device packaging. Defendants gained from each purchase of the product in which the IFU was found, and, because doctors were repeat customers, Defendants stood to gain from future sales to these same customers. The misleading adverse events section in each IFU was related to these gains. The evidence has shown that Defendants featured IFU information and directed doctors to read the package inserts pervasively throughout their marketing. (See discussion at Section V.E, G.1 and Violations Appendix at pp. 8-23.) The Court finds that each and every instance in which Defendants disseminated an IFU that concealed the serious long-term risks caused by the mesh served their marketing purpose of driving future use of the devices by doctors.

2. The People's proposed count limiting the IFU-based violation count to in-package IFUs is an undercount of the true number of deceptive IFUs that Defendants circulated in order to drive the use of pelvic mesh by doctors in their practice. The evidence presented at trial establishes that Defendants also disseminated IFUs, or excerpts of IFUs, through their sales representatives and through doctor-directed websites. (See 7/24/19 Tr. 11:7-18 [Michelle Garrison testifying that sales reps are trained on IFUs and that IFUs can be downloaded from the Ethicon website], 12:25-13:7 [testifying that sales reps were trained to "direct physicians to the IFU for information about risks and complications"]; PX4807 [9/5/17 Dep. Tr. of Scott Jones] at 213:05-213:19 [testifying that sales representatives "could be asked at any time by any customer about what was contained within the instructions for use," and "if there were questions about the IFU" in the operating room, "we could answer them."]; [9/6/17 Dep. Tr. of Scott Jones] 387:07-388:10 [testifying that the "full package insert" or IFU was "available on our website," the "JJHCS [Johnson & Johnson Health Care Systems] and the Gateway website, so there were several locations where a physician could find the IFU"]; 437:04-438:02 [testifying that if a physician asked during a sales conversation about the risks associated with a mesh device, he "could have pointed to whatever risks, warnings, precautions we had" in the IFU labeling].)

3. Evidence at trial showed the number of mesh device "units" Defendants sold in California on an annual basis from 2005 to February 2018. (PX4118; 8/6/2019 Tr. 88:1-89:12.) Certain mesh devices came in "multi-pack units" containing more than one device. (PX4118 at 021-022; 8/6/2019 Tr. 90:5-23.) Accounting for these multipacks, the Court finds that Defendants sold the following numbers of mesh devices in California[1]:

- **46,895** SUI mesh devices sold in California from 2005-2018
- **6,177** POP mesh devices sold in California from 2005-2012
- **35,217** SUI mesh devices sold in California from 2008-2018

---

[1] (PX4118 at 021-022, Ex.1; *see also* 8/6/2019 Tr. 92:12-93:19 [SUI units]); ((PX4118-021, -022 & Ex.1; *see also* 8/6/2019 Tr. 93:20-94:6 [POP units].)

- **3,948** POP mesh devices sold in California from 2008-2012

4. The Court notes that evidence regarding the true number of deceptive IFUs distributed via Defendants' sales representatives and websites was not available or presented, and cannot be estimated or inferred based on available testimony. Therefore, the Court grants penalties on the smaller subset of IFUs that were distributed as package inserts because it can be reasonably quantified.

5. Taking into account the October 17, 2008 (for UCL) and October 17, 2009 (for FAL) statutory cut-off periods, the Court's counts of in-package IFU violations of the UCL and FAL subject to penalties are as follows[2]:

In-Package IFU Violations Subject to Penalties[3]	
POP IFUs Distributed (Approx.)	**Violation Count**
Oct. 17, 2008 through 2012	3,163 UCL Violations
Oct. 17, 2009 through 2012	2,323 FAL Violations
SUI IFUs Distributed (Approx.)	**Violation Count**
Oct. 17, 2008 through Feb. 2018	32,180 UCL Violations
Oct. 17, 2009 through Feb. 2018	28,677 FAL Violations
Total: 66,343 UCL and FAL penalty violations for the distribution of misleading IFUs in the package inserts for SUI and POP mesh.	
Alternate In-Package IFU Violation Counts [If the Court were to exclude from its violation counts SUI IFUs distributed after the third quarter of 2015 (by multiplying the 2015 annual total by ¾)]	
POP IFUs Distributed (Approx.)	**Violation Count**
Oct. 17, 2008 through 2012	3,163 UCL Violations
Oct. 17, 2009 through 2012	2,323 FAL Violations
SUI IFUs Distributed (Approx.)	**Violation Count**
Oct. 17, 2008 through Sept. 2015	24,765 UCL Violations
Oct. 17, 2009 through Sept. 2015	21,262 FAL Violations
Alternate Total: 51,513 UCL and FAL violations for the distribution of misleading IFUs in the package inserts for SUI and POP mesh.	

[2] Defendants' device sales figures capture only annual sales numbers, so in order to account only for devices and IFUs sold in the last two months of the year, the Court will divide the total sales for 2008 (in the case of the UCL) and 2009 (in the case of the FAL) by six. (*Cf.* 8/6/2019 Tr. 94:7-14 [forensic accountant's testimony that one could estimate the last three months of the year by dividing by four].)

[3] (8/6/19 Tr. 92:12-94:6; PX4118-021, -022 & Ex. 1.)

II. Print Marketing Materials

1. Defendants' did not retain data regarding the total number of print marketing materials sent in to California prior to 2012. (PX4614 at 8 [Defendants' Amended Response to the People's Special Interrogatory No. 6 acknowledging that they cannot "identif[y] a source to confirm the total number of written materials sent to California prior to January 2012."].)

2. Defendant could only identify 6,310 printed pelvic mesh materials sent into California. They assembled this list of 6,310 printed pelvic mesh marketing materials sent into California between July 2008 and December 2011 using Literature Depot shipment confirmation emails contained in their document production. (PX4614 at 8.) They also admitted that the list is incomplete, and that they do not know what percentage of the unknown total number of pre-2012 California shipments it represents. (*Ibid.*)

3. The data retained and produced by Defendants only included plausibly complete Literature Depot shipment confirmations for one sales representative, Jason Logan.[4] (8/6/2019 Tr. 58:18-59:14, 60:3-17; 62:8-14 [The People's expert, Travis Armstrong, testifying that after undertaking a diligent search of Defendants' document production, he only found shipment confirmation emails in the custodial files for three California sales representatives, even though there were 26 sales representatives assigned to California sales territories during the statutory time period]; PX4592 at 14-18 [Exhibit A to Defendants' Response to Special Interrogatory No. 21]; PX4604 at 30-32 [Exhibit 2 to Defendants' Second Amended Response to Special Interrogatory No. 21].) Accordingly, Mr. Armstrong concluded that the 33 shipment confirmation emails contained in Mr. Logan's custodial file were the only available source of data on which he could plausibly base an estimate of the number of printed marketing materials shipped to sales representatives from Literature Depot before 2012. (8/6/2019 Tr. 62:18-63:4.)

4. Given the paucity of the data retained by Defendants, the Court concludes the extrapolation analysis undertaken by Mr. Armstrong is a reasonable (and perhaps the only possible) approach to arrive at an estimation of the print distribution activity of the 26 California sales representatives employed by Defendants to sell mesh.[5] The Court therefore finds that it was reasonable for Mr. Armstrong to assume that Mr. Logan was sufficiently representative of other sales representatives to form the basis for a state-wide extrapolation, especially in the absence of

---

[4] Mr. Armstrong inferred that two of the three custodial files for California sales representatives must be incomplete because (a) they contained implausibly few shipment confirmation emails relative to the length of time those custodians were employed, and (b) he reviewed emails from those custodians discussing Literature Depot orders for which he could find no accompanying shipment confirmation emails. (8/6/2019 Tr. 58:18-59:14; 60:3-17; 62:8-14.) The Court finds that these inferences were reasonable.

[5] The Court notes that if it chose not to credit Mr. Armstrong's estimates, it could have instead counted as print marketing violations the admittedly incomplete list of materials that Defendants identified were sent from Literature Depot to California between July 2008 and December 2011, for a total of roughly 6,310 print marketing violations. But because the Court finds Mr. Armstrong's estimates well-grounded and reliable, it need not limit itself to what Defendants acknowledge is an incomplete list.

contradictory data regarding other sales representatives' ordering behavior. To construct his estimate, Mr. Armstrong had to extrapolate Mr. Logan's ordering patterns to other sales representatives by tallying his annual order rate and calculating the total orders that would have been placed by other full-time sales representatives employed in California each year as though they ordered at the same rate. (8/6/19 Tr. 66:13-25.) For the purposes of his calculation, Mr. Armstrong reasonably assumed that Mr. Logan's ordering patterns were similar to those of his fellow sales personnel. (8/12/19 Tr. 120:23-121:11.) By category, Mr. Logan ordered the following number of materials for each year from 2008 through 2011:

Logan Mesh Marketing Orders, 2008 to 2011				
Year	**2008**	**2009**	**2010**	**2011**
SUI Patient Brochures	150	850	100	700
SUI Patient In-Office Marketing	3	12	-	185
SUI Patient Mailers	-	100	-	-
SUI Physician Sales Aids	-	40	-	60
POP Patient Brochures	129	575	450	200
POP Patient In-Office Marketing	3	2	-	-
POP Physician Sales Aids	-	145	70	16
Total	**285 (153 SUI, 132 POP)**	**1,724 (1,002 SUI, 722 POP)**	**620 (100 SUI, 520 POP)**	**1,161 (945 SUI, 216 POP)**

(8/6/2019 Tr. 65:9-17; see also PX4780; Jason Logan Orders.)[6]

5. Defendants have suggested that Mr. Logan should not be considered representative of other sales personnel because he was at one point a high-performing seller. Mr. Armstrong testified that he studied a deposition of Mr. Logan in the course of preparing his opinion, and learned that (a) Mr. Logan had only been a top seller for approximately five months in 2010 (8/12/19 Tr.141:21-28); and (b) Mr. Logan "attributed any relatively higher sales rates in his territory to luck rather than promotional activities," from which the Court can infer that Logan's temporarily high sales performance likely did not lead to a meaningful increase in his use of marketing materials (8/12/19 Tr. 142:5-9). Defendants have not presented any contrary

[6] The Court notes that as set forth in the chart of Mr. Logan's original orders, the overwhelming majority of the marketing materials from which Mr. Armstrong extrapolated his totals were patient brochures (83%), followed by doctor sales aids (9%), while only a relatively small portion were in-office marketing materials (5%) and mailers (3%).

evidence showing that Mr. Logan ordered more materials than other sales representatives in California.

6. Mr. Armstrong used the Jason Logan orders along with Defendants' testimony regarding the number of active sales representatives in California each year from 2008 through 2011 to estimate the number of pelvic mesh print marketing items ordered for distribution by all California sales representatives during this period. (8/6/2019 Tr. 62:18-63:4.) In doing so, the Court notes that Mr. Armstrong accounted for the fact that some sales representative worked only a portion of particular years. (8/6/2019 Tr. 66:13-25.)

7. As discussed in Sections V.D-G, the Court concluded that Defendants consistently and pervasively misled consumers about the risks of mesh devices throughout all of their marketing communications as set forth in the Violations Appendix. While Mr. Armstrong's calculations do not presume that every sales representative ordered precisely the same marketing materials, the Court finds that Mr. Armstrong's results provide a reasonable basis for estimating the total number of 2008-2011 violations Defendants committed when they shipped print marketing materials to sales representatives for distribution in California.

8. Based on Mr. Armstrong's estimates (8/6/2019 Tr. 74:28-75:6), the Court finds the following number of violations of the FAL and UCL:

Penalty Count: Print Marketing Materials From 2008 to 2011[7]										
Year	**Post-Oct. 17, 2008**		**Post-Oct. 17, 2009**		**2009**		**2010**		**2011**	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	579	-	-	2717	16,300	-	6,992	6,992	9,298	9,298
Total	**52,176 UCL and FAL Violations**									

III. Online Advertising and Website Visits

1. The Court finds that the number of visits to www.PelvicHealthSolutions.com's mesh-related subpages by California consumers is a reasonable measure of the number of violations arising from the website for penalty purposes. Defendants' primary patient-facing website, www.PelvicHealthSolutions.com, made many of the same untrue and misleading statements and omissions contained in Defendants' print marketing materials consistently from 2009 onward, and was a violation of the UCL and FAL. (See Section V.F; see, e.g., PX4668 at 3-5 [presenting incomplete risk information and minimizing risks with the statement "[a]ll surgical procedures present some risks"]; PX4657 at pp. 64-66, 69 [TVT pages with same] & 72, 75, 78 [Prolift sub-pages minimizing risks of Prolift by emphasizing "[a]ll surgical procedures present some risks" and presenting incomplete risk information]; Violations Appendix: Patient Websites.) Those statements were made on the subpages of the website related to SUI and POP

[7] In order to account for the UCL's October 17, 2008 statute of limitations and the FAL's October 17, 2009 statute of limitations, the Court has divided the 2008 figures by six for the UCL violations count and divided the 2009 figures by six for the FAL violations)

products. (See, e.g., PX4668; PX4657 at 25-30, 37-42, 63-66, 69-75, 78; see also 8/6/19 Tr. 131:25-132:10.)

2. The Court finds that all visits to www.PelvicHealthSolutions.com's mesh-related subpages by California consumers are reasonably likely to be related to Defendants' gain or opportunity for gain. Evidence presented at trial shows that the website was meant to be reached by patients showing an active interest in SUI, POP, or mesh products, as opposed to passive web surfers with no connection to Defendants' business interest. Defendants ran numerous Google AdWords campaigns, a form of internet advertising in which search terms related to SUI, POP, TVT, or Prolift would return sponsored links to Defendants' mesh-related subpages. They also ran banner ad campaigns on websites targeted to women with pelvic floor conditions and linked to the website in an email-blast advertisement that went out to women who expressed interest in SUI. (8/6/19 Tr. 140:3-20, 141:2-20; PX0731: PX0423.)

3. Defendants provided a variety of incomplete data sources related to PelvicHealthSolutions.com web traffic, including (a) data tracking visits to www.PelvicHealthSolutions.com *generally*, which give no indication of which subpage each visitor viewed (8/6 Tr. 142:26-143:3, 143:11-144:13; PX4115 at Ex. 1), and (b) "click-through" data capturing the subset of visitors who arrived at PelvicHealthSolutions.com by clicking on Google AdWords links and banner advertisements, which either indicate the subpage each visitor landed on or the product their click related to (8/6/19 Tr. 143:11-144:13, 158:7-159:28). Both the website traffic and click-through data contained temporal gaps, and none of the data indicated which website visitors were located in California. (*Id.* at 142:22-25, 147:1-149:7, 155:20-157:28; see PX4115 at Ex. 1 [traffic data]; PX0302; PX0303; PX0731; PX0733; PX0796; PX0792; PX0793; PX0794; PX0795; PX0800; PX0803; PX0804; PX0801; PX0802 [click-through data]).

4. In order to estimate the number of violations, Mr. Armstrong used the available click-through data to estimate the portion of total web visitors that viewed subpages related to mesh, and used data to estimate the portion of those web visitors located in California. (8/6/19 Tr. 144:28-145:9, 145:17-146:3, 151:1-153:19, 153:28-154:10.) Relying on limited but detailed Google AdWords data, which showed the precise subpage that each viewer landed on after clicking on an AdWord, Mr. Armstrong estimated that 45% of visitors to PelvicHealthSolutions.com were exposed to mesh-related content (34% to SUI/TVT and 11% to POP, respectively). (8/6 Tr. 143:11-144:13.)

5. Mr. Armstrong then used two different approaches, as set forth in the table below, to further estimate the number of those visitors located in California: one relying on California's share of the national population, and the other based on California's share of Defendant's total national sales of mesh products. (8/6 Tr. 144:28-145:16.) While the Court finds that these are both reasonable methodological choices, the absence of any evidence suggesting that SUI or POP disease rates are different in California than in other parts of the country militates in favor of the population analysis, which the Court adopts.

Penalty Counts: PelvicHealthSolutions.com		
Method	UCL Violations (2009-2012)	FAL Violations (Oct. 17, 2009-2012)
Based on California's portion of national population	29,011 UCL Violations[8]	21,839 FAL Violations[9]
Based on California's portion of Defendants' mesh sales (alternative method)[10]	14,072 UCL Violations	11,651 FAL Violations

6. The Court also finds that Mr. Armstrong's estimates of the number of California consumers to PelvicHealthSolutions.com's mesh-specific subpages are likely underinclusive of the true number of UCL and FAL violations arising out of Defendants' deceptive patient-facing web content. Mr. Armstrong's estimates do not cover the entire period during which Defendants' placed misleading content on the internet. (8/6 Tr. 131:4-10; PX4118 [Response to Amended Response to Special Interrogatory No. 154 stating that PelvicHealthSolutions.com went online in March 2009, replacing a host of older patient-facing websites related to Defendants' mesh products that were online for several months during the statutory period.].)[11] Moreover, Defendants failed to produce any data regarding visits to PelvicHealthSolutions.com for the first five months it was active, so Mr. Armstrong left that time period out of his calculations. (8/6 Tr. 132:22-28.)

IV. Sales Representative Detailing

1. The Court finds that it can reasonably infer that each mesh-related sales conversation gave rise to a violation. Evidence presented at trial established Defendants' sales representatives were trained to and did convey deceptive or misleading information to the healthcare professional customers they detailed in the field. (See Section III.B.1 [uniform message; sales representatives were trained to deliver the specific marketing messages contained in mesh sales aids]; Violations Appendix; PX4807 at 145:22-146:2, 146:4-13; 172:15-174:2; 179:21-180:6; 196:13-197:1.)

2. The Court also finds that it can reasonably infer that all sales-detailing conversations with California healthcare providers related to Defendants' mesh products likely gave rise to a violation of the UCL or FAL. Defendants went to great lengths to ensure that their

---

[8] (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.)

[9] (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.) The Court divided the 2009 visits (8,606) by six (*cf.* 8/6/2019 Tr. 94:7-14) and then added them to Mr. Armstrong's estimates to reach the FAL violations count ((8,606 / 6) + 6,994 + 5,973 + 7,438 = 21,839).

[10] (8/6/2019 Tr. 146:28-147:3; PX4115.)

[11] The older patient-facing websites not included in Mr. Armstrong's estimates contained much of the same deceptive content that appeared later on PelvicHealthSolutions.com. (See, e.g., PX4654 [gynecare.com page deceptively promising "complete description of risks"].)

sales force and their marketing materials all delivered consistent messaging to physician customers. (See Section III.B.1.)

3. Mr. Armstrong provided this Court with a range of possible estimates of the number of mesh sales-detailing conversations that took place annually in California during the relevant period, calculating approximately how many mesh-related sales conversations a sales representative would have likely had per year if they had averaged either 5, 10, 15, or 22 total sales conversations per week, respectively, for reasons explained below. (8/6 Tr. 103:24-108:12.) Defendants were unable to produce a list of California healthcare providers to whom Defendants' sales representatives marketed mesh products, or documentation of all sales calls that took place in California. (See PX4592; 8/6 Tr. 103:16-20). Lacking accurate sales call data, Mr. Armstrong looked instead to a three-day itinerary prepared by company witness Michelle Garrison when she was a sales representative working in the field—an itinerary that Ms. Garrison, while testifying at deposition as Defendants' person most qualified regarding sales representative duties, described as "fairly representative" of how sales representatives spend their days. (8/6 Tr. 103:24-105:20; PX0871 [Garrison itinerary showing a mix of "cases and appointments," with notes indicating her objectives]; 7/24/19 Tr. 8:11-9:16, 41:10-42:24, 45:16-26, 47:12-15.)

4. The Court finds that mesh did not need to be identified in the "Objectives" section of Ms. Garrison's itinerary. (7/25/19 Tr. 16:10-17:8 [Ms. Garrison testifying that "the goal of the sales call was always contained within the objective."].) For example, entry number 3 spanning the second and third pages of the itinerary does not mention mesh under "Objective," which says only "Revisit conclusions from previous discussions. Delve deeper into the realm of biologics. Discuss Flex HD." (PX0871 at 002- 003.) But immediately above the "Objective" section, under the same doctor's name, its states "Follow-up meeting to several discussions we have had surrounding the disease state of POP," and in the section following "Objective" it reads "Growth Target (TVT-O, Prolift)." (*Ibid.*) The Court draws the reasonable inference that contrary to Ms. Garrison's testimony, the document itself clearly indicates that sales representative visits involve mesh discussions even when mesh is not named in the "Objective" section. The Court further concludes that the fact that Ms. Garrison's testimony directly contradicts the contents of her own itinerary is further reason to give little weight to her revisionary testimony. (Compare 7/25/19 Tr.16:10-17:8 with PX0871 at 2, 3.)

5. The Court further finds that it was reasonable for Mr. Armstrong to count Ms. Garrison's operating-room cases alongside her appointments, because her own itinerary notes indicate that she expected to have sales conversations with the operating surgeons at some point before or after each procedure. (See PX0871.) Testimony presented at trial also indicates that sales representatives could perpetuate Defendants' deceptive conduct while in the operating room, such as by directing physicians to consult deceptive IFUs. (7/25/19 Tr. 58:24-60:8; PX4807 [9/5/17 Dep. Tr. of Scott Jones] at 213:05-213:19.)

6. Finally, the Court gives weight to Ms. Garrison's testimony that she spent 15 percent of her time as a sales representative having conversations about pelvic mesh as opposed to the other Women's Health products in her portfolio. (See 7/24/19 Tr.188:11-18 & 189:16-24.). By the Court giving credit to this testimony, the Court finds the low-end of Mr. Armstrong's

estimates as set forth below: about five-mesh related sales visits per week issued. (8/6/2019 Tr. 107:20-108:12; PX0871 [Garrison's three-day itinerary shows her meeting with 18 individuals].)

Penalty Count: Sales Representative Detailing[12]								
[illegible]	22/Week		5/Week [Alternate Count]		10/Week [Alternate Count]		15/Week [Alternate Count]	
[illegible]	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
[illegible]								
[illegible]	1,374	-	312	-	625	-	937	-
[illegible]	-	1,595	-	362	-	725	-	1,087
[illegible]	9,568	-	2,175	-	4,349	-	6,524	-
[illegible]	11,412	11,412	2,594	2,594	5,187	5,187	7,781	7,781
[illegible]	8,104	8,104	1,842	1,842	3,684	3,684	5,526	5,526
[illegible]	5,581	5,581	1,268	1,268	2,537	2,537	3,805	3,805
Total	**36,039**	**26,692**	**8,191**	**6,066**	**16,382**	**12,133**	**24,573**	**18,199**

V. Meals Provided to Healthcare Providers

1. The Court finds that all of Defendants' meals featuring presentations and meals featuring conversations with sales representatives disseminated the same deceptive marketing messages that pervade Defendants' other marketing materials, and therefore all violated the UCL and FAL. The evidence presented at trial shows that offering meals to California healthcare providers was a means by which Defendants marketed their pelvic mesh products. Defendants generally paid for meals in two contexts: (1) lunch or dinner speaker events hosted for physician audiences, such as promotional educational presentations or symposia attached to medical conferences, and (2) business meals consisting of sales conversations with sales representatives at a restaurant. (See, e.g., PX4632 at 18 [Defendants' Supp. Response to Special Interrogatory 205] [Ethicon "sponsored educational lunch or dinner speaker events . . . in which presentations were made to surgeons in order to provide information about [Ethicon's] pelvic mesh products, or more generally, treatment options for SUI or POP"]; 7/24/19 Tr.47:25-28, 51:18-52:11, 175:17-176:1 [Ms. Garrison describing how she would discuss Ethicon's products with doctors over business meals].)

---

[12] (8/6/2019 Tr. 107:20-108:12.)

[13] The Court divides Mr. Armstrong's estimates by six to limit the count to the last two months of the year. (*Cf.* 8/6/2019 Tr. 94:7-14.)

[14] The Court divides Mr. Armstrong's estimates by six to limit the count to the last two months of the year. (*Cf.* 8/6/2019 Tr. 94:7-14.)

2. The Court can reasonably infer that every mesh-related meal-based speaking event violated the UCL and FAL. Defendants' former consultant and paid presenter, Dr. Douglas Grier, testified that the presentations given at meal-based speaking events were all drafted and approved by Ethicon. (8/22/19 Tr. 98:2-18.) Examples of the promotional presentations delivered to physicians over meals at luncheons, conferences, or symposia indicate that misrepresentations were regularly disseminated at those events. (*E.g.*, PX0507; 8/22/19 Tr. 43:14-20, 50:21-27, 54:2-55:1, 98:2-5 [Dr. Grier attended and was paid to speak at Ethicon-sponsored dinner lectures, including on JX11608, "The Science of 'What's Left Behind"]; 8/21/19 Tr. 140:2-4 [Dr. Kahn "attended meals that were paid for by pelvic mesh manufacturers"]; 8/26/19 Tr. 159:9-11, 171:22-172:1 [Dr. Lane attended an Ethicon dinner on the TVT with her fellowship mentor]; 9/18/19 Tr. 181:1-182:3 [Dr. Rosenblatt was paid by Defendants to give seminars at meals hosted by the company].) Ms. Garrison also testified that "every business meal had to have a bona fide business purpose," meaning it had to be related to a sales representative's job—selling mesh. (7/24/19 Tr. 52:2-5, 52:26-53:4 [defining bona fide purpose as "the purpose of understanding if there was an unmet need that [Defendants'] products could fulfill"].)

3. Defendants' meal expense data does not indicate which meals involved their pelvic mesh products. However, the Court finds that corporate witness Michelle Garrison's testimony provides a benchmark to estimate the portion of sales representatives' meals provided to health care professionals. Two-thirds of the meetings listed in Ms. Garrison's "fairly representative" sales representative itinerary involved Defendants' pelvic mesh products as opposed to the other products in the Women's Health portfolio. (PX0871.) Accordingly, the Court shall apply the two-thirds benchmark provided by Ms. Garrison's itinerary to the meal numbers identified in Mr. Armstrong's testimony and Defendants' expense data. (*See* 8/6/19 Tr. 84:12-19 & 87:2-7; PX0001.) Mr. Armstrong's estimates yield the following estimates of UCL and FAL violations occurring over meals at which Defendants would more likely than not deliver misleading communications about pelvic mesh.

Penalty Count: Misleading Statement over Meals[15]						
Sales Rep % Time Spent on Mesh	100%		66% [2/3 Benchmark]		15%[16] [Alternate Count]	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL
Year						
Post-Oct 17, 2008[17]	571	-	377	-	86	-

[15] (*See* 8/6/19 Tr. 84:12-19, 87:2-7; PX0001.)

[16] Estimated violations based on applying the lower benchmark of Ms. Garrison's trial testimony (15% of her time spent on mesh) rather than her deposition testimony (66%) to the meals identified in Mr. Armstrong's testimony and Defendants' expense data (*see* 8/6/19 Tr. 84:12-19 & 87:2-7; PX0001.)

[17] The Court divides Mr. Armstrong's estimates by six to limit the count to the last two months of the year. (*Cf.* 8/6/2019 Tr. 94:7-14.)

Penalty Count: Misleading Statements [illegible]						
[illegible]	100%		66% [2/3 Benchmark]		15%[16] [Alternate Count]	
[illegible] Oct. 15, 2009	-	543	-	359	-	82
2009	3,260	-	2,152	-	489	-
2010	2,813	2,813	1,857	1,857	422	422
2011	1,760	1,760	1,162	1,162	264	264
2012	806	806	532	532	121	121
2013	1,246	1,246	822	822	187	187
2014	1,520	1,520	1,003	1,003	228	228
2015	446	446	294	294	67	67
Total	**12,422**	**9,134**	**8,199**	**6,029**	**1,864**	**1,371**

VI. Field Marketing

1. The Court finds that all of Defendants' mesh-related field marketing activities—which consisted of health fairs, public relations, primary care physician outreach, patient outreach, and patient education events—disseminated the same deceptive marketing messages that pervade Defendants' other marketing materials, and therefore all violated the UCL and FAL. (See Violations Appendix, particularly pp. 1, 7.) The Court also finds that the number of attendees or impressions generated by each mesh-related activity is a reasonable basis for counting violations for penalty purposes.

2. It is reasonable for the Court to infer that deceptive statements were disseminated through each documented Field Marketing activity. Speaking events targeting primary care providers and patients featured presentations that excerpted misleading and deceptive IFU information, and repeated many of the same deceptive marketing messages contained in Defendants' professional education and print marketing materials. (See, e.g., JX10226 [primary care presentation excerpting misleading risk information from IFU], JX11302 [same]; JX11343 [POP Patient Education Presentation with misleading risk information]; JX11347 [SUI Patient Education Presentation with same]; see also Violations Appendix: Patient Presentations & Primary-Care Physicians Materials; PX4771 at 64:16-67:06 [presenters at field marketing events could only present Ethicon-generated content and could only distribute Ethicon-approved visual aids and handouts].) The same messages pervaded patient outreach materials, such as mailers. (See, e.g., JX10275 at 2, 13-14; see also Violations Appendix: Patient Materials – Other Advertising.) Defendants used public appearances such as health fairs to "present patient information, product information, condition information," which the Court can reasonably infer to include marketing materials, marketing messages, and risk information that it has already found to be deceptive. Defendants also handed out their misleading brochures as part of field

---

[18] The Court divides Mr. Armstrong's estimates by six to limit the count to the last two months of the year. (*Cf.* 8/6/2019 Tr. 94:7-14.)

marketing events and activities (see, e.g., PX4771 at 205:03-22 [Defendants always brought a minimum of one printed brochure per expected attendee to hand out at patient education events]). Lastly, Defendants provided hospitals with public relations kits that the Court finds were reasonably likely to perpetuate deceptive messages about the benefits of mesh but not the risks. (8/6/19 Tr. 34:3-8.)

3. To count the violations arising out of Defendants' field marketing for penalty purposes, the Court need not look further than Defendants' own data recording the number of attendees or impressions associated with each completed field marketing activity. Defendants' Field Marketing manager, Jason Goodbody, maintained "tracker" spreadsheets documenting all of the field marketing activities Defendants conducted in 2009, 2010, and 2011.[19] (PX0358; PX0299.) The trackers record unambiguously whether any given activity relates to a mesh product. (PX4771 at 279:22-280:05 [Mr. Goodbody's field marketing event tracker "records the brand platform to which each tracked event relates," so there "really isn't any ambiguity about whether or not a particular event related to an SUI or POP product"]; PX0358; PX0299.) For most entries, the trackers record as applicable either the number of attendees or the number of impressions generated. (PX0358; PX0299.) Given the consistency with which Defendants' marketing materials convey the same misrepresentations about their mesh products, it is more likely than not that attendees at Defendants' field marketing events, or the persons captured in Defendants' impressions counts, were exposed to those misrepresentations as well.

4. The Court finds that Mr. Armstrong provided reasonable counts of violations for penalty purposes arising out of field marketing activities based on the attendee and impressions data listed in Mr. Goodbody's tracker for California field marketing efforts related to mesh products:

Total Field Marketing UCL & FAL Violations: 2009-2011[20]		
Violation Type	Total	
	UCL	FAL[21]
Health Fairs	**2,575**	**2,505**
Patient Education	**593**	**433**
Patient Outreach	**500**	**500**
Public Relations	**22,500**	**22,500**
Primary Care	**309**	**294**

[19] While Defendants did conduct field marketing activities in 2008, Defendants made no data available for that period. (8/6/19 Tr. 27:1-26, 28:18-20.)

[20] (8/6/2019 Tr. 32:20-23, 32:24-34:1, 33:7-10, 34:15-18, 35:9-13; PX0358 [2009 figures]; PX0299 [2010 and 2011 figures].)

[21] The Court reaches this number by tabulating the California-based events that occurred in 2009 as listed in the "Tracking" tab of PX0358.

Violations Appendix

Key to Violations Appendix

This key provides a description of the specific manner in which each piece of marketing catalogued in the following appendix was misleading. However, as described in the Court's order, there are just two fundamental ways in which Defendants' marketing materials were misleading:

- **The material excerpted or directed consumers to Defendants' misleading IFUs.**
- **The material presented the benefits of mesh without all of the known risks.**

In other words, the common, overarching deception that runs through each of Defendants' marketing materials, and which underlies the examples below, is Defendants' failure to communicate all the known, serious, long-term risks specific to their mesh products.

Note: Within the following appendix, materials that Jason Logan distributed are noted with *. Materials that Archer Corporate Services distributed are noted with **. Materials that both Archer and Logan distributed are noted with ***.

I. Patient/PCP-directed marketing:

Advertising that mesh would provide lifestyle benefits with minimal risks and/or painting an overwhelmingly positive picture of mesh (e.g., through misleading statements like 97% of women cured and satisfied) without disclosing known serious, long-term complications specific to mesh by:

1. **Including a misleadingly incomplete risks discussion**: In the section or paragraph discussing risks (e.g., "What Are the Risks" section), including a misleadingly incomplete description of risks and/or misleadingly presenting the risks as common to all pelvic surgery procedures instead of identifying the serious risks introduced by mesh; or

2. **Excerpting misleadingly incomplete adverse events information from the IFU**: Reprinting or summarizing the misleadingly incomplete "adverse events" section of the IFU (e.g., as "Essential Product Information"); or

3. **Stating, "For a complete description of risks, see the attached product information" or otherwise directing consumers to the misleadingly incomplete IFU or IFU excerpt:** Directing consumer to the misleadingly incomplete "adverse events" section of the IFU or summary (e.g., "Essential Product Information") for product/risk information.

II. Doctor-directed marketing and sales rep training/materials:

1. **Advertising sells benefits while omitting known risks:** Advertising the benefits and positive outcomes of mesh, including improved quality of life and sexual function, without disclosing 1) the dangerous properties of mesh known to the company, such as chronic foreign body reaction, infection/biofilm, and contracture; 2) the mesh-specific complications known to the company, such as chronic pain, chronic dyspareunia, and urinary dysfunction; or 3) the possible need for mesh removal and the dangers of removal.

2. Misrepresenting risks introduced by mesh by:

   a. **Excerpting misleadingly incomplete adverse events information from the IFU**: Reprinting or excerpting the misleadingly incomplete "adverse events" section of the IFU.

b. **Stating, "See package insert for full prescribing information" or otherwise directing consumers to misleadingly incomplete IFU :** Directing consumer to the misleadingly incomplete IFU or "adverse events" section of the IFU for product/risk information.

3. **Misleading statements about mesh properties:** Advertising the positive properties of mesh, without disclosing risks, so as to mislead doctors into believing that there are no added risks to using mesh by:

a. **Misleadingly stating that mesh resists infection or similar language without disclosing known risk of mesh infection/biofilm:** Misleadingly stating that mesh resists infection (e.g., is inert to infection, does not potentiate infection, is macroporous, allows for macrophage penetration, or does not harbor bacteria) without disclosing the risk of biofilm/infection; and/or

b. **Misleadingly stating that mesh has healthy tissue incorporation or similar language without disclosing known risk of contracture:** Misleadingly stating that mesh fosters healthy tissue incorporation (e.g., incorporates into tissue, acts like healthy native tissue, allows for tissue ingrowth, allows for integration with tissue, or allows for proper tissue incorporation) without disclosing the risk of shrinkage and contracture; and/or

c. **Misleadingly stating that mesh has minimal foreign body response/inflammation or similar language without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications:** Misleadingly stating that mesh may cause a minimal foreign body reaction or inflammatory reaction (e.g., mesh causes no, minimal, insignificant, or transitory foreign body response or inflammation; mesh causes less inflammation in surrounding tissue; mesh has low or reduced tissue reactivity; or mesh is inert, biocompatible, or histologically well tolerated) without disclosing the risk of chronic foreign body reactions and inflammatory reaction, leading to serious complications; and/or

d. **Misleadingly stating that mesh is soft, elastic, or resists wound contraction without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening:** Misleadingly stating that mesh is soft, elastic, or resists wound contraction (e.g., mesh is soft, supple, elastic, or pliable; mesh has bidirectional elasticity; mesh leads to a softer and more supple vagina; or mesh resists wound contraction) without disclosing the risk of contracture/shrinkage, which can result in stiffness and hardening, leading to serious complications.

4. **Using Ulmsten/Nilsson studies to paint misleadingly positive picture**: Misleadingly using the Ulmsten or Nilsson studies to tout the benefits of mesh and make risks seem negligible without disclosing the significant risk of urinary complications and the risk of serious, long-term complications specific to or introduced by mesh.

5. **Advertising sells benefits of TVT-O without disclosing known risk of severe, long-term leg pain:** Misleadingly advertising the benefits of TVT-O without disclosing the risk of severe, long-term leg pain.

PATIENT PRESENTATIONS				
Exhibit	Document Name	Bates number	Date	Violations
JX10835	PROLAPSE/SUI Patient Seminar Presentation	ETH.MESH.00142997	3/7/2007	1. Includes a misleading/incomplete risks discussion at pages JX10835.30 and 10835.57
JX11343	POP Patient Education Presentation	ETH.MESH.02232308	11/29/2011	1. Includes a misleading/incomplete risks discussion at pages JX11343.21-JX11343.22 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11343.25-JX11343.26 3. States, "Please refer to the GYNECARE PROLIFT+M and GYNECARE PROSIMA Pelvic Floor Repair system brochure for a complete list of benefits, drawbacks and risks associated with this procedure" at page JX11343.21
JX11347	SUI Patient Education Presentation	ETH.MESH.02236886	12/13/2011	1. Includes a misleading/incomplete risks discussion at page JX11347.22 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11347.24 3. States, "Please refer to the GYNECARE TVT Retropubic Tension-Free Suppor for Incontinence patient brochure for a complete list of benefits, drawbacks and risks associated with this procedure" at page JX11347.22
JX11595	SUI Patient Outreach Presentation	ETH.MESH.01660949	8/6/2008	1. Includes a misleading/incomplete risks discussion at page JX11595.21 2. States, "For more information on risks please click this link http://www.whatshappeningdownthere.com/pdf/TVT_EssentialProductInformation.pdf" at page JX11595.21
JX11618	EWH&U Urinary Incontinence Deck for Assisted Living	ETH.MESH.02343658	10/15/2008	1. Includes a misleading/incomplete risks discussion at page JX11618.23 2. States, "For more information on risks please visit this site http://www.whatshappeningdownthere.com/pdf/TVT_EssentialProductInformation.pdf" at page JX11618.23

PATIENT BROCHURES				
Exhibit	Document Name	Bates number	Date	Violations
JX10420	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (Resubmission of	ETH.MESH.00144270	6/27/2001	1. Includes a misleading/incomplete risks discussion at page JX10420.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10420.9
JX10199	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure reprint	ETH.MESH.00155619	12/8/2004	1. Includes a misleading/incomplete risks discussion at page JX10199.8 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10199.8 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10199.8
JX10213*	GYNECARE TVT Family of Products Patient Brochure 3/09	ETH.MESH.00161969	12/10/2008	1. Includes a misleading/incomplete risks discussion at page JX10213.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10213.15 3. States, "For a complete description of risks, see the attached product information" at page JX10213.14
JX10202*	GYNECARE TVT* Tension-free Support for Incontinence Patient Brochure	ETH.MESH.00162841	9/27/2006	1. Includes a misleading/incomplete risks discussion at page JX10202.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10202.15 3. States, "For a complete description of risks, see the attached product information" at page JX10202.14
JX10206	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (not including TVT SECUR)	ETH.MESH.00163582	5/30/2007	1. Includes a misleading/incomplete risks discussion at page JX10206.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10206.15 3. States, "For a complete description of risks, see the attached product information" at page JX10206.14
JX10205*	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (including TVT SECUR)	ETH.MESH.00163644	5/30/2007	1. Includes a misleading/incomplete risks discussion at page JX10205.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10205.15 3. States, "For a complete description of risks, see the attached product information" at page JX10205.14
JX10786	GYNECARE TVT Patient Brochure	ETH.MESH.00166633	7/12/2006	1. Includes a misleading/incomplete risks discussion at page JX10786.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10786.15 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10786.14 and "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10786.15
JX11568	GYNECARE TVT Tension-free Support for Incontinence Abbreviated Brochure	ETH.MESH.00166868	9/1/2004	1. Includes a misleading/incomplete risks discussion at page JX11568.4 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11568.4 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX11568.4
JX10200	GYNECARE TVT* Tension-free Support for Incontinence Patient Education Brochure	ETH.MESH.00658421	4/13/2005	1. Includes a misleading/incomplete risks discussion at page JX10200.8 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10200.8 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10200.8
JX10988	POP Patient Brochure	ETH.MESH.02229359	2/10/2010	1. Includes a misleading/incomplete risks discussion at page JX10988.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10988.18-19
JX10989***	Prolapse Patient Brochure 2010	ETH.MESH.02229379	2/10/2010	1. Includes a misleading/incomplete risks discussion at page JX10989.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10989.18-19
JX10977	Prolapse Patient Brochure 2009	ETH.MESH.02229951	1/20/2010	1. Includes a misleading/incomplete risks discussion at page JX10977.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10977.18-19
JX11167	Prolapse Patient Brochure 2010 - Spanish Version	ETH.MESH.02231492	9/20/2010	1. Includes a misleading/incomplete risks discussion at page JX11167.14 2. Excerpts misleadingly incomplete adverse events information from the IFU a pages JX11167.18-19
JX10223**	GYNECARE TVT Patient Brochure - 2011	ETH.MESH.02236180	2/7/2011	1. Includes a misleading/incomplete risks discussion at page JX10223.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10223.8
JX10222*	GYNECARE TVT Patient Brochure	ETH.MESH.02236580	1/26/2011	1. Includes a misleading/incomplete risks discussion at page JX10222.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10222.15 3. States, "For a complete description of risks, see the attached product information" at page JX10222.14
JX10197	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (TVT016R1) - Review for Reprint	ETH.MESH.02619504	10/16/2002	1. Includes a misleading/incomplete risks discussion at page JX10197.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10197.2 and JX10197.8 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10197.7
JX10198	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (TVT016R3)	ETH.MESH.02619601	3/3/2004	1. Includes a misleading/incomplete risks discussion at page JX10198.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10198.15 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10198.14
JX10210	GYNECARE TVT Family of Products Patient Brochure	ETH.MESH.03458123	3/19/2008	1. Includes a misleading/incomplete risks discussion at page JX10210.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10210.15 3. States, "For a complete description of risks, see the attached product information" at page JX10210.14

PATIENT BROCHURES				
Exhibit	Document Name	Bates number	Date	Violations
JX10829	SUI Awareness Campaign Materials	ETH.MESH.03460801	2/7/2007	1. Includes a misleading/incomplete risks discussion at page JX10829.5 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10829.6 3. States, "For a complete description of risks, see the adverse reactions section of the product information that follows" at page JX10829.5
JX10722	GYNECARE PROLIFT* Pelvic Floor Repair System Patient Brochure	ETH.MESH.03905968	11/9/2005	1. Includes a misleading/incomplete risks discussion at page JX10722.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10722.8
JX10800	GYNECARE PROLIFT* Pelvic Floor Repair Systems Patient Brochure	ETH.MESH.03905976	11/15/2006	1. Includes a misleading/incomplete risks discussion at page JX10800.13 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10800.14-15 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10597.14
JX11599*	Pelvic Organ PROLAPSE Patient Brochure	ETH.MESH.03906037	10/22/2008	1. Includes a misleading/incomplete risks discussion at pages JX11599.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11599.15
JX10597	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (TVT016R3)	ETH.MESH.08003181	3/3/2004	1. Includes a misleading/incomplete risks discussion at page JX10597.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10597.15 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10597.14
JX11621	GYNECARE TVT Family of Products Patient Brochure	ETH.MESH.08003279	12/10/2008	1. Includes a misleading/incomplete risks discussion at page JX11621.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11621.15 3. States, "For a complete description of risks, see the attached product information" at page JX11621.14
JX10868**	Gynecare TVT Patient Brochure	ETH.MESH.08003295	10/15/2012	1. Includes a misleading/incomplete risks discussion at page JX10868.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10868.8
JX11338*	Prosima VSD Brochure	ETH.MESH.08692838	11/9/2011	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11338.1
JX11468	TVT Spanish Patient Brochure	ETH.MESH.09744826	3/7/2013	1. Includes a misleading/incomplete risks discussion at page JX11468.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11468.6
JX11463**	TVT Patient Brochure 2013	ETH.MESH.09744840	2/14/2013	1. Includes a misleading/incomplete risks discussion at page JX11463.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11463.6
JX10227	Gynecare TVT Patient Brochure	ETH.MESH.09744848	10/15/2012	1. Includes a misleading/incomplete risks discussion at page JX10227.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10227.8
JX11445**	TVT Patient Brochure	ETH.MESH.09744858	12/10/2012	1. Includes a misleading/incomplete risks discussion at page JX11445.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11445.6
JX11420	Gynecare TVT Patient Brochure	ETH.MESH.13681369	10/15/2012	1. Includes a misleading/incomplete risks discussion at page JX11420.7 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11420.8
JX10229	Incontinence Patient Brochure (not including TVT SECUR)	ETH.MESH.13694138	2/14/2013	1. Includes a misleading/incomplete risks discussion at page JX10229.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10229.6
JX11325***	Spanish GYNECARE TVT Patient Brochure, Translated from GYNECARE TVT English Patient Brochure	ETH.MESH.13753847	8/24/2011	1. Includes a misleading/incomplete risks discussion at page JX11325.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11325.15 3. States (in Spanish), "For a complete description of risks, see the attached product information" at page JX11325.14
JX10516	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (TVT016R1) - Review for Reprint	ETH.MESH.15151657	10/16/2002	1. Includes a misleading/incomplete risks discussion at page JX10516.4 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10516.2 and JX10516.3 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10516.4
JX10639	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure reprint	ETH.MESH.22414327	12/8/2004	1. Includes a misleading/incomplete risks discussion at page JX10639.14 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10639.15 3. States, "For a complete description of risks, see the adverse events section of the attached product information" at page JX10639.14
JX10232	TVT Patient Brochure	ETH.MESH.22824765	11/14/2014	1. Includes a misleading/incomplete risks discussion at page JX10232.11 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10232.12
JX10233	GYNECARE TVT Patient Brochure	ETH.MESH.22824789	3/25/2015	1. Includes a misleading/incomplete risks discussion at page JX10233.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10233.6 3. States, "Review the Essential Product Information provided in this brochure for more information on potential risks" at page JX10233.6

PATIENT WEBSITES				
Exhibit	Document Name	Bates number	Date	Violations
PX2543	www.pelvichealthsolutions - Risk Information: Gynecare Prolift (11/17/2011)	WA-AG-JJETH-00003057	11/17/2011	1. Excerpts misleadingly incomplete adverse events information from the IFU at page PX2543 2. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX2543
PX2568	www.pelvichealthsolutions.com - What to Expect (01/03/2013) (WA-AG-JJETH-00003082-83)	WA-AG-JJETH-00003082	1/3/2013	1. Includes a misleading/incomplete risks discussion at page PX2568 2. States, "For a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information" at page PX2568.1 and "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX2568.2
PX4654	gynecare.com	ETH.MESH.00144084	Last copyright 2006	1. Includes a misleading/incomplete risks discussion at page PX4654 2. States, "For a complete description of risks, view Essential Product Information" at page PX4654.1
PX4656	gynecare.com	ETH.MESH.00155362	Last copyright 2007	1. States, "For full information on GYNECARE TVT Tension-free Support For Incontinence, view Essential Product Information" at page PX4656.
PX4657	pelvichealthsolutions.com	ETH.MESH.02229749	Last copyright 2010	1. Includes a misleading/incomplete risks discussion at pages PX4657.65 and PX4657.72 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages PX4657.69, PX4657.75, and PX4657.78 3. States, "For a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information" at page PX4657.65 and "For a complete description of risks related to this treatment, please see Risk Information" at page PX4657.72. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at pages PX4657.63-73 and PX4657.76-78
PX4659	pelvichealthsolutions.com (ETH.MESH.19808204)	ETH.MESH.19808204	2/17/2009	1. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX4659
PX4660	pelvichealthsolutions.com (ETH.MESH.19808205)	ETH.MESH.19808205	2/17/2009	1. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX4660
PX4661	pelvichealthsolutions.com (ETH.MESH.19808206)	ETH.MESH.19808206	2/18/2009	1. Includes a misleading/incomplete risks discussion at page PX4661 2. States, "For a complete description of risks related to this treatment, please see Adverse Reactions section of the Risk Information" and "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX4661
PX4662	pelvichealthsolutions.com (ETH.MESH.19808211)	ETH.MESH.19808211	2/17/2009	1. Excerpts misleadingly incomplete adverse events information from the IFU at page PX4662 2. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at page PX4662
PX4668	pelvichealthsolutions.com	ETH.MESH.PM.000242	Last copyright 2013	1. Includes a misleading/incomplete risks discussion at page PX4668.4 2. Excerpts misleadingly incomplete adverse events information from the IFU at page PX4668.5 3. States, "For a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information" at page PX4668.4. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at pages PX4668.2-5
PX4802	Stipulated Exhibits for Deposition Excerpts of Linda Linton	ETH.MESH.02229988	Last copyright 2010	1. Includes a misleading/incomplete risks discussion at pages PX4802.55 and PX4802.62 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages PX4802.59 and PX4802.66 3. States, "For a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information" at page JX4802.55 and "For a complete description of risks related to this treatment, please see Risk Information" at page JX4802.62. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at pages PX4802.53-66

PATIENT MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX10221**	GYNECARE TVT RETROPUBIC - Mesh Placement Slim Jim for Patients	ETH.MESH.02237841	12/9/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10221.2 2. States, "Please see Important Safety Information on Other Side" at page JX10221.1
JX10240	GYNECARE TVT* Tension Free-free Support For Incontinence Call Center FAQs	ETH.MESH.00146355	11/7/2007	1. Includes a misleading/incomplete risks discussion at page JX10240.6
JX10241	PROLIFT Call Center FAQs	ETH.MESH.00146364	11/7/2007	1. Includes a misleading/incomplete risks discussion at pages JX10241.3-JX10241.4
JX10275	Joint GYNECARE TVT/GYNECARE PROLIFT Co-op Mailer	ETH.MESH.03458298	4/16/2008	1. Includes a misleading/incomplete risks discussion at pages JX10275.2, JX10275.13, and JX10275.14
JX10284*	GYNECARE TVT * Tension-free Support for Incontinence Patient Mailer Without GYNECARE SECUR	ETH.MESH.03458463	4/30/2008	1. Includes a misleading/incomplete risks discussion at page JX10284.1
JX10291	GYNECARE PROLIFT Pelvic Floor Repair System Mix and Match co op Ad Summary Sheet	ETH.MESH.03458507	5/21/2008	1. Includes a misleading/incomplete risks discussion at page JX10291.1
JX10294	Incontinence Mix and Match co op Ad Summary Sheet	ETH.MESH.03458515	5/21/2008	1. Includes a misleading/incomplete risks discussion at page JX10294.1
JX10296	GYNECARE TVT Tension-free Support for Incontinence Mix and Match co op Ad Summary Sheet	ETH.MESH.03458512	5/21/2008	1. Includes a misleading/incomplete risks discussion at page JX10296.1
JX10778	Incontinence & GYNECARE TVT* Tension-free Support for Incontinence FAQs	ETH.MESH.02619360	5/24/2006	1. Includes a misleading/incomplete risks discussion at page JX10778.6
JX10782	Prolapse & GYNECARE PROLIFT* Pelvic Floor Repair System FAQs	ETH.MESH.00144997	6/7/2006	1. Includes a misleading/incomplete risks discussion at pages JX10782.3-JX10782.4 2. 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10782.9
JX10802	GYNECARE TVT Tension-free Support for Incontinence Patient Ad	ETH.MESH.03460640	11/29/2006	1. Includes a misleading/incomplete risks discussion at page JX10802.1
JX10813	GYNECARE PROLIFT* Pelvic Floor Repair System Print Ad	ETH.MESH.00147654	1/17/2007	1. Includes a misleading/incomplete risks discussion at page JX10813.1
JX10817	GYNECARE TVT* Family of Products Ad	ETH.MESH.00155330	1/24/2007	1. Includes a misleading/incomplete risks discussion at page JX10817.1
JX10822	GYNECARE TVT* SECURE System Co-Op Ads	ETH.MESH.00155335	1/31/2007	1. Includes a misleading/incomplete risks discussion at pages JX10822.1 and JX10822.2
JX10827	GYNECARE TVT* SECUR Patient Mailer	ETH.MESH.00142449	2/7/2007	1. Includes a misleading/incomplete risks discussion at page JX10827.3
JX10830	GYNECARE PROLIFT* Pelvic Floor Repair System Coop Ads	ETH.MESH.03460809	2/14/2007	1. Includes a misleading/incomplete risks discussion at pages JX10830.1, JX10830.2, JX10830.3, and JX10830.4
JX10831	GYNECARE TVT* Tension Free Support For Incontinence Print Co- op Ads	ETH.MESH.00145218	2/14/2007	1. Includes a misleading/incomplete risks discussion at pages JX10831.1 and JX10831.2
JX10856	GYNECARE PROLIFT Patient Mailer	ETH.MESH.02619294	7/11/2007	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10856.4-JX10856.5
JX10861	GYNECARE PROLIFT Patient Testimonial DVD	ETH.MESH.00166780	8/22/2007	1. Includes a misleading/incomplete risks discussion at page JX10861.6 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX10861.8-JX10861.9
JX10867	GYNECARE TVT Family of Products Patient Mailer	ETH.MESH.00148764	9/26/2007	1. Includes a misleading/incomplete risks discussion at page JX10867.1
JX10893	SUI Press Kit	ETH.MESH.13653535	6/15/2009	1. Includes a misleading/incomplete risks discussion at page JX10893.6, JX10893.8, and JX10893.10
JX11052*	GYNECARE TVT Incontinence Screening Aid - 2010	ETH.MESH.02236762	6/28/2012	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11052.2 2. States, "Please see important Safety Information on reverse side" at page JX11052.1
JX11096	Prolapse Press Kit	ETH.MESH.02233249	6/8/2010	1. Includes a misleading/incomplete risks discussion at pages JX11096.6 and JX11096.8 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11096.10 and JX11096.11 3. States, "Please see enclosed prescribing information" at pages JX11096.5 and JX11096.7. States, "Please refer to the full package insert for complete product information including warnings, precautions and adverse reactions" at page JX11096.11
JX11206	Prolapse Waiting Room Slim Jim	ETH.MESH.02232347	11/5/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11206.2 2. States, "See Important Safety Information on Other Side" at page JX11206.1
JX11207	GYNECARE TVT Waiting Room Slim Jim	ETH.MESH.02236578	11/8/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11207.2 2. States, "See Important Safety Information on Other Side" at page JX11207.1
JX11229***	GYNECARE TVT ABBREVO - Mesh Placement Slim Jim	ETH.MESH.02235324	12/8/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11229.2 2. States, "Please see important Safety Information on Other Side" at page JX11229.1
JX11230***	GYNECARE TVT EXACT - Mesh Placement Slim Jim	ETH.MESH.02237658	12/8/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11230.2 2. States, "Please see important Safety Information on Other Side" at page JX11230.1

PATIENT MATTERS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX11231*	GYNECARE TVT SECUR - Mesh Placement Slim Jim	ETH.MESH.02237848	12/9/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11231.2 2. States, "Please see important Safety Information on Other Side" at page JX11231.1
JX11232***	GYNECARE TVT-O - Mesh Placement Slim Jim	ETH.MESH.02237834	12/9/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11232.2 2. States, "Please see important Safety Information on Other Side" at page JX11232.1
JX11238	SUI POP Patient Flip Chart	ETH.MESH.02231566	12/21/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11238.11 and JX11238.22
JX11250	Patient Counseling Flip Chart for SUI and POP	ETH.MESH.02232119	1/31/2011	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11250.11 and JX11250.22
JX11442	SUI Patient Counseling Guide	ETH.MESH.13683876	12/5/2012	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11442.9
JX11475	TVT Waiting Room Slim Jim TVT 332-12	ETH.MESH.25534664	5/1/2013	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11475.2 2. States, "See Important Safety Information on Other Side" at page JX11475.1
JX11476	GYNECARE TVT Obturator - Mesh Placement for Patient Consult TVTO-345-12	ETH.MESH.09744870	5/3/2013	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11476.2 2. States, "Please see Important Safety Information on Other Side" at page JX11476.1
JX11477	GYNECARE TVT ABBREVO - Mesh Placement Sheet for Patient Consult TVTA-357-10	ETH.MESH.13683960	5/7/2013	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11477.2 2. States, "Please see Important Safety Information on Other Side" at page JX11477.1
JX11478	Gynecare TVT Incontinence Screening Aid TVT-343-12	ETH.MESH.25535069	5/7/2013	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11478.2 2. States, "Please see important Safety Information on reverse side" at page JX11478.1
JX11479	TVT Exact Mesh Placement Slim Jim for PT Consult TVTE 333-12	ETH.MESH.25534687	5/7/2013	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11479.2 2. States, "Please see Important Safety Information on Other Side" at page JX11479.1
JX11612*	GYNECARE TVT Office Poster	ETH.MESH.02236732	4/15/2009	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11612.1
PX0423	Email Blast Copy Review Document	ETH.MESH.13718147	Last copyright 2009	1. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and contraindications for the Ethicon products featured on this page" at PX0423.3

PRIMARY-CARE PHYSICIAN MATERIALS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX10226	Female Urinary Incontinence PCE	ETH.MESH.02236708	4/11/2011	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10226.16
JX11053	Prolift PCP education letter template	ETH.MESH.13711169	5/3/2010	1. Includes a misleading/incomplete risks discussion at page JX11053.2
JX11055	TVT PCP education letter template	ETH.MESH.13711087	5/3/2010	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX1055.2
JX11302	Pelvic Organ Prolapse Primary Care Awareness Education Presentation	ETH.MESH.13758189	5/13/2011	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11302.19-JX11302.21

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX10201	GYNECARE TVT SECUR* System Professional Education Presentation	ETH.MESH.00166670	7/12/2006	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10201.14
JX10207	GYNECARE TVT SECUR Professional Education Presentation	ETH.MESH.00166805	8/23/2007	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10207.20 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10207.3
JX10208	GYNECARE TVT SECUR Professional Education Presentation – for Medtronic EWH&U Prof Ed Pilot Program	ETH.MESH.00166789	8/23/2007	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10208.12 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10208.2
JX10209	TVT SECUR Professional Education Preceptor Slide Deck – Summit	ETH.MESH.00148625	2/6/2008	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10209.38 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10209.4
JX10220	GYNECARE TVT ABBREVO Professional Education Slides	ETH.MESH.02235388	8/20/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10220.14 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX10220.24 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10220.24
JX10225	TVT EXACT Professional Education deck	ETH.MESH.02235536	3/23/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10225.31
JX10789	GYNECARE TVT SECUR System R&D Presentation	ETH.MESH.00166692	7/12/2006	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10789.14
JX10840	GYNECARE PROLIFT* Surgeon Resource Monograph	ETH.MESH.03460813	4/4/2007	1. Advertising sells benefits while omitting known risks
JX10846	AUA PROLIFT Presentation	ETH.MESH.00147356	5/9/2007	1. Advertising sells benefits while omitting known risks
JX10862	GYNECARE TVT SECUR Professional Education Presentation	ETH.MESH.00370392	8/22/2007	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10862.41
JX10863	GYNECARE TVT SECUR Professional Education Presentation — for Medtronic EWH&U Prof Ed Pilot Program	ETH.MESH.00370417	8/22/2007	1. Advertising sells benefits while omitting known risks 2. States, "For more information refer to full instructions for use" at page JX10863.25 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX10863.4-JX10863.5
JX10941	Prosima Prof Ed Deck Oct 09	ETH.MESH.13634707	10/21/2009	1. Advertising sells benefits while omitting known risks 2. States, "IFU: Refer to Instruction for Use for the Detailed description on surgical technique and important clinical information" at pages JX10941.1-JX10941.20

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	Document Name	Bates number	Date	Violations
JX11110	TVT EXACT Webinar Professional Education Deck	ETH.MESH.00295355	7/13/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including indications, contraindications, warnings, precautions and adverse reactions, see full prescribing information" at page JX11110.8 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11110.31-JX11110.32
JX11141	2010 TVT EXACT IUGA deck	ETH.MESH.01652176	8/19/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including indications, contraindications, warnings, precautions and adverse reactions, see full prescribing information" at page JX11141.8 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11141.15-JX11141.16
JX11142	Prosima 2 Year Data	ETH.MESH.02233333	8/19/2010	1. Advertising sells benefits while omitting known risks 2. States, "All surgical procedures have risks. For complete product details, see IFU" at page JX11142.13
JX11143	Prosima Revised Webinar Deck	ETH.MESH.02233346	8/19/2010	1. Advertising sells benefits while omitting known risks 2. States, "All surgical procedures have risks. For complete product details, see IFU" at page JX11143.21
JX11147	GYNECARE TVT ABBREVO Professional Education Slides	ETH.MESH.00575093	8/20/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11147.15
JX11148	GYNECARE TVT ABBREVO Related Presentations at ICS IUGA	ETH.MESH.01201984	8/20/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11148.38
JX11169	GYNECARE TVT ABBREVO Abbreviate Professional education deck	ETH.MESH.02235121	9/30/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11169.35 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX11169.18 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11169.18
JX11184	GYNECARE TVT ABBREVO Professional Education Deck Ver 2	ETH.MESH.09161588	10/13/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11184.56 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX11184.20 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11184.20
JX11197	GYNECARE TVT ABBREVO Professional education deck version 3	ETH.MESH.09161609	10/26/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11197.42 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX11197.15 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11197.15

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	Document Name	Bates number	Date	Violations
JX11221	GYNECARE TVT ABBREVO Professional Education deck ver 4	ETH.MESH.08231789	11/19/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11221.48 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX11221.25 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11221.25
JX11259	TVT ABBREVO Prof Ed Slides Revised	ETH.MESH.00354732	2/16/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11259.46 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JX11259.18 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11259.18
JX11273	TVT EXACT Professional Education deck	ETH.MESH.03626792	3/23/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11273.32
JX11283	AUA Slings Study Presentation	ETH.MESH.02236693	4/11/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11283.15
JX11311	Prosima Prof Ed Deck 2011	ETH.MESH.06584713	6/14/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11311.72 3. States, "Please refer to the full package insert for complete product information including warnings precautions and adverse reactions" at page JX11311.72
JX11405	Erickson Abbrevo Webinar	ETH.MESH.13745275	8/21/2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11405.18
JX11490	Evolution of Sub-urethral Slings for the Surgical Correction of Female Stress Urinary Incontinence (SUI) - Obturator	ETH.MESH.13739540	6/25/2013	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11490.38
JX11491	Evolution of Sub-urethral Slings for the Surgical Correction of Female Stress Urinary Incontinence (SUI) - Retropubic	ETH.MESH.13704630	6/25/2013	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11491.28
JX11558	TVT EXACT Professional Education deck	ETH.MESH.09218199	7/23/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including indications, contraindications, warnings, precautions and adverse reactions, see full prescribing information" at page JX11558.12 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11558.20-JX11558.21

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX11608	The Science of What's Left Behind (Doug Grier Presentation)	ETH.MESH.00995520	4/15/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information form the IFU at page JX11608.38 3. Misleadingly states that mesh "is highly inert," without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications, at page JX11608.12 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11608.12 and JX11608.18-JX11608.20 5. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11629	The Science of What's Left Behind Abbreviated Mesh Presentation	ETH.MESH.03460270	4/15/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11629.8 3. Misleadingly states that mesh "is highly inert," without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications, at page JX11629.7 4. Using Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11629.6-JX11629.7
PX4809	2010 TVT EXACT IUGA deck	ETH.MESH.23973951	Created on: 8/31/2010; last modified on: 4/5/2012	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including indications, contraindications, warnings, precautions and adverse reactions, see full prescribing information" at page PX4809.7 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages PX4809.4 and PX4809.14-PX4809.15
PX4810	TVT EXACT Updated Prof Ed Slide Deck	ETH.MESH.08117473	Copyright: 2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page PX4810.52 3. States, "For complete product details, see Instructions for Use" at page PX4810.11 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages PX4810.8 and PX4810.19-4810.20

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX10538	GYNECARE TVT Tension -free Support for incontinence blue mesh Sales Aid	ETH.MESH.03457388	5/14/2003	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10538.6 3. Misleadingly states, "porous structure of mesh allows for rapid tissue ingrowth," without disclosing known risk or contracture, at page JX10538.3 4. Misleadingly states, "Proven biocompatibility" and "no foreign body reaction after PROLENE mesh implantation," without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications, at page JX10538.3 5. Misleadingly states, "bi-directional mesh weave adapts to stresses of the body," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10538.3 6. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10538.3
JX10713	GYNECARE TVT* Obturator System Tension Free Support for Incontinence Sales Aid	ETH.MESH.00161953	8/31/2005	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10713.2 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10713.2 4. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX10727	GYNECARE GYNEMESH Sales Aid - Annual Review	ETH.MESH.00569445	12/21/2005	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10727.2 3. Misleadingly states, "Does not harbor bacteria" and "Allows for macrophage penetration," without disclosing known risk of mesh infection/biofilm, at page JX10727.1 4. Misleadingly states, "Low tissue reactivity," "inert synthetic mesh," and "Acts as a scaffold for tissue-ingrowth for rapid healing," without disclosing known risk or contracture, at page JX10727.1 5. Misleadingly states, "Lightweight, soft and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10727.1
JX10741	GYNECARE PROLIFT* Pelvic Floor Repair System Sales Aid — Annual Review	ETH.MESH.03460397	2/1/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10741.4 3. States, "For complete product information, consult product package insert" at page JX10741.4 4. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10741.6 5. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10741.6 6. Misleadingly states, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10741.6

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX10745	GYNECARE TVT SECUR System Sales Aid	ETH.MESH.00158289	2/1/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10745.3 3. Misleadingly states, "Unique elastic properties to maximize clinical response," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10745.4 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX10745.4 and JX10745.5
JX10762	GYNECARE TVT Sales Aid slim jim	ETH.MESH.00169748	3/22/2006	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10762.4 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10762.2 4. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX10763	GYNECARE TVT SECUR System Sales Aid —Resubmission	ETH.MESH.00169769	3/22/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10763.5 3. Misleadingly states, "Unique elastic properties to maximize clinical response," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10763.6 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX10763.1 and JX10763.7
JX10791	GYNECARE TVT SECUR* Sales Aid (Resubmission)	ETH.MESH.00165358	8/16/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10791.5 3. Misleadingly states, "Unique elastic properties to maximize clinical response," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10791.6 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX10791.1 and JX10791.7
JX10795	GYNECARE GYNEMESH* Slim Jim	ETH.MESH.00157044	10/25/2006	1. Advertising sells benefits while omitting known risks 3. States, "For full product information please refer to the Package Insert" at page JX10795.2 4. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10795.2 5. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10795.2
JX10804	GYNECARE TVT Family of Products Slim Jim Brochure	ETH.MESH.00161512	12/6/2006	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10804.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX10804.1 and JX10804.2 4. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain at page JX10804.2

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX10806	New GYNECARE PROLIFT* Pelvic Floor Systems Sales Aid	ETH.MESH.00161467	12/6/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10806.3 3. States, "For complete product information, consult product package insert" at page JX10806.3 4. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10806.2 5. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk or contracture, at page JX10806.2 6. Misleadingly states, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10806.2
JX10858	TVT SECUR Sales Aid Brochure	ETH.MESH.00166287	7/25/2007	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10858.3 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10858.3
JX10978*	Prosima Launch Slim Jim	ETH.MESH.02233729	1/20/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at pages JX10978.2 and JX10978.3
JX11101	Think Again Sales Aid	ETH.MESH.02233263	6/16/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, see Instructions for Use" at page JX11101.3
JX11112**	TVT EXACT slim jim	ETH.MESH.02236952	7/14/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11112.12-11112.15 3. States, "For complete product details, see Instructions for Use" at page JX11112.16 4. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11112.3
JX11155	GYNECARE TVT-O Slim Jim	ETH.MESH.02236604	8/26/2010	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions and adverse reactions, see Full Prescribing Information" at page JX11155.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11155.4 4. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11165**	GYNECARE TVT-O Slim Jim	ETH.MESH.02232349	9/16/2010	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions and adverse reactions, see Full Prescribing Information" at page JX11165.1 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain

DOCTOR DIRECTED SALES AIDS				
Exhibit	Document Name	Bates number	Date	Violations
JX11227***	GYNECARE TVT ABBREVO Sales Aid	ETH.MESH.02235326	12/2/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11227.4 3. States, "For complete product details, see Instructions for Use" at page JX11227.4
JX11228**	GYNECARE TVT ABBREVO Slim Jim	ETH.MESH.02235330	12/2/2010	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11228.16 3. States, "Please refer to the INSTRUCTIONS FOR USE included with this device for indications, contraindications, warnings, precautions and other important information about the GYNECARE TVT ABBREVO Continence System" at page JX11228.15
JX11241*	Prosima 2011 Sales Aid	ETH.MESH.02233902	1/3/2011	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11241.5 3. States, "For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full Instructions for Use" at page JX11241.5
JX11396**	TVT Exact Sales Aid	ETH.MESH.02235661	6/19/2012	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, see Instructions for Use" at page JX11396.4
JX11464	GYNECARE TVT ABBREVO Sales Aid TVTA 325-12	ETH.MESH.13681529	2/22/2013	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11464.4 3. States, "For complete product details, see Instructions for Use" at page JX11464.4
JX11484**	TVT Obturator Brochure	ETH.MESH.13700041	5/23/2013	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including warnings, precautions, and adverse events see Instructions for Use" at page JX11484.1 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11485**	TVT Retropubic Brochure	ETH.MESH.13699772	5/23/2013	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including warnings, precautions, and adverse events see Instructions for Use" at page JX11485.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11485.2
JX11546	GYNECARE TVT Obturator Sales Aid	ETH.MESH.24254181	4/6/2015	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11546.1 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11547	GYNECARE TVT Retropubic Sales Aid	ETH.MESH.24254222	4/6/2015	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11547.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11547.2

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
JX11553*	Prosima Launch Sales Aid	ETH.MESH.02233634	12/23/2009	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions and adverse reactions, see Instructions for Use" at pages JX11553.2 and JX11553.3
JX11597*	TVT Family of Products Brochure	ETH.MESH.02343072	9/10/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to full package insert for complete product information, including warnings, precautions, and adverse reactions" at page JX11597.6 3. Misleadingly states, "does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX11597.4 4. Misleadingly states, "Macroporous mesh fosters tissue incorporation," without disclosing known risk of contracture, at page JX11597.4 5. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain at pages JX11597.2 and JX11597.4 6. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page at page JX11597.3
JX11622*	GYNECARE PROLIFT +M Pelvic Floor Repair System Sales Detail Aid	ETH.MESH.00165801	12/17/2008	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11622.6 3. Misleadingly states, "Resists wound contraction (shrinkage)," "Softer, more supple tissue," and "Bi-directional properties," without disclosing the known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11622.5
JX11626	PROLIFT +M Brochure	ETH.MESH.19809966	3/4/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11626.6 3. Misleadingly states, "Resists wound contraction (shrinkage)," "Result in softer, more supple tissue," and "Bi-directional properties," without disclosing the known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11626.4
JX11628*	TVT Competitive Sales Aid	ETH.MESH.19810076	3/11/2009	1. Advertising sells benefits while omitting known risks 2. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11628.4 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
PX0104	TVT doctor brochure, Nov. 3, 2008 "OVER 11 YEARS of clinical data"	ETH.MESH.00165299	11/3/2008	1. Advertising sells benefits while omitting known risks 2. States, "Please refer to the full package insert for complete product information including warnings precautions and adverse reactions" at page PX0104.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX0104.1

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
PX0127	Gynecare TVT - 5 Years of Proven Performance - Lasting freedom for your SUI patients	ETH.MESH.00339437	Copyright: 2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page PX0127.6 3. Misleadingly states, "porous structure of mesh allows for rapid tissue ingrowth," without disclosing known risk or contracture, at page PX0127.3 4. Misleadingly states, "Proven biocompatibility" and "no foreign body reaction after PROLENE mesh implantation" without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications, at page PX0127.3 5. Misleadingly states, "bi-directional mesh weave adapts to stresses of the body," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page PX0127.3 6. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX0127.3

DOCTOR-DIRECTED WEBSITES				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
PX2437	www.ethicon360.com - Gynecare Prosima Pelvic Floor Repair System (05/13/2010)	WA-AG-JJETH-00002818	5/13/2010	1. States, "For complete indications, and important information on contraindications, warnings, [see] full prescribing information" at page PX2437
PX2444	www.ethicon360.com - Gynecare TVT Family of Products (12/17/2011)	WA-AG-JJETH-00002826	12/17/2011	1. Advertising sells benefits while omitting known risks 2. States, "For complete indications, contraindications, warnings,precautions, and adverse reactions, click Prescribing Information" at page PX2444 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX2444
PX4658	ethicon360.com	ETH.MESH.02236918		1. Advertising sells benefits while omitting known risks 2. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX4658.2, PX4658.4, PX4658.8, PX4658.13, and PX4658.18 3. Advertising sells benefits of TVT-O, without disclosing known risk of serious leg pain, at pages PX4658.13-14
PX4664	ethicon360.com (ETH.MESH.19809660)	ETH.MESH.19809660	3/12/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages PX4664.6, PX4664.36, and PX4664.39-40
PX4665	ethicon360.com (ETH.MESH.19809803)	ETH.MESH.19809803	4/16/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at pages PX4665.8 and PX4665.79-80 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX4665.2

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX10266	GYNECARE PROLIFT* Pelvic Floor Repair System Ad for AUA	ETH.MESH.03458288	4/9/2008	1. Advertising sells benefits while omitting known risks 2. States, "See Package Insert for full Prescribing Information" at page JX10266.1 3. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10266.1 4. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10266.1 5. Misleadingly states, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10266.1
JX10268	GYNECARE TVT SECUR Tension-Free Support for Incontinence Ad for AUA	ETH.MESH.03458285	4/9/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10268.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10268.1
JX10277	TVTO Ad	ETH.MESH.03458351	4/16/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10277.1 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX10299	GYNECARE TVT Family "Bouncy Ball" Professional Ad	ETH.MESH.03458659	6/4/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10299.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10299.1
JX10712	GYNECARE TVT* Obturator System Tension Free Support for Incontinence One Year Data Newsletter	ETH.MESH.02347155	8/31/2005	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10712.2 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX10742	GYNECARE TVT SECUR System Convention Panel and Journal Ad	ETH.MESH.00143568	2/1/2006	1. Advertising sells benefits while omitting known risks 2. States, "See representative for a full package insert" at page JX10742.2
JX10764	GYNECARE TVT SECUR* System Journal Ad —Resubmission	ETH.MESH.00169756	3/22/2006	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX10764.1
JX10792	GYNECARE PROLIFT* Convention Panel	ETH.MESH.00144961	9/13/2006	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10792.2 3. States, "For complete product information, consult product package insert" at page JX10792.2
JX10803	GYNECARE PROLIFT Professional Ad	ETH.MESH.00161490	12/6/2006	1. Advertising sells benefits while omitting known risks 2. States, "See Package Insert for full Prescribing Information" at page JX10803.1 3. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10803.1 4. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10803.1 5. Misleadingly states, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10803.1

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX10839	Urology Times Supplement	ETH.MESH.00155130	3/28/2007	1. Advertising sells benefits while omitting known risks, at page JX10839.11 2. States, "See Package Insert for full Prescribing Information" at page JX10839.11 3. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10839.11 4. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10839.11 5. Misleadingly states, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10839.11
JX10851	GYNECARE PROLIFT Systems Convention Panel	ETH.MESH.00143468	5/23/2007	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10851.2 3. States, "Please see representative for a full package insert" at page JX10851.1. States, "For complete product information, consult product package insert" at page JX10851.2
JX10852	GYNECARE PROLIFT* Convention Panel Update	ETH.MESH.02619401	5/23/2007	1. Advertising sells benefits while omitting known risks 2. States, "Please see representative for a full package insert" at page JX10851.2
JX10879	GYNECARE TVT Kaiser One Pager	ETH.MESH.02237660	6/10/2009	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions and adverse reactions, see full prescribing information" at page JX10879.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX10879.1 4. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX10896	Kaiser One Page on PROLIFT	ETH.MESH.02232802	6/19/2009	1. Advertising sells benefits while omitting known risks 2. Misleadingly states, "Knitted monofilament mesh does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX10896.1 3. Misleadingly states, "Large, 2.4 mm pore size fosters good tissue incorporation," without disclosing known risk of contracture, at page JX10896.1
JX10899*	Pinnacle Rebuttal Guide	ETH.MESH.02232805	6/23/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10899.1
JX10909	Kaiser One Page on PROLIFT +M	ETH.MESH.02232771	8/5/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10909.1 3. Misleadingly states, "Large Pore Size," without disclosing known risk of contracture, at page JX10909.1 4. Misleadingly states, "Bidirectional Flexibility," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10901.1
JX10919	AUGS Advertisement for PROLIFT_M	ETH.MESH.13591410	9/8/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10919.1
JX10928	AUGS Convention Flyer	ETH.MESH.02232912	9/22/2009	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX10928.2, and states, "For complete product information, including warnings, precautions, and adverse events, see reverse" at page JX10928.1

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX11001	TVT Obturator 1-pager	ETH.MESH.02237066	2/23/2010	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions, and adverse reactions, see Full Prescribing Information" at pages JX11001.1 and JX11001.2 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11002	TVT Retropubic 1-pager	ETH.MESH.02236235	2/22/2013	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions, and adverse reactions, see Full Prescribing Information" at pages JX11009.1 and JX11009.2 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11009.1
JX11009	TVT Family 1-pager	ETH.MESH.02237103	2/26/2010	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions, and adverse reactions, see Full Prescribing Information" at pages JX11001.1 and JX11001.2 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11001.1
JX11140	Prosima MRI Flashcard	ETH.MESH.13756066	8/18/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at pages JX11140.1 and JX11140.2
JX11149	Prosima Journal Ad for AAGL	ETH.MESH.13730143	8/24/2010	1. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at page JX11149.1
JX11150	Anatomical considerations flip chart GYNECARE TVT-O	ETH.MESH.13729294	8/25/2010	1. States, "Please refer to the INSTRUCTIONS FOR USE included with this device for indications, contraindications, warnings, precautions and other important information about the GYNECARE TVT Obturator System" at page JX11150.25
JX11158*	GYNECARE TVT ABBREVO Sell Sheet	ETH.MESH.02235119	9/8/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete indications, and important information on contraindications, warnings, precautions, and adverse reactions, see Full Prescribing Information" at page JX11158.2
JX11159	Prosima MRI Flashcard 2	ETH.MESH.02233840	9/14/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at pages JX11159.1 and JX11159.2
JX11170	Think Again Ad	ETH.MESH.02233313	9/30/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product information, including warnings, precautions, and adverse reactions, see Instructions for Use" at page JX11170.1
JX11176	GYNECARE TVT ABBREVO Clinical Data review Flashcard	ETH.MESH.13757973	10/11/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including warnings, precautions, and adverse reactions, see Instructions for Use" at page JX11176.2 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11203	TVT EXACT/TVT ABBREVO Flyer for AAGL	ETH.MESH.13579039	11/2/2010	1. States, "For indications, contraindications, warnings, precautions, and adverse reactions, please reference full package inserts" at page JX11203.2
JX11212	Prosima Journal Ad for AJOG	ETH.MESH.02233896	11/11/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at page JX11212.1
JX11215*	Dyspareunia and PFR Flip chart	ETH.MESH.13577867	11/12/2010	1. Advertising sells benefits while omitting known risks 2. States, "Please refer to the full package insert for complete product information including warnings, precautions and adverse reactions" and "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page JX11215.10
JX11224	Gynecare PROLIFT+M Success Flashcard	ETH.MESH.13583688	11/29/2010	1. Advertising sells benefits while omitting known risks 2. States, "For complete contraindications, warnings, precautions, and adverse reactions, see Instructions for Use" at pages JX11224.1 and JX11224.2

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX11383	TVT Abrevvo SGS Journal Ad	ETH.MESH.13649504	3/22/2012	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11383.1
JX11384	TVT Exact SGS Journal Ad	ETH.MESH.13649488	3/22/2012	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11384.1
JX11393	Clinical Data Project Incontinence	ETH.MESH.05128296	6/13/2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11393.6
JX11397	TVT Data Applet	ETH.MESH.13663112	6/28/2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11397.19 and JX11397.20
JX11423	TVT ABBREVO 3-Year Data Flashcard	ETH.MESH.13681042	10/26/2012	1. Advertising sells benefits while omitting known risks 2. States, "For complete product details, including warnings, precautions, and adverse reactions, see Instructions for Use" at page JX11423.2 3. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain
JX11441	Clinical Data Project Incontinence	ETH.MESH.13739531	12/5/2012	1. Advertising sells benefits while omitting known risks 2. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11441.6
JX11444	GYNECARE TVT Family of Products EPI	ETH.MESH.25535112	12/6/2012	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11444.2-JX11444.5
JX11457	Gynecare Portfolio Presentation	ETH.MESH.13685892	1/6/2013	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions, and adverse reactions, see full prescribing information" at pages JX11457.15-JX11457.17 and JX11457.19 3. Misleadingly states, "large pore size" and "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at pages JX11457.15 and JX11457.19 4. Misleadingly states, "low stiffness," without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX11457.15 5. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11457.15
JX11473	Gynecare TVT O Slim Jim TVTO with Procedure 335-12	ETH.MESH.25534718	5/1/2013	1. Advertising sells benefits while omitting known risks 2. States, "For indications, contraindications, warnings, precautions and adverse reactions, see Full Prescribing Information" at JX11473.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11473.4
JX11533	SADSL_TVT overview	ETH.MESH.24253416	8/19/2014	1. Advertising sells benefits while omitting known risks 2. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11533.2
JX11551	Gynecologic Surgery Value Prop One-Page Leave Behind	ETH.MESH.24254387	6/24/2015	1. Excerpts misleadingly incomplete adverse events information from the IFU at pages JX11551.4-JX11551.5
JX11598	TVT Family Professional Ad	ETH.MESH.02343089	9/10/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to full package insert for complete product information including warnings, precautions, and adverse reactions" at page JX11598.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page JX11598.1

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	Document Name	Bates number	Date	Violations
JX11600	EWH&U Capabilities Presentation	ETH.MESH.00400532	10/8/2008	1. Advertising sells benefits while omitting known risks 2. States, "Please refer to the full package insert for complete product information including warnings, precautions and adverse reactions" at pages JX11600.21 and JX11600.24 3. Misleadingly states, "Knitted monofilament does not potentiate infection," without disclosing known risk of mesh infection/biofilm, at page JX11600.16 4. Misleadingly states, "Large pore size fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX11600.16 5. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11600.12 and JX11600.45 6. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain at pages JX11600.12 and JX11600.46-JX11600.47
JX11623	PROLIFT +M Print Ad	ETH.MESH.19810567	1/21/2009	1. Excerpts misleadingly incomplete adverse events information from the IFU at page JX11623.1
PX0265	GYNECARE TVT Family of Products and 11.5 Year Data AUGS Insertion Card	ETH.MESH.03459106	8/20/2008	1. Advertising sells benefits while omitting known risks 2. States, "Refer to package insert for complete product information including warnings, precautions, and adverse reactions" at page PX0265.1 3. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at page PX0265.1

SALES REPRESENTATIVE TRAINING MATERIALS				
Exhibit	Document Name	Bates number	Date	Violations
JX11108	Think Again Annotated Sales Aid	ETH.MESH.02233278	7/1/2010	1. Training sells benefits while omitting known risks
JX11129	GYNECARE TVT O selling guide	ETH.MESH.02236596	8/3/2010	1. Advertising sells benefits of TVT-O without disclosing known risk of serious leg pain 2. Uses Ulmsten/Nilsson studies to paint misleadingly positive picture at pages JX11129.4 and JX11129.6