APPENDIX A

Court of Appeal, Fourth District, Division 1, California.

The PEOPLE, Plaintiff and Respondent,

v.

JOHNSON & JOHNSON et al., Defendants and Appellants.

D077945

Filed 04/11/2022

As Modified on Denial of Rehearing 04/27/2022

APPEAL from a judgment of the Superior Court of San Diego County, Eddie C. Sturgeon, Judge. Affirmed as modified. (Super. Ct. No. 37-2016-00017229-CU-MC-CTL)

Attorneys and Law Firms

O'Melveny & Myers, Charles C. Lifland, Jason Zarrow, Lauren F. Kaplan, Los Angeles, Stephen D. Brody, and Martha F. Hutton, for Defendants and Appellants.

Horvitz & Levy, David M. Axelrad, Burbank, and Scott P. Dixler for the Advanced Medical Technology Association as Amicus Curiae on behalf of Defendants and Appellants.

Barnes & Thornburg and Kevin D. Rising, Los Angeles, for the American Urogynecological Society, the Society of Gynecologic Surgeons, the American Association of Gynecologic Laparoscopists, and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction as Amicus Curiae on behalf of Defendants and Appellants.

California Appellate Law Group, Ben Feuer, San Francisco, and Julia Partridge for the U.S. Chamber of Commerce and American Tort Reform Association as Amicus Curiae on behalf of Defendants and Appellants.

Tucker Ellis, Mollie F. Benedict, and Peter L. Choate, Los Angeles, for the Washington Legal Foundation as Amicus Curiae on behalf of Defendants and Appellants.

Rob Bonta, Attorney General, Nicklas Akers, Assistant Attorney General, Jon Worm, Adelina Acuña, Tina Charoenpong, Monica J. Zi, Gabriel Shaeffer, and Daniel Osborn, Deputy Attorneys General, for Plaintiff and Respondent.

McCONNELL, P. J.

I

INTRODUCTION

Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (collectively, Ethicon) appeal an adverse judgment following a bench trial. The trial court levied nearly $344 million in civil penalties against

Ethicon for willfully circulating misleading medical device instructions and marketing communications that misstated, minimized, and/or omitted the health risks of Ethicon's surgically-implantable transvaginal pelvic mesh products. The court found Ethicon committed 153,351 violations of the Unfair Competition Law (UCL) (Bus. & Prof. Code,[1] § 17200 et seq.) and 121,844 violations of the False Advertising Law (FAL) (§ 17500 et seq.), and it imposed a $1,250 civil penalty for each violation.

Ethicon contends the judgment must be reversed because: (1) the trial court applied the wrong legal standards when determining that Ethicon violated the UCL and FAL. (2) substantial evidence did not support the court's findings that Ethicon's medical device instructions and marketing communications were likely to deceive doctors and patients; (3) the safe harbor doctrine precluded findings of liability; (4) the civil penalties violated Ethicon's rights under the free speech clauses of the state and federal constitutions; (5) the court abused its discretion by counting each deceptive communication as a separate violation and setting $1,250 as the civil penalty for each violation; and (6) the civil penalties violated Ethicon's due process rights and the excessive fines clauses of the state and federal constitutions.

We conclude the trial court erred in just one respect. In addition to penalizing Ethicon for its medical device instructions and printed marketing

---

[1] Further undesignated statutory references are to the Business and Professions Code.

communications, the court penalized Ethicon for its oral marketing communications—specifically, for deceptive statements Ethicon purportedly made during one-on-one conversations with doctors, at Ethicon-sponsored lunch events, and at health fair events. However, there was no evidence of what Ethicon's employees and agents actually said in any—let alone all—of these oral marketing communications. Therefore, we conclude substantial evidence did not support the trial court's factual finding that Ethicon's oral marketing communications were likely to deceive doctors, and we amend the judgment to strike the nearly $42 million in civil penalties that were imposed for these communications.

We discern no other error and affirm the judgment as modified.

II

BACKGROUND

A

Stress Urinary Incontinence and Pelvic Organ Prolapse

Since the late 1990s, Ethicon has manufactured, marketed, and sold pelvic mesh products intended to treat two conditions that can affect women—stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

SUI is a chronic condition characterized by urine leakage during everyday activities such as laughing,

coughing, sneezing, or exercising. Approximately one third of women experience SUI at some point in their lives. SUI is not life-threatening, but it can impair a patient's quality of life and limit the range of activities in which she can participate.

POP is a disorder whereby the muscles and tissue in the pelvis weaken and cause pelvic organs to prolapse (i.e., descend) into, and sometimes outside of, the vagina. Most patients who suffer from POP experience pressure in the pelvis or vagina. It is difficult for some patients with POP to urinate, have bowel movements, or engage in sexual intercourse.

SUI and POP can sometimes be treated through nonsurgical means. For example, patients can perform pelvic floor exercises known as kegel exercises to strengthen the muscles around the urethra. They can also insert a device called a pessary into the vagina to stop urine leakage. POP can be treated nonsurgically through the use of a pessary or a hormone estrogen cream.

Non-mesh surgical methods can sometimes be used to treat SUI and POP as well. SUI can be surgically treated through the Burch procedure, whereby an incision is made into the abdomen and sutures are placed to extend the neck of the bladder. POP can be surgically treated through a native tissue repair whereby sutures are inserted to support the top of the vagina.

B

Ethicon's Pelvic Mesh Products

Starting in the 1990s, Ethicon began to manufacture and sell surgically-implantable transvaginal pelvic mesh products for the treatment of SUI and POP. All of Ethicon's pelvic mesh products were (and are) composed, at least in part, of a synthetic polypropylene mesh. When the mesh functions as intended, it elicits an acute inflammatory response that causes scar tissue to grow through the mesh's pores and incorporates the mesh into the patient's body.

In 1998, Ethicon released TVT (tension-free vaginal tape), Ethicon's first pelvic mesh product for the treatment of SUI. TVT is a precut strip of mesh that can be surgically inserted in the vagina and enclosed underneath the midurethra like a sling. A midurethral sling pushes the urethra closed when pressure is exerted (e.g., during a cough) to stop urine leakage. After the release of TVT, Ethicon developed and sold additional iterations of midurethral slings including the TVT-Obturator, TVT-Abbrevo, TVT-Exact, and TVT-Secur. These products will be referred to as the SUI devices.

During the 2000s, Ethicon released pelvic mesh products to treat POP. In 2002, it released Gynemesh PS, a flat sheet of mesh that a surgeon can hand cut and implant in the pelvic floor to support the pelvic organs. After the release of Gynemesh PS, Ethicon developed and sold various iterations of pre-cut Gynemesh PS strips called Prolift, Prolift-M, and

Prosima. These products will be referred to as the POP devices.

C

FDA Regulation of Pelvic Mesh Implants

In 2008, the U.S. Food and Drug Administration (FDA) issued a public health notification alerting health care providers about complications from pelvic mesh implants used to treat SUI and POP. It stated the most frequent complications were "erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence," as well as "bowel, bladder, and blood vessel perforation during insertion." The notification warned that, in some cases, "vaginal scarring and mesh erosion [could lead] to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia," i.e., pain during sexual intercourse. It advised that complications were "rare," but could have "serious consequences."

In 2011, the FDA issued an update to its public health notification, which focused specifically on complications relating to pelvic mesh implants used to treat POP. The update stated, "surgical mesh for transvaginal repair of POP [was] an area of continuing serious concern." It stated the FDA had determined that serious complications associated with surgical mesh for POP repair were not rare —a change from the FDA's earlier public health notification. The update stated the most frequent complications were "mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain,

infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems." The update identified "recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems" as other common complications. According to the update, many of the complications required intervention, some of them required repair surgeries, and some of them were incapable of being resolved. Additionally, the update stated mesh POP repairs introduced risks that were not present in non-mesh POP repairs, and mesh POP repairs did not improve systematic results or quality of life compared to non-mesh POP repairs.

In 2012, the FDA ordered Ethicon to conduct post-market surveillance studies for one of its SUI devices (TVT-Secur) and three of its POP devices (Prolift, Prolift-M, and Prosima). Instead of conducting these post-market surveillance studies, Ethicon stopped selling the products commercially. Ethicon also changed the indication for its fourth POP device (Gynemesh PS) from a transvaginal indication to an abdominal-only indication. Ethicon continued selling its other SUI devices (TVT, TVT-Obturator, TVT-Abbrevo, and TVT-Exact) up to and throughout the present lawsuit.

Ethicon's competitors continued to sell pelvic mesh products for transvaginal repair of POP, even after Ethicon stopped selling most of its POP devices. However, in April 2019, the FDA concluded there was not a reasonable assurance of safety and effectiveness for any commercially-available pelvic mesh products intended for transvaginal repair of POP. Therefore,

the FDA ordered all remaining manufacturers of surgical mesh intended for transvaginal repair of POP to stop selling and distributing such products.

D

Ethicon's Communications About Its Pelvic Mesh Products

During the relevant timeframe, Ethicon disseminated three categories of communications giving rise to the violations at issue here: (1) Instructions for Use (IFUs); (2) marketing communications directed to California doctors; and (3) marketing communications directed to California patients.

The first category consists of IFUs. IFUs are packets of information that accompany medical devices. They contain graphical depictions of the device and information describing the device, the device's indications and contraindications, clinical performance results for the device, and adverse reactions associated with the device, among other topics. IFUs accompanied all of Ethicon's pelvic mesh products.[2]

The second category consists of marketing communications directed to doctors, which took a variety of forms. Ethicon sent sales representatives to doctors' offices with printed product brochures and sales

[2] The IFUs for Ethicon's products remained largely unchanged from the launch of the products until 2015. At or about that time, a Canadian regulatory agency requested that Ethicon amend the labeling for its products. In response, Ethicon augmented the adverse events sections of its IFUs.

aids for its products. It recruited preceptors and key opinion leaders to discuss the products at sponsored trainings, conferences, and professional education events. Further, it advertised in medical journals, took health care professionals out to meals, and sponsored booths at health fairs and other events.

The third category consists of marketing communications directed to patients. Ethicon marketed its pelvic mesh products to patients through printed brochures, counseling materials, mailers, and public relations events. It advertised online to drive patient traffic to its promotional website, which contained information about SUI, POP, and Ethicon's products. Ethicon also operated a telephone hotline and a Find-A-Doctor directory service, which referred patients to doctors who could implant Ethicon's products.

E

The Present Action

In 2016, the Attorney General filed an enforcement action against Ethicon on behalf of the People of the State of California. The operative complaint alleged Ethicon violated the UCL and FAL by disseminating deceptive advertisements relating to its pelvic mesh products.

Specifically, the operative complaint alleged Ethicon's IFUs and marketing communications contained the following misstatements, half-truths, and/or omissions: (1) they falsely stated the pelvic mesh products were approved by the FDA when in fact they were cleared by the FDA under section 510(k) of the

Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.); (2) they omitted known risks and complications associated with the products; (3) they misrepresented the relative risks associated with the products compared to non-mesh surgical treatment options; (4) they misrepresented the severity and frequency of the risks that were disclosed; and (5) they overstated the benefits and effectiveness of the products.

The operative complaint alleged Ethicon's IFUs and marketing communications violated the UCL and FAL. It requested injunctive relief, civil penalties of $2,500 for each UCL violation occurring on or after October 17, 2008, and civil penalties of $2,500 for each FAL violation occurring on or after October 17, 2009.[3]

F

The Statement of Decision and Judgment

After a nine-week bench trial, the trial court issued an extremely thorough, 128-page statement of decision finding Ethicon liable for 153,351 UCL violations and 121,844 FAL violations.

---

[3] The UCL has a four-year statute of limitations (§ 17208) and the FAL has a three-year statute of limitations (Code Civ. Proc., § 338, subd. (h)). However, the parties executed a tolling agreement, effective October 17, 2012. Thus, the earliest date Ethicon could be held liable for UCL violations was October 17, 2008, and the earliest date it could be held liable for FAL violations was October 17, 2009.

At the outset of the statement of decision, the court found there were serious, long-term risks and complications associated with Ethicon's pelvic mesh products of which Ethicon was aware. In reaching this finding, the court cited to, and credited, testimony from three experts called by the Attorney General: (1) Dr. Bruce Rosenzweig; (2) Dr. Vladimir Iakovlev; and (3) Dr. Michael Margolis.

Dr. Rosenzweig is a urogynecologist who has performed surgical treatments for 325–350 women suffering from pelvic mesh complications. He testified the mesh in Ethicon's products has the following dangerous properties: (1) it can elicit chronic foreign body responses (chronic inflammation); (2) it can shrink and contract; (3) it can deform (rope, fray, curl, and lose pore size or particles); (4) it can degrade; and (5) bacteria can adhere to the mesh and produce a subclinical infection. He testified these properties can cause chronic pain, dyspareunia, decreased sexual function, partner pain (hispareunia), mesh exposure through the surface of the vagina, mesh erosion into another organ, distortion and shortening of the vagina, urinary problems, and urinary and bladder infections.

Dr. Iakovlev is an anatomical pathologist who has examined about 500 mesh explants including pelvic mesh explants. He testified pelvic mesh can produce chronic inflammation, scarring and bridging fibrosis, scar contraction resulting in mesh contraction, nerve growth around and through the mesh, mesh exposure, and mesh erosion. He testified the mesh can also degrade and fold, ball, or curl into itself.

Dr. Margolis is a urogynecologist who specializes in the treatment of mesh complications. He has treated approximately 1,000 patients with mesh complications and performed mesh explant surgeries on about 600 patients. Ethicon manufactured 60 to 75 percent of the mesh products Dr. Margolis has explanted from his patients. Dr. Margolis testified transvaginal mesh products can produce complications including urinary dysfunction, dyspareunia, hispareunia, severe chronic pain (including pelvic, vaginal, leg, and groin pain), mesh erosion, infections, vaginal stiffening or distortion, shrinkage or contracture of the mesh, bowel and defecatory dysfunction, and fistulas. He also testified pelvic mesh cannot be fully explanted if four or more weeks have passed since implantation. According to Dr. Margolis, mesh can be impossible to explant after four weeks because it causes the formation of scar tissue that cements the mesh in place.

The court also cited testimony from Ethicon's own medical directors showing that Ethicon's mesh products carry risks of serious, long-term complications. Dr. Piet Hinoul, Ethicon's Global Head for Medical, Clinical, and Preclinical Affairs, testified the mesh can produce chronic foreign body reactions and biofilm infections, and the mesh can shrink or contract. He testified complications associated with the SUI devices can include a lifelong and recurrent risk of mesh exposure through the vagina and/or mesh erosion, contracture of the tissue surrounding the mesh leading to chronic pain, debilitating and life-changing chronic pain, chronic groin pain, chronic dyspareunia, and pain to partner. He testified the POP devices

carry the same risks, and mesh shrinkage can distort the vaginal cavity and cause interference with sexual intercourse. According to Dr. Hinoul, Ethicon knew of all these risks when it launched its products.

Next, the court found Ethicon knowingly misstated or omitted these risks in its IFUs. Broadly speaking, the misstatements and omissions concerned: (1) the full range of complications associated with Ethicon's products; (2) the severity and duration of the complications; (3) the source of the complications—i.e., whether they were unique to the products or typical of pelvic surgeries generally; and (4) the necessity of mesh removal.

In particular, the court found the IFUs for the SUI devices were misleading in the following respects: (1) the IFUs from 1998–2015 stated there could be "transitory local irritation at the wound site and a transitory foreign body response" resulting in mesh extrusion or exposure, and the IFUs from 2015 onwards stated there could be mesh "extrusion, exposure, or erosion," but the IFUs did not disclose the risk of chronic foreign body reaction or the lifelong risks of mesh exposure and erosion; (2) the IFUs from 1998–2015 stated "transient leg pain" could occur but did not disclose the risk of chronic pain, and the IFUs from 2015 onwards stated the products could cause acute or chronic pain but did not disclose the risk of debilitating or life-changing pain; (3) the IFUs from 1998–2015 did not disclose the risks of dyspareunia, mesh contraction, or pain to partner, and the IFUs from 2015 onwards did not disclose the risk of mesh contraction; (4) the IFUs from 1998–2015 stated that

potential urinary dysfunction complications were just like the risks presented by other incontinence procedures; and (5) the IFUs from 1998–2015 did not reference the possible need for mesh removal or the irreversibility of mesh complications, and none of the IFUs stated adverse reactions may not resolve following mesh removal.

The court found the IFUs for the POP devices were deceptive as well. It found they were deceptive because: (1) the IFUs from 2003–2012 identified erosion and extrusion as complications, and the IFUs from 2015 identified mesh extrusion, exposure, and erosion as complications, but none of the IFUs disclosed that the risks of vaginal exposure and erosion were lifelong and recurrent; (2) the IFUs from 2003–2012 identified pain as a complication, some of the IFUs from 2003–2012 identified "transient leg pain" as a complication, and the IFU from 2015 identified acute and/or chronic pain as a complication, but none of the IFUs disclosed that the pain could be debilitating and incapacitating; (3) certain IFUs from 2003–2012 did not disclose the risk of dyspareunia or pain to partner; (4) certain IFUs from 2003–2012 did not disclose the risk of urinary dysfunction; and (5) the IFUs from 2003–2012 did not reference the possible need for mesh removal, and none of the IFUs stated that adverse reactions may not resolve following mesh removal.

Additionally, the court found all of Ethicon's IFUs were deceptive because they stated the polypropylene mesh composing the products was not subject to degradation or weakening by the action of tissue

enzymes. According to the court, the evidence showed that mesh can oxidize, or degrade, resulting in cracking or fragmentation on the mesh surface.

The court found Ethicon's marketing communications to doctors were deceptive, too. The court found Ethicon's printed marketing materials excerpted, or referred doctors to, the incomplete list of risks in the IFUs and/or they failed to disclose the full range of serious, long-term risks of which Ethicon was aware. The court attached a violations appendix to the statement of decision, which identified the deceptive quality or qualities of each printed, doctor-focused advertisement that was admitted into evidence.[4] Further, the court found Ethicon's sales representatives were trained to convey deceptive and misleading information to healthcare professionals.

The court found Ethicon's marketing communications to patients were deceptive as well. It found each communication was deceptive for one or more of the following reasons: (1) it omitted severe and potentially debilitating risks known to Ethicon and/or misleadingly stated the risks were common to all pelvic surgeries; (2) it referred patients to additional product information for a complete discussion of risks,

---

[4] In a footnote in its briefing, Ethicon implies that the court erred in admitting certain marketing materials into evidence. "An appellant cannot bury a substantive legal argument in a footnote and hope to avoid waiver of that argument." (*Holden v. City of San Diego* (2019) 43 Cal.App.5th 404, 419, 255 Cal.Rptr.3d 873.) To the extent Ethicon suggests the court erred by admitting these materials, Ethicon has waived its argument. (*Id.* at pp. 419–420, 255 Cal.Rptr.3d 873.)

but the additional information was incomplete; and/or (3) it excerpted adverse event or risk information from the incomplete IFUs. The violations appendix catalogued the way or ways in which each patient-focused marketing communication was deceptive.

The court then found Ethicon actively concealed the product risks from the public. For instance, the court found Ethicon rejected a suggestion made by Dr. Axel Arnaud, one of Ethicon's own medical directors, to amend the Prolift IFU in 2005—a proposed amendment that would have disclosed that Ethicon's mesh could produce vaginal erosion and retraction resulting in anatomical distortion of the vaginal cavity and interference with sexual intercourse. The court found Ethicon also failed to implement a suggestion made by Ethicon associate medical director Dr. Meng Chen to update the IFUs in late 2008 or early 2009—a proposed update that would have removed all references to the "transitory" nature of the risks concerning irritation and foreign body response.[5]

The court found Ethicon also downplayed or undercut the FDA's public health notification and update for the purpose of concealing the risks associated with Ethicon's products. Ethicon instructed its sales representatives to avoid initiating conversations with doctors about the public health notification.

---

[5] In an email to her colleagues, Dr. Chen stated she was unsure whether the IFUs'" very general statement" about the risk of a "transitory irritation" and "transitory foreign body" response was "sufficient." She stated that, "from what [she saw] each day, these patient experiences [were] not 'transitory' at all."

Then, after the FDA issued its update finding serious complications associated with surgical mesh for POP repair were not rare, Ethicon paid consultants to author an article refuting the update.

Next, the court found the IFUs and marketing communications were likely to deceive doctors and patients alike. It found doctors read and rely on IFUs and marketing materials when counseling and treating patients. Further, it found doctors were not generally familiar with the risks specific to pelvic mesh products. The court found, in particular, that the recent advent of the products meant many doctors did not learn about them during medical school or their residency programs. The court also found Ethicon's efforts to undercut the FDA's public health notification and update nullified whatever information doctors may otherwise have acquired regarding the risks associated with pelvic mesh products. Because the IFUs and marketing communications were likely to deceive doctors and patients, the court found Ethicon violated the UCL and FAL.

After finding that Ethicon's IFUs and marketing communications were likely to deceive doctors and patients, the court determined the number of UCL and FAL violations. It reasoned the violation count should include all "quantifiable instances of [Ethicon's] circulation or dissemination of deceptive messages"–i.e., it counted each IFU or marketing communication as a separate violation. Employing this methodology, the court found Ethicon committed 153,351 UCL violations and 121,844 FAL violations. The court attached

a penalty appendix to the statement of decision explaining its calculations.[6]

The court then set the amount of each civil penalty at $1,250 per violation—half the amount the Attorney General requested. The court reasoned $1,250 per violation was warranted, in lieu of a lower amount, because: (1) Ethicon's misconduct was "grave" and "egregious," as Ethicon withheld crucial information about products that were permanently implanted into patients, caused some patients

---

[6] The court calculated the number of statutory violations as follows:

1. IFUs–35,343 UCL violations and 31,000 FAL violations;
2. Printed marketing materials that Ethicon's sales representatives requested through an online portal to be distributed to doctors–41,277 UCL violations and 27,115 FAL violations;
3. Printed marketing materials that were requested through Ethicon's public telephone hotline–4,792 UCL violations and 3,513 FAL violations;
4. Visits to Ethicon's mesh product website and subpages–29,011 UCL violations and 21,839 FAL violations;
5. Professional education and training presentations given to doctors (*e.g.*, lectures)–61 UCL violations and 50 FAL violations;
6. Sales representative detailing (*e.g.*, sales representatives' promotion of Ethicon's products during visits to doctors' offices)–8,191 UCL violations and 6,066 FAL violations;
7. Ethicon-sponsored meals (usually between sales representatives and health care providers)–8,199 UCL violations and 6,029 FAL violations; and
8. Field marketing activities including health fairs, patient outreach events, patient education presentations, public relations materials (PR kits), and primary care provider outreach–26,477 UCL violations and 26,232 FAL violations.

"debilitating, chronic pain," and "destroy[ed] patients' sexual, urinary and defecatory functions –consequences that go to the very core of personal identity, dignity, and quality of daily life"; (2) there were hundreds of thousands of violations (and, according to the court, there were likely "far more violations" that were excluded from the violations count); (3) Ethicon's misconduct was persistent and spanned 17 years; (4) Ethicon knowingly misrepresented and concealed the information at issue; and (5) the $344 million civil penalty award represented less than one percent of defendant-parent company Johnson & Johnson's $70.4 billion net worth.[7]

At the request of the court, the parties submitted supplemental briefing concerning the necessity of injunctive relief. After the submission of briefing, the court declined to award injunctive relief for four reasons. First, Ethicon amended the IFUs for its SUI products in 2015 and, in the process, remedied many misleading statements contained therein. Second, Ethicon was already in the process of amending its product labeling to comply with a 42-state consent order entered as part of a separate legal proceeding. Third, the current information in the public domain was sufficient to inform health care providers of the risks of the pelvic mesh products. Fourth, an injunction requiring Ethicon to update its labeling without

[7] In the trial court, the parties executed a stipulation that treats all three defendants the same for purposes of their ability to pay a civil penalty award.

FDA approval could subject Ethicon to liability under federal law.

The court imposed $343,993,750 in civil penalties against Ethicon and entered judgment for the Attorney General.

III

DISCUSSION[8]

A

Governing Laws

1

Unfair Competition Law

The Unfair Competition Law, or UCL, forbids unfair competition, which is defined as "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by" the False Advertising Law. (§ 17200.) The UCL's "'purpose is to protect both consumers and competitors by promoting fair

[8] We have considered the parties' appellate briefs and *amici curiae* briefs filed by interested third parties with our permission. Amici include the Advanced Medical Technology Association; the American Urogynecological Society, the Society of Gynecologic Surgeons, the American Association of Gynecologic Laparoscopists, and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction; the U.S. Chamber of Commerce and American Tort Reform Association; and the Washington Legal Foundation.

competition in commercial markets for goods and services.'" (*Abbott Laboratories v. Superior Court* (2020) 9 Cal.5th 642, 651, 264 Cal.Rptr.3d 788, 467 P.3d 184 (*Abbott Labs*).)

"'In service of that purpose, the Legislature framed the UCL's substantive provisions in "'broad, sweeping language"' ' [citation] to reach 'anything that can properly be called a business practice and that at the same time is forbidden by law' [citation]. 'By proscribing "any unlawful" business practice, " section 17200 'borrows' violations of other laws and treats them as unlawful practices" that the unfair competition law makes independently actionable.'" (*Abbott Labs*., *supra*, 9 Cal.5th at pp. 651–652, 264 Cal.Rptr.3d 788, 467 P.3d 184.) "However, the law does more than just borrow. The statutory language referring to 'any unlawful, unfair *or* fraudulent' practice (italics added) makes clear that a practice may be deemed unfair even if not specifically proscribed by some other law. 'Because … section 17200 is written in the disjunctive, it establishes three varieties of unfair competition—acts or practices which are unlawful, or unfair, *or* fraudulent.'" (*Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 180, 83 Cal.Rptr.2d 548, 973 P.2d 527 (*Cel-Tech*).)

UCL actions may be brought by the Attorney General, designated public prosecutors, or persons who have suffered injury in fact and lost money or property due to the unfair competition. (§ 17204.) "[T]he primary form of relief available under the UCL to protect consumers from unfair business practices is an

injunction ...." (*In re Tobacco II Cases* (2009) 46 Cal.4th 298, 319, 93 Cal.Rptr.3d 559, 207 P.3d 20 (*Tobacco II*).) "The purpose of such relief, in the context of a UCL action, is to protect California's consumers against unfair business practices by stopping such practices in their tracks." (*Id.* at p. 320, 93 Cal.Rptr.3d 559, 207 P.3d 20.)

The Attorney General and other "authorized public prosecutors have an additional tool to enforce the state's consumer protection laws: civil penalties. 'Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General'" or other specified public prosecutors. (*Abbott Labs.*, *supra*, 9 Cal.5th at p. 652, 264 Cal.Rptr.3d 788, 467 P.3d 184, quoting § 17206, subd. (a).) Civil penalties "are *mandatory* once a violation of [the UCL] is established, and a penalty must be imposed for each violation." (*People v. First Federal Credit Corp.* (2002) 104 Cal.App.4th 721, 732, 128 Cal.Rptr.2d 542 (*First Federal*).)

2

False Advertising Law

The False Advertising Law, or FAL, "broadly prohibit[s] false or misleading advertising, declaring that it is unlawful for any person or business to make or distribute any statement to induce the public to enter into a transaction '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.'" (*Nationwide Biweekly Administration, Inc. v. Superior Court* (2020) 9 Cal.5th 279, 306, 261 Cal.Rptr.3d 713, 462 P.3d 461 (*Nationwide*), quoting § 17500.) The FAL is "'designed to protect consumers from false or deceptive advertising.'" (*Id.* at p. 305, 261 Cal.Rptr.3d 713, 462 P.3d 461; *see Kwikset Corp. v. Superior Court* (2011) 51 Cal.4th 310, 331, 120 Cal.Rptr.3d 741, 246 P.3d 877 ["The UCL and false advertising law are both intended to preserve fair competition and protect consumers from market distortions."].)

"Like the choice of the term 'unfair' in the UCL, the governing substantive standard of the FAL—prohibiting advertising that is 'untrue or misleading' [citation]—is set forth in broad and open-ended language that is intended to permit a court of equity to reach any novel or creative scheme of false or *misleading* advertising that a deceptive business may devise." (*Nationwide*, *supra*, 9 Cal.5th at p. 308, 261 Cal.Rptr.3d 713, 462 P.3d 461.) "[T]he FAL prohibits ' "not only advertising which is false, but also advertising which[,] although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public." [Citation.] Thus, to state a claim under either the UCL or the false advertising law, based on false advertising or promotional practices, "it is necessary only to show that 'members of the public are likely to be deceived.'" " (*Ibid.*)

FAL actions may be brought by the Attorney General, designated public prosecutors, or "any person who has suffered injury in fact and has lost money or property" as a result of a violation of the FAL. (§ 17535.) The trial court may enjoin FAL violators. (*Ibid.*) Similar to the UCL, the Attorney General and other public prosecutors may seek civil penalties not to exceed $2,500 for each violation of the FAL. (§ 17536, subd. (a).)

The remedies and penalties provided for in the UCL and FAL generally are cumulative to each other and to remedies and penalties available under other laws. (§§ 17205, 17534.5.) Thus, conduct that violates both the UCL and FAL can result in separate penalties of up to $2,500 for each UCL violation and for each FAL violation. (*See People v. Toomey* (1984) 157 Cal.App.3d 1, 22, 203 Cal.Rptr. 642 [the UCL and FAL "allow for cumulative remedies, indicating a legislative intent to allow … double fines"].)

B

The Trial Court Applied the Correct Legal Standards

Ethicon's primary contention on appeal is that the trial court applied the wrong legal standards under the UCL and FAL. Ethicon argues the court erred in three respects: (1) by failing to consider whether the IFUs and doctor-focused marketing communications were misleading from the perspective of doctors, as opposed to members of the public; (2) by not applying the legal standard governing omissions-based claims; and (3) by failing to consider whether Ethicon's

misstatements, half-truths, and omissions were material. We address these arguments in turn.

1

Target Audience Standard

i

"To prevail on a claim under the fraudulent prong of the Unfair Competition Law 'based on false advertising or promotional practices,' the plaintiff must ' "show that 'members of the public are likely to be deceived.' " " [Citations.] An advertisement or promotional practice is likely to deceive if it includes assertions that are (1) untrue, or (2) "'true[, but are] either actually misleading or which [have the] capacity, likelihood or tendency to deceive or confuse the public.' " (*Shaeffer v. Califia Farms, LLC* (2020) 44 Cal.App.5th 1125, 1135, 258 Cal.Rptr.3d 270 (*Shaeffer*).) The FAL "substantively overlap[s]" with the fraudulent prong of the UCL and the "burden under these provisions is the same: To prevail on a claim under the false advertising law, [the plaintiff] must show that ' "'members of the public are likely to be deceived ....' " " (*Id.* at p. 1136, 258 Cal.Rptr.3d 270; *see also Chapman v. Skype Inc.* (2013) 220 Cal.App.4th 217, 226, 162 Cal.Rptr.3d 864 [for claims under "'the UCL or the false advertising law, based on false advertising or promotional practices, "it is necessary only to show that 'members of the public are likely to be deceived' " "] (*Chapman*).)

In assessing the likelihood of deception, the challenged advertisement or practice is typically viewed

"through the eyes of the 'reasonable consumer'—that is, the 'ordinary consumer acting reasonably under the circumstances....'" (*Shaeffer*, *supra*, 44 Cal.App.5th at p. 1135, 258 Cal.Rptr.3d 270.) However, "'[w]here the advertising or practice is targeted to a particular group or type of consumers, either more sophisticated or less sophisticated than the ordinary consumer, the question whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily directed.'" (*In re Vioxx Class Cases* (2009) 180 Cal.App.4th 116, 130, 103 Cal.Rptr.3d 83 (*Vioxx*), quoting *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 509–510, 129 Cal.Rptr.2d 486 (*Lavie*).)

The primary evidence of likelihood of deception is the challenged advertisement or practice itself. (*People v. Overstock.com, Inc.* (2017) 12 Cal.App.5th 1064, 1080-1081, 219 Cal.Rptr.3d 65 (*Overstock.com*); *Brockey v. Moore* (2003) 107 Cal.App.4th 86, 100, 131 Cal.Rptr.2d 746.) Additionally, courts should "examine the knowledge base of the targeted consumer in assessing whether, under the circumstances, the conduct or advertisement is likely to deceive the targeted consumer." (*Patricia A. Murray Dental Corp. v. Dentsply International, Inc.* (2018) 19 Cal.App.5th 258, 272, 273–275, 227 Cal.Rptr.3d 862 (*Dentsply*) [considering dentists' professional knowledge when determining whether medical device directions were likely to deceive dentists]; *accord Vioxx*, *supra*, 180 Cal.App.4th at p. 130, fn. 14, 103 Cal.Rptr.3d 83 [conduct may be an "unfair business practice when directed toward consumers" and "not an unfair

practice when directed toward a financially sophisticated business with [specialized] knowledge"].)

ii

Ethicon claims the court did not apply the target audience standard because it failed to assess whether Ethicon's IFUs and doctor-focused marketing communications were deceptive from the perspective of doctors, as opposed to members of the general public. In particular, Ethicon asserts the court did not consider doctors' knowledge or expectations when analyzing whether the IFUs and advertisements were likely to deceive.

Even the most cursory review of the statement of decision discloses the trial court applied the correct target audience standard. Under a heading captioned "Statement of Applicable Law," the statement of decision recited the correct legal standard and stated the trial court's role was to "determine [the] likelihood of deception from the standpoint of the target audience." Then, over the course of dozens of pages, the statement of decision applied that legal standard to the facts and, ultimately, determined the IFUs and marketing materials were likely to deceive doctors.

For instance, the trial court considered the knowledge base of doctors to whom the IFUs and marketing communications were directed. It found "many physicians practicing today" did not learn how to implant mesh in medical school or their residency programs because pelvic mesh products were not launched until the 1990s. The court found the scientific literature on pelvic mesh products did not fill in

doctors' knowledge gap because doctors labor under busy schedules and struggle to keep up-to-date with the scientific literature. Further, the court noted several defense witnesses, including surgical specialists and urogynecologists, were unaware of complications unique to pelvic mesh products apart from vaginal erosion and exposure—even though these complications were "well-known to the company from launch." For all these reasons, the court rejected Ethicon's contention that it could not "be liable for hiding serious and long-term mesh risks in its IFUs and marketing materials because doctors already knew these risks."

The court then found doctors "read the IFU[s] and use manufacturer marketing material as a source of information in making treatment decisions." In support of this finding, the court cited a written discovery response from Ethicon admitting IFUs were one of its "primary means for distributing printed information about its medical devices …." It cited deposition testimony from Dr. Hinoul, who stated Ethicon expects doctors to rely on the warnings, complications, and adverse events listed in IFUs to counsel patients, and a "surgeon should be able to solely rely on the IFU." The court also cited the testimony of Dr. Charles Nager, a defense expert and urogynecologist, who testified that professional journal advertisements and sales marketing drove the use of pelvic floor mesh kits among doctors. Further, the court noted that doctor witnesses for both parties claimed they relied on IFUs and believed other doctors did the same.

Next, the court considered the text of each IFU and printed marketing communication in meticulous

detail. It analyzed the text of the IFUs and determined they were likely to deceive doctors because they misstated or omitted: (1) the range of complications associated with mesh; (2) the severity or duration of the complications; (3) the source of the complications; and/or (4) the potential irreversibility of the complications. The court also catalogued the deceptive qualities of each printed doctor-focused marketing communication in a voluminous appendix.

Finally, the court found "*doctors* were likely to be deceived by [Ethicon's] deceptive marketing, both in the IFUs and throughout their other marketing materials." (Italics added.) The court reiterated this finding throughout the statement of decision. It "conclude[d] that the People of the State of California ('Plaintiff') ha[d] proven by a preponderance of the evidence that [Ethicon] deceptively marketed [its] pelvic mesh products in the state of California and that *[its] marketing was likely to deceive reasonable doctors* and reasonable lay consumers." (Italics added.) It found Ethicon "deceptively marketed its [SUI] and POP mesh devices through a combination of false statements, misleading half-truths, and omissions that were *likely to deceive doctors* …." (Italics added.) Elsewhere in the statement of decision, the court determined Ethicon's "misleading half-truths and omissions … were *likely to deceive physicians* in violation of the UCL and FAL." (Italics added.)

As these findings and conclusions make abundantly clear, the trial court correctly applied the target audience legal standard.

iii

Ethicon advances three counter-arguments in support of its claim that the trial court failed to consider whether the IFUs and marketing communications were deceptive from the perspective of their target audience.

First, they cite *Lavie*, *supra*, 105 Cal.App.4th at page 508, 129 Cal.Rptr.2d 486, a case in which our colleagues in the First District Court of Appeal determined that the usual "standard to be applied in assessing whether … conduct or [an] advertisement violates the UCL is whether it is 'likely to deceive' the [reasonable] consumer"—not a "least sophisticated consumer" standard that presumably would make it easier for a UCL plaintiff to prove liability. After reaching this conclusion, the *Lavie* court opined that "'[l]ikely to deceive' implies more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the phrase indicates that the ad is such that it is probable that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." (*Ibid.*) Ethicon claims the trial court erred because "it did not mention the 'significant portion' requirement at all."

The trial court did not err. The *Lavie* court's reference to a "significant portion of the general consuming public or of targeted consumers" did not establish a new, standalone requirement for a plaintiff to prove UCL liability. (*Lavie*, *supra*, 105

Cal.App.4th at p. 508, 129 Cal.Rptr.2d 486.) Rather, it characterized the circumstances under which a defendant's conduct or advertisement is likely to deceive the general public or the target audience. As previously discussed, the trial court repeatedly cited and applied this legal standard.

In any event, a court's "failure to 'discuss' a particular standard does not imply it applied an incorrect standard. Error on appeal must be affirmatively shown by the record, and '[w]e presume the trial court knew and properly applied the law absent evidence to the contrary.'" (*J.H. v. G.H.* (2021) 63 Cal.App.5th 633, 644, 277 Cal.Rptr.3d 882 (J.H.); *see Committee for Responsible Planning v. City of Indian Wells* (1989) 209 Cal.App.3d 1005, 1011, 257 Cal.Rptr. 635 [appellant did not establish that trial court applied wrong standard where minute order did "not state the court's reasons" for denying motion].) Thus, the mere fact the statement of decision did not discuss *Lavie*'s "significant portion" language does not establish that the trial court necessarily erred.

Second, Ethicon claims the court erroneously believed Ethicon could be held liable for failing to disclose *all* risks associated with its pelvic mesh products, even if doctors were already aware of the risks. In support of this argument, Ethicon relies on the following sentence plucked from the statement of decision: Ethicon "knew that it was required to include all risks reasonably associated with the device in the IFUs, whether already known to doctors or not." Ethicon claims this statement, divorced from its context, proves the court did not consider the

knowledge and experience of doctors when it assessed whether Ethicon violated the UCL and FAL.

Ethicon's citation is selective and misleading. Immediately prior to the sentence just discussed, the court referred to an earlier section of the statement of decision in which the court found a "manufacturer is expected to include all adverse reactions reasonably associated with the use of the device in the IFU." In support of this finding, the court cited a memorandum from the director of the FDA's Office of Device Evaluation (ODE), in which the director instructed ODE reviewers and industry members that the adverse reaction sections in IFUs should include "all adverse reactions reasonably associated with the use of the device …." The court also supported its finding with a citation to testimony from one of the Attorney General's witnesses, former FDA Commissioner Dr. David Kessler, who referenced the ODE memorandum just discussed, and opined that–in his view–federal regulations governing device labeling did not permit device manufacturers to omit adverse events merely because they were commonly known to practitioners.

Given this context, it is clear the court was not purporting to summarize or apply state law when it said Ethicon was required to include all risks in its IFUs. Nor was it suggesting that, as a matter of state law, doctors' knowledge and experience was irrelevant when assessing whether the IFUs and marketing communications were likely to deceive doctors. Rather, it was merely noting, in passing, its understanding that federal regulations and the FDA's

guidance on device labeling required all adverse events to be disclosed as a matter of federal law. Immediately after making this tangential observation, the court conducted the analysis demanded by state law. The court's brief reference to Ethicon's ostensible duties under federal law—a fleeting aside that the court did not focus on anywhere else in the 128-page statement of decision—does not establish that the court applied the wrong standard when assessing Ethicon's liability under state law.[9]

Third, Ethicon argues that certain findings in the trial court's order denying injunctive relief prove the court did not apply the correct legal standard in the statement of decision. In its injunctive relief order, the court found "there [was] sufficient current information in the public domain to inform physicians of the current risks of defendants' products." According to Ethicon, this finding is irreconcilable with the statement of decision and proves the court applied the wrong legal standard.

We disagree. Certainly, the injunctive relief order does not expressly state that the trial court applied the wrong legal standard when it assessed Ethicon's liability in the statement of decision. Nor is that the only conceivable inference that can be drawn from the injunctive relief order, or even the most reasonable one. On the contrary, there are many other rational explanations for why the trial court could have found

---

[9] We offer no opinion as to whether federal law requires that medical device manufacturers disclose all adverse events in their IFUs.

that Ethicon's IFUs and marketing communications were likely to deceive doctors during the statutory liability period that ended in 2018, while also finding that there was sufficient current information in the public domain to warrant the denial of injunctive relief in June 2020.

On the eve of trial, the FDA ordered all manufacturers of surgical mesh intended for transvaginal POP repair to stop selling and distributing their products. Surely, this sweeping action drew public scrutiny to the safety and effectiveness of pelvic mesh products. The present litigation itself—a high-profile case involving a $344 million judgment issued against a multi-billion dollar company—likely brought significant attention to these issues as well. Further, the present case is not the only legal matter concerning the deceptive nature of Ethicon's IFUs and marketing communications. Shortly before the court issued its statement of decision, Ethicon settled with government officials from 42 other jurisdictions to resolve allegations that Ethicon inadequately disclosed the risks of its pelvic mesh products. This settlement likely generated awareness about the risks and complications associated with Ethicon's pelvic mesh products, too.

Simply put, the statement of decision and the trial court's order denying injunctive relief are easily reconcilable, and the injunctive relief order contains no express or implied indication that the trial court applied the wrong legal standard when it rendered the statement of decision.

2

Omissions Standard

Next, Ethicon contends the trial court applied the wrong legal standard because it "failed to mention—let alone apply—the standard for omissions claims." Ethicon's argument fails for several reasons.

As an initial matter, Ethicon faults the trial court for failing to apply the legal standard governing omissions-based claims, but it does not clearly identify the legal standard it thinks the trial court *should have* applied. By failing to adequately develop its argument, Ethicon has waived its claim of error.[10] (*See Cahill v. San Diego Gas & Electric Co.* (2011) 194 Cal.App.4th 939, 956, 124 Cal.Rptr.3d 78 [" "When an appellant fails to raise a point, or asserts it but fails to support it with reasoned argument and citations to authority, we treat the point as waived.""]; *Sevidal v. Target Corp.* (2010) 189 Cal.App.4th 905, 928, 117 Cal.Rptr.3d 66 [failure to develop legal argument waives appellate challenge].)

---

[10] Ethicon filed a petition for rehearing challenging our determination that it waived its claim of error concerning the trial court's alleged failure to apply the correct legal standard for omissions-based claims. We reject Ethicon's argument. Ethicon's merits briefs purport to discuss the *circumstances* under which an omissions-based claim may be raised, but they do not set forth the proper *legal standard* a court must employ when assessing such a claim. Thus, Ethicon's argument is waived. Even if Ethicon had preserved its argument, our disposition of the case would remain the same because, as we will soon discuss, the argument fails on the merits.

In the alternative, Ethicon's argument fails because, as previously noted, the court's mere failure to discuss a standard does not compel a conclusion that the court applied the wrong standard. (*See J.H.*, *supra*, 63 Cal.App.5th at p. 644, 277 Cal.Rptr.3d 882.) On the contrary, "[i]t is a basic presumption indulged in by reviewing courts that the trial court is presumed to have known and applied the correct statutory and case law in the exercise of its official duties," absent an affirmative showing to the contrary. (*Keep Our Mountains Quiet v. County of Santa Clara* (2015) 236 Cal.App.4th 714, 741, 187 Cal.Rptr.3d 96.)

Finally, Ethicon's argument fails on the merits. A fraudulent or deceptive omission is actionable if it is "contrary to a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose." (*Daugherty v. American Honda Motor Co., Inc.* (2006) 144 Cal.App.4th 824, 835, 51 Cal.Rptr.3d 118; *see Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249, 255, 134 Cal.Rptr.3d 588 (*Collins*) ["fraud or deceit encompasses the suppression of a fact by one who is bound to disclose it, or the suppression of a fact that is contrary to a representation that was made"].) In other words, omissions-based claims can be pure-omissions claims or partial-misrepresentation claims.

In assessing whether an omission is fraudulent or deceptive, courts typically consider whether the omission satisfies one or more of the four factors set forth in *LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 336, 60 Cal.Rptr.2d 539. As this court explained in *LiMandri*:

> "There are 'four circumstances in which nondisclosure or concealment may constitute actionable fraud: (1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material facts.'"

(*LiMandri*, at p. 336, 60 Cal.Rptr.2d 539; *see Collins*, *supra*, 202 Cal.App.4th at p. 255, 134 Cal.Rptr.3d 588 [applying the *LiMandri* factors to determine whether a failure to disclose constituted actionable fraud or deceit]; *Hodsdon v. Mars, Inc.* (9th Cir. 2018) 891 F.3d 857, 863 [synthesizing state law and concluding an omission is actionable if, among things, it satisfies one of the *LiMandri* factors].)

The court considered, and issued findings, pertinent to the third *LiMandri* factor—that is, whether Ethicon actively concealed material facts. It found Ethicon took "active, willful measures for nearly twenty years to suppress information and conceal serious risk and complication information from physicians and patients." In particular, it found Ethicon knew all along that its SUI devices could lead to a variety of complications, yet it "willfully hid harmful information about the company's devices" to avoid negative public reaction. Further, it found Ethicon undertook "marketing efforts focused on downplaying and rebutting the FDA's notices" regarding pelvic

mesh products, including paying consultants to author an article to refute the notices.

The court also considered, and rendered findings, relevant to the fourth *LiMandri* factor—that is, whether Ethicon made partial representations and concealed material facts. The statement of decision is replete with such findings, but a few illustrative examples prove the point. The court found "[d]efendants' 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." It reasoned that "[b]y only disclosing an incomplete list of risks that only tells half the story—the benign half—[Ethicon's] IFUs misled consumers about the *whole* picture of possible mesh risks." Further, it found Ethicon's marketing materials included "misleadingly incomplete" risks discussions and "refer[red] to misleadingly incomplete IFUs for product and risk information."

For all these reasons, we conclude Ethicon has failed to carry its burden of establishing that the trial court applied the wrong legal standard when assessing the Attorney General's omissions-based claims.

3

Materiality Standard

Finally, Ethicon claims the court applied the wrong legal standard because it "ignored California's materiality requirement."

As previously noted, the governing standard in a false advertising case is whether " "members of the public are likely to be deceived."" (*Nationwide*, *supra*, 9 Cal.5th at p. 308, 261 Cal.Rptr.3d 713, 462 P.3d 461.) If the challenged advertisement is likely to deceive, it is actionable "without individualized proof of deception, reliance and injury." (*Massachusetts Mutual Life Ins. Co. v. Superior Court* (2002) 97 Cal.App.4th 1282, 1288, 119 Cal.Rptr.2d 190; *see Prata v. Superior Court* (2001) 91 Cal.App.4th 1128, 1137, 111 Cal.Rptr.2d 296 ["The Legislature considered [the UCL's] purpose so important that it authorized courts to order restitution without individualized proof of deception, reliance and injury if necessary to prevent the use or employment of an unfair practice."], italics omitted.)

In false advertising cases, the concept of materiality can be relevant when a court considers whether the named plaintiff in a private action has standing to asserta claim. (*See*, *e.g.*, *Chapman*, *supra*, 220 Cal.App.4th at pp. 228–230, 162 Cal.Rptr.3d 864.) A class representative in a private action must prove he or she actually relied on the deceptive advertising to have standing under the UCL.[11] (*Tobacco II*, *supra*, 46 Cal.4th at pp. 326–328, 93 Cal.Rptr.3d 559, 207 P.3d 20.) Within this context, "a presumption, or at

---

[11] Previously, the UCL "authorized 'any person acting for the interests of itself, its members or the general public' [citation] to file a civil action for relief. Standing to bring such an action did not depend on a showing of injury or damage." (*Californians for Disability Rights v. Mervyn's, LLC* (2006) 39 Cal.4th 223, 228, 46 Cal.Rptr.3d 57, 138 P.3d 207.)

least an inference, of reliance arises wherever there is a showing that a misrepresentation was material. [Citations.] A misrepresentation is judged to be "material" if "a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question" [citations], and as such materiality is generally a question of fact unless the "fact misrepresented is so obviously unimportant that the jury could not reasonably find that a reasonable man would have been influenced by it."'" (*Id.* at p. 327, 93 Cal.Rptr.3d 559, 207 P.3d 20.)

The question of materiality can also arise when a court must determine whether class treatment is warranted in a private action seeking restitution under the UCL or FAL. (*See, e.g.*, *Downey v. Public Storage, Inc.* (2020) 44 Cal.App.5th 1103, 1115, 258 Cal.Rptr.3d 290 ["[W]here plaintiffs seek to certify a class aimed solely at recovering restitution under the unfair competition law or false advertising law and define the members of the class as anyone who purchased the good or service to which the advertisement pertains, those plaintiffs must prove … the deception was material."].) In such cases, materiality can tend to show a classwide presumption of reliance—a presumption that, in turn, can assist a plaintiff to establish the well-defined community of interest necessary to obtain class certification. (*See Tucker v. Pacific Bell Mobile Services* (2012) 208 Cal.App.4th 201, 228, 145 Cal.Rptr.3d 340 ["'[I]f the issue of materiality or reliance is a matter that would vary from consumer to consumer, the issue is not subject to common proof, and the action is properly not certified as

a class action.'"]; *Weinstat v. Dentsply International, Inc.* (2010) 180 Cal.App.4th 1213, 1223, fn. 8, 103 Cal.Rptr.3d 614 [reversing class decertification order, in part, because "[t]he safety of the [defendant's product] would be material to *any* [consumer]" and, thus, "[t]here [were] no individual issues concerning the nature and extent of [the] material misrepresentations"].)

The parties have not referred us to any legal authorities in which materiality has been considered in a government enforcement action filed by the Attorney General or another public prosecutor to obtain civil penalties on behalf of the People. Nor have we uncovered such authority after conducting our own review of the case law. But, assuming without deciding that a materiality standard is implicit in the likelihood of deception standard applicable in *all* fraudulent and deceptive advertising cases, Ethicon has failed to establish that the court misapplied the materiality standard.

Ethicon's argument is based solely on the court's alleged failure to discuss materiality. However, as we have explained, we must presume the court applied the correct legal framework in the absence of a contrary indication in the record. (*J.H.*, *supra*, 63 Cal.App.5th at p. 644, 277 Cal.Rptr.3d 882; *Keep Our Mountains Quiet*, *supra*, 236 Cal.App.4th at p. 741, 187 Cal.Rptr.3d 96.) Because Ethicon points us to no contrary indication, we presume the court did not err.

Further, it is apparent from the appellate record that the trial court believed Ethicon's misstatements

and omissions were material. The court found Ethicon misrepresented and concealed "serious risk and complication information," including "medically significant" information that affected medical decision-making. The court found Ethicon's misconduct "had real consequences for real people." It found that, as a result of Ethicon's deception, doctors were unable to "factor [the risks] into their patient counseling and treatment decisions," or to "provide the information necessary to inform and counsel their patients." According to the court, Ethicon "depriv[ed] 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 depriv[ed] patients of the ability to make informed decisions about their own care."

As these findings demonstrate, the trial court believed Ethicon's misstatements and omissions were extremely significant. It found, and we agree, that they had real, serious, and long-lasting consequences—sometimes tragic and permanent consequences—for patients. While the trial court may not have uttered the precise word "materiality," the concept of materiality was unquestionably implicit in the court's findings. On this basis as well, we discern no legal error.

C

Substantial Evidence Supported Most of the Court's Findings Regarding Likelihood of Deception

The trial court found Ethicon's IFUs and marketing communications were likely to deceive doctors and

patients regarding the scope, duration, severity, source, and potential irreversibility of the complications associated with Ethicon's pelvic mesh products. Ethicon contends there was insufficient evidence to support these findings.

As we will explain, we reject Ethicon's argument in large part. In essence, Ethicon asks this court to assume the role of trier of fact and replace many of the trial court's findings with Ethicon's preferred findings. This we will not do. However, we agree with Ethicon on one point: there was insufficient evidence concerning the content of thousands of oral marketing communications that were penalized by the trial court. Because there was insufficient evidence to establish the content of these communications, we conclude substantial evidence did not support the court's finding that Ethicon's oral marketing communications were likely to deceive doctors.

1

Substantial Evidence Review

We apply a substantial evidence standard of review to the trial court's factual findings, including the court's findings that Ethicon's IFUs and marketing communications were likely to deceive their target audiences. (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1079, 219 Cal.Rptr.3d 65; *People ex rel. Bill Lockyer v. Fremont Life Ins. Co.* (2002) 104 Cal.App.4th 508, 520, 128 Cal.Rptr.2d 463 (*Fremont*).)

"[W]hen 'a finding of fact is attacked on the ground that there is not any substantial evidence to

sustain it, the power of an appellate court *begins* and *ends* with the determination as to whether there is any substantial evidence contradicted or uncontradicted which will support the finding of fact.' [Citations.]" [Citation.] [A defendant] raising a claim of insufficiency of the evidence assumes a "daunting burden."'" (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1079, 219 Cal.Rptr.3d 65.) "'The substantial evidence standard of review is generally considered the most difficult standard of review to meet, as it should be, because it is not the function of the reviewing court to determine the facts.'" (*Alper v. Rotella* (2021) 63 Cal.App.5th 1142, 1148, 278 Cal.Rptr.3d 388.)

"The test 'is simply whether there is substantial evidence in favor of the respondent. If this "substantial" evidence is present, no matter how slight it may appear in comparison with the contradictory evidence, the judgment must be upheld.'" (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1079, 219 Cal.Rptr.3d 65.) "The usual meaning of 'substantial evidence' is 'evidence that is "of ponderable legal significance," "reasonable in nature, credible, and of solid value," and "'substantial' proof of the essentials which the law requires in a particular case."'" (*Cal. Renters Legal Advocacy and Education Fund v. City of San Mateo* (2021) 68 Cal.App.5th 820, 852, 283 Cal.Rptr.3d 877.)

2

Substantial Evidence Supported the Finding that Ethicon's IFUs Were Likely to Deceive Doctors

Ethicon claims substantial evidence did not support the trial court's finding that its IFUs were likely to deceive doctors. It attacks the court's finding in two ways—first, by claiming doctors do not read or rely on IFUs when counseling and treating patients; and second, by arguing that doctors' education, training, and experience precluded a finding that they were likely to be deceived by Ethicon's IFU's.

i

We begin with Ethicon's assertion that doctors do not review or rely on IFUs to counsel and treat patients. Contrary to Ethicon's claim, ample evidence established that doctors review and rely on IFUs for these purposes.

Some of Ethicon's own witnesses testified to this fact. For instance, Ethicon medical director Dr. Martin Weisberg testified in deposition that he depends on IFUs, reviews them to properly warn his patients, and reads them to "learn about [a] product" and make sure he uses a product "the way that it's designed to be used." Dr. Piet Hinoul, Ethicon's Global Head for Medical, Clinical, and Preclinical Affairs, testified a "surgeon should be able to solely rely on [an] IFU," and Ethicon expects doctors to rely on warnings, complications, and adverse events listed in IFUs. Ethicon medical director Dr. David Robinson testified Ethicon expects surgeons to rely on IFUs to accurately

disclose product risks. Moreover, defense expert Dr. Karyn Eilber testified IFUs are a helpful source of information about mesh. Ethicon even provided a discovery response stating IFUs were "[o]ne of [its] primary means for distributing printed information about its medical devices …."

The Attorney General's witnesses also rendered testimony from which it can reasonably be inferred that doctors read and rely on IFUs. Dr. Margolis testified that when he was a practitioner, he personally reviewed the IFU for one of Ethicon's SUI devices to learn how to explant the device. Further, Dr. Rosenzweig testified that one of the purposes of an IFU is to "describe for doctors … the adverse events that are associated with [a] medical device."

Ethicon cites testimony from certain of its witnesses to suggest IFUs are used, if at all, merely to refresh a doctor's memory about a device's implantation procedure after a treatment decision has been made. We acknowledge there was evidence from which the trial court could have found that doctors read IFUs for this limited purpose only. But the court rejected that position and instead found that doctors read and rely on IFUs to make treatment decisions and counsel patients.

When reviewing this finding, our task is "to determine whether there is any substantial evidence, contradicted or uncontradicted, to support the [judgment]. [Citation] If there is substantial evidence which supports the disputed finding, the judgment will be upheld even though substantial evidence to

the contrary also exists and the trier of fact might have reached a different conclusion had it believed other evidence." (*Lobo v. Tamco* (2014) 230 Cal.App.4th 438, 442, 178 Cal.Rptr.3d 515.) Applying this standard of review, we conclude substantial evidence supported the court's finding that doctors read and rely on IFUs when making treatment decisions and counseling their patients.

ii

Next, Ethicon contends the IFUs were not likely to deceive doctors because doctors already knew—based on their education, training, and experience—the full range of complications that were misstated or omitted in the IFUs, the severity and duration of the complications, and the possible need for mesh removal. We reject this contention, and conclude there was substantial evidence to support the trial court's contrary finding that the IFUs were likely to deceive doctors about these issues.

As noted, the primary evidence in deciding whether an advertisement is likely to deceive is the text of the advertisement itself—or, in this case, the IFU. (*Overstock.com*, *supra*, 12 Cal.App.5th at pp. 1080–1081, 219 Cal.Rptr.3d 65.) The text of the IFUs supports the court's finding that the IFUs were likely to deceive doctors. As discussed above, witnesses called by both parties testified doctors read and rely on IFUs to learn about the full range of adverse events and complications associated with medical devices.

However, it is undisputed that at least a subset of Ethicon's IFUs (the IFUs accompanying the SUI devices from 1998–2015, and the IFUs accompanying certain POP devices from 2003–2012) did not identify the full range of complications associated with Ethicon's pelvic mesh products—including, at minimum, pain, dyspareunia, hispareunia, and urinary complications. The simple fact that witnesses from both parties testified they expect IFUs to list the full range of complications associated with medical devices, yet at least some of the IFUs for Ethicon's pelvic mesh products did not list the full range of complications for those products, gives rise to a strong inference that these IFUs were likely to deceive doctors.

The trial court found Ethicon's IFUs were likely to mislead doctors about the duration of the complications associated with its pelvic mesh products as well—a finding that is well-supported by the evidence. In some cases, the IFUs stated the complications were merely transitory, when in fact they could be chronic. For instance, some IFUs (the IFUs accompanying the SUI devices from 1998–2015, and the IFUs accompanying POP devices from 2003–2012) stated the devices could cause "transitory local irritation," a "transitory foreign body response," and "transient leg pain," when in fact—as the defense witnesses conceded—the products were known to cause chronic foreign body responses or chronic and debilitating pain. These inaccuracies suggest the IFUs were likely to deceive doctors about the duration of complications associated with Ethicon's pelvic mesh products.

In other cases, Ethicon's IFUs were deceptive insofar as they noted that some complications may not resolve. For example, the IFUs for the SUI devices and the POP devices from 2015 onwards stated that complications such as pelvic pain or pain with intercourse "may not resolve." These statements may be accurate, or at least unlikely to deceive doctors, when read in isolation. However, the IFUs containing these statements did not disclose that *other* chronic complications—such as hispareunia or mesh extrusion or exposure—may not resolve over time. The fact the IFUs disclosed the chronic nature of some chronic complications, while omitting the chronic nature of other complications, is additional evidence the IFUs were likely to deceive doctors.

Further, the court found all of the IFUs were likely to deceive because they were silent about the possibility that mesh implants may need to be removed (the IFUs prior to 2015), or they stated that the mesh may need to be removed and revision surgeries may be needed to treat complications (the IFUs from 2015 onwards). As the court explained, none of the IFUs stated that the mesh implants may not be able to be removed, or that complications associated with Ethicon's products may not resolve through revision surgeries. We conclude the court reasonably inferred this finding from the text of the IFUs. The likelihood of deception was particularly strong for the IFUs in effect from 2015 onwards. By stating the mesh may need to be removed and revision surgeries may need to be performed, these IFUs gave a misleading impression that the mesh could be removed and

revision surgeries could treat the mesh complications, even though that was not always true.

As noted, we must also consider the knowledge base of the consumer when assessing the likelihood of deception where, as here, the challenged advertisement or practice is directed to a particular audience—in this case, doctors. (*Dentsply*, *supra*, 19 Cal.App.5th at pp. 273–275, 227 Cal.Rptr.3d 862.) Significant portions of the statement of decision focused on whether doctors' education, training, and experience precluded them from being deceived by Ethicon's IFUs. (*See ante* Part III.B.1.) Ultimately, the court rendered findings that doctors were likely to be deceived by Ethicon's IFUs, notwithstanding their education, training, and experience. For the following reasons, we conclude substantial evidence supported these findings.

First, there was substantial evidence that many practicing doctors went to medical school or completed their residency programs before Ethicon released its pelvic mesh products. Therefore, they did not learn about the complications associated with Ethicon's pelvic mesh products in medical school or in their residency programs. For instance, one of the Attorney General's experts, Dr. Margolis, testified he did not learn how to explant mesh in medical school or his residency program because Ethicon's products had not been released yet. Defense expert Dr. Nager added, "people who may have trained many, many years ago are not familiar with the most—best procedures to treat prolapse."

Second, substantial evidence was elicited that the medical literature, journals, studies, and other sources of information may not, in practice, apprise doctors of the risks associated with pelvic mesh. In a presentation designed for Ethicon's sales representatives, Ethicon stated, "[C]linicians are very busy people [and] it can be difficult for them to stay current with all of the new literature that is published. … [¶] In many cases, [we] are providing physicians with information that they may not otherwise have read about or learned because of time constraints." Thus, Ethicon's own internal documents showed that Ethicon viewed itself as many doctors' first and primary source of information regarding pelvic mesh products.

Other witnesses testified there was a dearth of high-quality studies concerning pelvic mesh complications. For instance, Dr. Rosenzweig testified the "overwhelming majority" of existing mesh studies were concerned with efficacy—i.e., whether mesh works—not mesh complications. He added that "[t]here [were] no … long-term randomized control trials where safety [of mesh was] the primary endpoint."

Defense expert Dr. Eilber corroborated Dr. Rosenzweig's testimony on this point. She co-authorized a study that reviewed evidence about the efficacy and safety of mesh products used to treat SUI and POP. As part of the study, she and her co-authors searched for articles concerning outcomes and complications of transvaginal mesh used to treat SUI and POP from January 2010 to September 2018. According to Dr. Eilber, the search revealed the "vast

majority" of mesh studies were not relevant to the outcomes and complications of transvaginal mesh. When testifying about the article, Dr. Eilber conceded that a lot of the studies included only small patient populations and most studies on mesh complications did not consist of high-quality evidence; as a result, the complication rate of transvaginal mesh insertion was, in Dr. Eilber's view, "not known as well as it could" have been.

Third, there was substantial evidence that doctors may not necessarily learn about the complications associated with transvaginal pelvic mesh products from their own experiences treating patients. According to defense expert Dr. Rosenblatt, Obstetrics and Gynecology (OB/ GYN) physicians who specialize in female pelvic medicine and reconstructive surgery (FPMRS), also known as urogynecologists, usually have a higher level of training than general OB/GYN physicians and may be more familiar with the literature on pelvic mesh surgeries than general OB/GYN physicians. However, FPMRS specialization is *not* a requirement for a physician to implant Ethicon's products. Thus, in practice, general OB/GYN physicians—who typically lack the specialized training and knowledge base of urogynecologists—routinely implant Ethicon's pelvic mesh products.

Further, defense expert Dr. Eilber testified that patients with mesh complications do not always return to the doctor who implanted the mesh. From this testimony, it can be inferred that an implanting doctor may not become aware of certain types of

complications, or any complications, that their own patients may experience post-implantation.

Fourth, there was evidence from which it could be reasonably inferred that the FDA was not fully aware of the range and prevalence of complications associated with pelvic mesh products during the statutory liability period. In its 2008 public health notification, the FDA listed certain complications associated with mesh used to treat SUI and POP, but it omitted other complications associated with the transvaginal placement of mesh—namely, pain to partner and mesh contraction. For the limited set of complications identified in the public health notification, the FDA stated that it believed the complications were "rare." Further, the FDA did not disclose that mesh removal may not be possible.

It was not until three years later, in 2011, that the FDA released an update advising doctors that complications associated with transvaginal pelvic mesh used to treat POP were "not rare," and that mesh "may expose patients to greater risk" than non-mesh repair. In the update, the FDA added new risks that were not previously disclosed in the 2008 public health notification—specifically, mesh contraction and pain to partner. Further, the FDA added new guidance indicating that "[c]omplete removal of mesh may not be possible …." In our view, the FDA's evolving advice regarding the range, frequency, and potential irreversibility of pelvic mesh complications gives rise to a reasonable inference that, at minimum, these issues were not so patently obvious and widely-known in the medical community that doctors could not have been

misled by Ethicon's intentional misstatements, half-truths, and omissions.

In its appellate brief, Ethicon cites evidence that doctors, especially those who perform mesh implantation surgeries, are familiar with the range and severity of pelvic mesh complications, as well as treatment options for such complications. According to Ethicon, this evidence—which largely consists of testimony from Ethicon's experts—conclusively established that Ethicon's IFUs were unlikely to deceive doctors.

However, the trial court strongly discredited Ethicon's experts and found they suffered from conflicts of interest that biased their opinions. The court noted that one of Ethicon's experts was a former preceptor for Ethicon who trained doctors to use the SUI devices. It found that another defense expert had been a paid consultant for Ethicon and other mesh manufacturers for more than 16 years. And it found that yet another defense expert had been a paid consultant for mesh manufacturers including Ethicon for more than 18 years, and that he had received millions of dollars from these relationships. "Venerable precedent holds that, in a bench trial, the trial court is the 'sole judge' of witness credibility. [Citation.] The trial judge may believe or disbelieve uncontradicted witnesses if there is any rational ground for doing so. [Citation.] The fact finder's determination of the veracity of a witness is final." (*Schmidt v. Superior Court* (2020) 44 Cal.App.5th 570, 582, 257 Cal.Rptr.3d 699.)

Further, our responsibility when reviewing a challenged finding is not to assess which party's evidence was more persuasive, or even whether we would have reached the same finding as the trier of fact if we were standing in its shoes. Instead, our role is to examine whether there was substantial evidence, controverted or uncontroverted, to establish the finding rendered by the trier of fact. (*See In re Travis C.* (2017) 13 Cal.App.5th 1219, 1225, 221 Cal.Rptr.3d 572.) Given the limited nature of our review, we conclude the trial court did not err in finding that Ethicon's IFUs were likely to deceive doctors.

We are relying exclusively on the evidence in the record as the basis for our determination that the trial court's factual findings were proper, as of course we must. (*See State Farm Fire & Casualty Co. v. Jioras* (1994) 24 Cal.App.4th 1619, 1625, 29 Cal.Rptr.2d 840 ["When a factual conclusion is attacked as lacking evidentiary support, our power is limited to determining whether the record contains substantial evidence, contradicted or uncontradicted, to support the decision."].) However, we note for the record that our determination is broadly consistent with appellate decisions from other jurisdictions in which courts have assessed the misleading effects of Ethicon's IFUs, the knowledge base of doctors who implant Ethicon's pelvic mesh products, and whether doctors could reasonably be deceived by Ethicon's misleading IFUs.

For example, *Kaiser v. Johnson & Johnson* (7th Cir. 2020) 947 F.3d 996 (*Kaiser*) concerned a patient who received a Prolift implant and experienced irreversible pelvic pain, bladder spasms, and pain during

intercourse. She filed a product liability suit against Ethicon pursuant to Indiana's product liability statute, alleging defective product design and failure-to-warn theories. (*Id.* at p. 1006.) After trial, a jury returned a verdict for the plaintiff on both theories and the plaintiff was awarded $10 million in compensatory damages and $10 million in punitive damages. (*Id.* at p. 1007.)

On appeal, Ethicon claimed the jury erred in finding that Prolift "expose[d] the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchase[d] the product with the ordinary knowledge about the product's characteristics common to the community of consumers." (*Kaiser*, *supra*, 947 F.3d at pp. 1008, 1014–1015.) It argued that "an ordinary pelvic-floor surgeon would be aware of the *possibility* of all relevant risks," and "surgeons could have learned more about Prolift's risks from medical literature." (*Id.* at pp. 1014, 1015, italics in original.) But the Seventh Circuit Court of Appeals rejected this contention, reasoning that "a reasonable jury could conclude that Prolift created risks beyond the expectations of ordinary pelvic-floor surgeons." (*Id.* at p. 1014.) It cited the trial testimony of physicians (including Dr. Rosenzweig, a witness called by the Attorney General in the present case) who stated that they were unaware of all of the risks associated with Prolift and the permanency of pelvic mesh complications. (*Id.* at pp. 1014–1015.)

The Seventh Circuit Court of Appeals also described the Prolift IFU as "brief" and "inadequate"

because the IFU failed to warn doctors "about Prolift's potential for permanent pelvic pain and sexual dysfunction," or "the frequency, severity, or permanence of Prolift's side effects." (*Kaiser*, *supra*, 947 F.3d at pp. 1015, 1016.) The court concluded that, "[g]iven the limited scope of the warnings in Prolift's Instructions for Use, a reasonable jury could conclude that Ethicon breached its duty to warn surgeons of its risks." (*Id.* at p. 1016.) On this basis, the court affirmed the jury's finding that Ethicon was liable on a failure-to-warn theory. (*Id.* at pp. 1015–1017.)

Similarly, in *Hrymoc v. Ethicon, Inc.* (N.J. Super. Ct. App. Div. 2021) 467 N.J. Super. 42, 249 A.3d 191 (*Hrymoc*), certification granted October 19, 2021, 085547, a patient suffered severe medical complications after receiving a Prolift implant. She sued Ethicon under New Jersey's products liability law and a jury returned a verdict in her favor on design defect and failure-to-warn theories of liability. (*Id.* at pp. 199–200.) The *Hrymoc* court reversed the judgment for a reason not relevant to the current appeal. But in the course of doing so, it opined that the jury reasonably found Ethicon's failure to warn was the proximate cause of the patient's injuries. (*Id.* at pp. 216–220.)

In relevant part, the New Jersey appellate court rejected Ethicon's claim that the patient's surgeon "relied solely on medical literature, the patient's presentation, and his own training and experience," rather than the Prolift IFU, when he recommended the device to the patient. (*Hrymoc*, *supra*, 249 A.3d at pp. 218–219.) As the court explained, there was

evidence that the patient's surgeon reviewed the IFU to learn about Prolift. (*Ibid.*) According to the court, there was also evidence that Ethicon omitted known material risks from the Prolift IFU, including "mesh contraction, chronic pain, vaginal distortion, dyspareunia, and the need for additional surgery," and there was evidence that the surgeon was "not aware of all the material risks of patient harm known by Ethicon at the time of plaintiff's surgery." (*Id.* at pp. 218, 219.) Thus, the court concluded that Ethicon's "failure to provide adequate warnings to [the implanting surgeon] was reasonably found to be a substantial factor in not alerting plaintiff about the risk of permanent and life-changing complications, depriving her of the opportunity to avert the 'medical catastrophe' that occurred." (*Id.* at p. 220.)

Hammons v. Ethicon, Inc. (Pa. Super. Ct. 2018) 190 A.3d 1248 (*Hammons*) also involved the adequacy of Ethicon's Prolift IFU. In an all-too-familiar story, a patient received a Prolift implant and thereafter experienced recurrent pain, pain during intercourse, incontinence, and recurrent prolapse. (*Id.* at pp. 1255–1256.) She sued Ethicon for products liability under Indiana's product liability statute on multiple theories including a failure-to-warn theory. (*Id.* at p. 1256.) After trial, a jury returned verdict in favor of the plaintiff and awarded her $5.5 million in compensatory damages and an additional $7 million in punitive damages. (*Id.* at p. 1258.)

The Pennsylvania appellate court affirmed the judgment and rejected Ethicon's claim that the patient failed to present evidence that Prolift's

inadequate warnings caused her injuries. (*Hammons*, *supra*, 190 A.3d at pp. 1269–1274, 1291.) Viewing the evidence in favor of the patient, the court determined that, "at the time of Prolift's product launch in March 2005, Ethicon was aware of serious risks caused by Prolift but failed to make these risks clear in its indications for use ('IFU') and patient brochures. (*Id.* at pp. 1270–1271; *id*. at p. 1271 ["The IFU and brochures failed to disclose the full extent of the risks posed by Prolift—risks that Ethicon knew about prior to the March 2005 product launch."].) The court cited evidence showing that "Ethicon's warnings were inadequate because they failed to convey Prolift's full risk profile, namely 'all the known complications, their severity, their frequency.'" (*Id.* at p. 1272.) Additionally, the court cited evidence that "physicians are 'dependent on the information that is provided by the manufacturer for the long-term risks or for the risks that are connected to th[e] device." (*Id.* at p. 1273.) Based on these findings, and others, the court concluded that "Ethicon failed to provide adequate warnings to [the surgeon] about the risks of Prolift, and that [the surgeon] neither knew *nor should have known independently* about these risks." (*Id.* at p. 1273, italics added.)

Finally, *Carlino v. Ethicon, Inc.* (Pa. Super. Ct. 2019) 208 A.3d 92 (*Carlino*) involved a patient who received a TVT implant and sued Ethicon for products liability after experiencing mesh exposure, recurrent pain in her vagina, and pain during intercourse. The jury found in favor of the patient, and she and her husband were awarded $3.5 million in compensatory damages and $10 million in punitive damages. (*Id.* at

p. 101.) The Pennsylvania appellate court affirmed the judgment and rejected Ethicon's challenge to the punitive damages award. (*Id.* at pp. 120–123.)

In upholding the punitive damages award, the *Carlino* court cited evidence that the TVT device "pose[d] a high risk of catastrophic injury to patients" and Ethicon should have, but did not, warn about the "risks of serious injuries, and about the severity, frequency, or permanency of those injuries." (*Carlino*, *supra*, 208 A.3d at pp. 121–122.) According to the court, "Ethicon knowingly understated the risks of the TVT in all six versions of the IFU published between 2000 and 2015. The IFU's adverse reactions section … failed to acknowledge new information Ethicon was obtaining from treaters and its own researchers on adverse effects associated with the TVT. [Citation.] In addition, Ethicon consistently and misleadingly informed physicians that the TVT produced few adverse results and was intentionally evasive about common complications." (*Id.* at p. 122.) As the court explained, "Ethicon knew that the TVT could cause permanent vaginal and muscular pain and sexual dysfunction, because of its mesh weight, pore size, pore collapse, and particle loss. Despite this knowledge, Ethicon promoted the TVT for patients who sought to fix SUI, knowingly understated the risks of the TVT in its IFU, and *consistently misled physicians* that the TVT produced few adverse results." (*Id.* at pp. 123, italics added.)

The *Kaiser*, *Hrymoc*, *Hammons*, and *Carlino* decisions arose in other jurisdictions and the plaintiffs' claims in those cases were predicated on legal

theories and trial records different than those presented here. However, each decision reveals a similar narrative: Ethicon disseminated IFUs that were likely to deceive doctors because the IFUs falsified or omitted the full range, severity, duration, and cause of complications associated with Ethicon's pelvic mesh products, as well as the potential irreversibility and catastrophic consequences of those complications. The statement of decision and the appellate record in the present case tell precisely the same story.

Viewing the evidence in the light most favorable to the People, as the prevailing party, we conclude there was substantial evidence to support the trial court's factual finding that Ethicon's IFUs were likely to deceive doctors.

3

Substantial Evidence Supported the Findings Regarding Ethicon's Written Marketing Communications, But Not its Oral Marketing Communications

Next, Ethicon asserts there was insufficient evidence to support the court's findings that its marketing communications were likely to deceive doctors. Ethicon claims the evidence did not show that doctors read and rely on marketing communications. Additionally, it argues there was insufficient evidence to support a finding that its marketing communications included one or more deceptive statements or

omissions.[12] We disagree with Ethicon's first argument; however, we accept Ethicon's second argument in part.

i

As noted, Ethicon claims its marketing communications were not likely to deceive doctors because doctors do not read or rely on marketing communications when deciding how to counsel and treat patients. Substantial evidence elicited at trial established otherwise.

According to testimony from Scott Jones, a former member of Ethicon's Global Strategic Marketing Department, medical professionals—not patients—are the main audiences for Ethicon's marketing efforts. When Ethicon conducts these marketing efforts, it provides physicians with material information regarding its products, including the benefits and risks of its products. As previously noted, Ethicon itself stated its sales representatives "provid[e] physicians with information they may not otherwise have read about or learned because of time constraints."

---

[12] Ethicon technically argues that the trial court abused its discretion in calculating the civil penalty award because the court assumed without sufficient evidence that each marketing communication included a deceptive misstatement or omission. However, in substance, Ethicon challenges the sufficiency of the evidence supporting the court's finding that each marketing communication was likely to deceive. We construe Ethicon's argument according to its substance.

The evidence showed these marketing efforts impacted doctors' decisions whether to procure and implant Ethicon's pelvic mesh products. For example, Jones testified that "doctors had to be convinced that your product was the best option to then recommend to patients …." When questioned whether Ethicon's professional education events were relevant to the commercial performance of Ethicon's products, he said: "[P]rofessional education events definitely had an impact. I think, doctors had to feel comfortable with the product, in terms of knowing that it was safe and effective and how to use the device. [¶] Obviously, if they felt comfortable that it was the right device and that it would get the outcomes they need[ed] for their patients, that would result in them using the device or procedure with their patients."

Defense expert and former Ethicon preceptor Dr. Nager also testified that Ethicon's industry training courses were "driving the use of mesh kits." He added that industry marketing drove product use among doctors because "[t]here were advertisements about the available mesh kits to treat pelvic organ prolapse. It was … present in [the] journals and … representatives … would go to physicians' offices and market the mesh kits."

Additionally, defense expert Dr. Eilber testified that a sales representative for a medical device is a source of information to which she personally would turn if she was unfamiliar with a medical device.

Collectively, this evidence established that Ethicon's marketing communications impacted doctors'

decisions to procure and implant Ethicon's pelvic mesh products.

ii

Next, we turn to Ethicon's claim that the court improperly assumed, without sufficient supporting evidence, that Ethicon's marketing communications were likely to deceive doctors.

In addressing this argument, we divide Ethicon's marketing communications into two categories: (1) written communications; and (2) oral communications. In the former category we include: the printed marketing materials that Ethicon's sales representatives requested through an online portal to be distributed to physicians; the printed marketing materials that were requested through Ethicon's public telephone hotline; Ethicon's mesh product website and subpages; professional education and training presentations given to physicians; and certain field marketing activities including PR kits and primary care provider outreach.[13] In the latter category, we include sales representative detailing; Ethicon-sponsored meals between sales representatives and doctors; and one field marketing activity—health fairs.

---

[13] We acknowledge Ethicon sometimes made oral representations in the course of providing these written marketing communications to doctors. However, we categorize them as written marketing communications—not oral marketing communications—because the court found the written marketing communications themselves were deceptive.

With respect to Ethicon's written marketing communications, we conclude the trial court did not improperly assume that the communications were deceptive. On the contrary, the court prepared a 23-page violations appendix cataloguing the precise manner by which each and every written or online marketing communication was likely to deceive doctors.[14]

However, we reach a different conclusion with respect to Ethicon's oral marketing communications. We are unable to find evidence in the record establishing the content of any of Ethicon's oral marketing communications, let alone each of the thousands of communications that were penalized here. The People have not provided us with any citations to the record sufficient to establish the content of these communications. In fact, the only evidence on this topic of which we are aware supports Ethicon's argument. The People's forensic accountant—who developed the methodologies underpinning the trial court's violations calculation—conceded he did not know whether any particular sales representative detailing activity was mesh-related; whether mesh was discussed during Ethicon's meals with health care providers; or what Ethicon's employees and agents even said during health fairs.

---

[14] To the extent Ethicon challenges the sufficiency of the evidence pertaining to each printed or online marketing communication, we are unable to assess the merits of the argument because Ethicon has not included each printed or market communication in the appellate record, nor has it made arguments specific to each such communication.

In its statement of decision, the trial court cited evidence that Ethicon's sales representatives "were trained and coached to deliver the same consistent messages that pervade[d] the company's print materials and IFUs …." According to the court, this "evidence establishe[d] that [Ethicon'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 [the] [c]ourt [could] infer that [each] mesh-related sales conversation gave rise to a violation."

Certainly, there was evidence showing that Ethicon *trained* its sales representatives to convey uniform marketing messages. For instance, former Ethicon sales manager Michelle Garrison testified that Ethicon's sales representatives went through a uniform training procedure; had access to the same marketing materials; were trained on how Ethicon's mesh devices are implanted; were trained about the risks and complications relating to Ethicon's devices; were trained on how to respond when doctors asked questions about complications; were trained on messages to convey for new products; and were trained they could direct physicians to IFUs for information about product risks and complications. She also agreed Ethicon's marketing techniques were intended to "provide uniformity to the information that sales reps would be giving to doctors …."

However, unlike the trial court, we conclude the uniform nature of Ethicon's sales representatives training does not, standing alone, give rise to a reasonable inference that every single one of Ethicon's

thousands of oral communications with doctors included false or misleading statements. The mere fact a sales representative may have been trained in a particular way—even in a manner that promoted the disclosure of misleading information—reveals little, if anything, about the content of any particular conversation that may have occurred many months or years later. Further, there is no evidence—at least none of which we are aware of—suggesting Ethicon's sales representatives read or recited a uniform script, Ethicon's IFUs, or Ethicon's printed marketing materials during their oral communications with doctors.

Simply put, there was no evidence of the actual substance of any of Ethicon's oral communications with doctors, let alone all of them. Further, there was insufficient evidence from which a court could reasonably infer that each one of Ethicon's oral communications with doctors, or any of them, included a false or misleading statement that was likely to deceive doctors. In the absence of such evidence, the trial court erred in finding that Ethicon's oral marketing communications violated the UCL and FAL.

We hasten to add that there is nothing inherently less problematic about a false or deceptive statement that is spoken aloud, as opposed to one that has been memorialized in writing. In an appropriate case, where the content and deceptive nature of the oral statement is established, the speaker may be held liable for violating the UCL or FAL. (*See People v. Dollar Rent-A-Car Systems, Inc.* (1989) 211 Cal.App.3d 119, 128–129, 259 Cal.Rptr. 191 [the FAL's prohibition against false or misleading

advertising "extends to the use of false or misleading oral statements"].) We merely conclude there was insufficient evidence in this case regarding the substance of Ethicon's oral marketing communications; thus, there was insufficient evidence that these communications were likely to deceive their target audiences.

Accordingly, we modify the judgment to strike the portion of the award imposing civil penalties based on Ethicon's oral marketing communications with doctors. In particular, we strike the portion of the judgment imposing civil penalties for the following activities and communications: sales representative detailing (8,191 UCL violations and 6,066 FAL violations; or $17,821,250 in penalties); Ethicon-sponsored meals (8,199 UCL violations and 6,029 FAL violations; or $17,785,000 in penalties); and health fairs (2,575 UCL violations and 2,505 FAL violations; or $6,350,000 in penalties). As amended, the judgment awards civil penalties to the People in the amount of $302,037,500.[15]

[15] We calculate this amount as follows: $343,993,750 (the civil penalties ordered by the trial court) minus $17,821,250 (the portion of the civil penalties attributable to sales representative detailing) minus $17,785,000 (the portion of the civil penalties attributable to Ethicon-sponsored meals) minus $6,350,000 (the portion of the civil penalties attributable to health fairs) equals $302,037,500.

Substantial Evidence Supported the Finding that Ethicon's Marketing Was Likely to Deceive Patients

The trial court also found Ethicon disseminated false and misleading marketing communications that were likely to deceive patients. Ethicon argues its communications were not misleading—an argument we construe as a sufficiency of the evidence challenge. So construed, the argument is meritless.

In its statement of decision, the court found Ethicon's marketing communications were likely to deceive patients because they: (1) included misleading or incomplete discussions of the risks associated with Ethicon's products; (2) referred the reader to the incomplete risk, adverse events, and safety information contained in the product IFUs; and/or (3) excerpted the incomplete risk and adverse event information from the product IFUs. Substantial evidence supported the court's findings.

To take one illustrative example, a TVT patient brochure in circulation in 2008 (court exhibit 10210) touts the benefits of TVT, proclaiming the device to be "clinically proven, safe and effective" for the treatment of SUI. It assures the patient "[t]here should be very little discomfort after the procedure." Then, at the very end of the brochure, it states (under a heading that reads "What are the risks?") as follows: "All medical procedures present risks. As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs. For a complete description of risks, see the attached product information."

Far from providing a complete description of risks, the product information attached to the brochure sets forth a significantly truncated description of warnings and adverse reactions. It states the patient may experience certain side effects such as transient leg pain lasting 24–48 hours or post-operative bleeding or infection. But this incomplete risk discussion omits virtually all of the most severe risks associated with the TVT device—including mesh exposure through the vagina, mesh erosion, tissue contracture leading to chronic pain, debilitating and life-changing chronic pain, chronic groin pain, chronic dyspareunia, and pain to partner. By listing a small handful of the TVT device's risks and then proclaiming the list to be complete, the advertisement paints a distorted and overly-rosy picture of the safety of the TVT device. The court did not err in finding this misleading advertisement, and others like it, were likely to deceive patients.

Ethicon contends its marketing communications were not likely to deceive patients because doctors in California have a duty to disclose to their patients the potential of death, serious harm, and other complications associated with a proposed procedure, as well as "'such additional information as a skilled practitioner of good standing would provide under similar circumstances.'" (*Daum v. SpineCare Medical Group, Inc.* (1997) 52 Cal.App.4th 1285, 1301–1302, 61 Cal.Rptr.2d 260, quoting *Cobbs v. Grant* (1972) 8 Cal.3d 229, 244–245, 104 Cal.Rptr. 505, 502 P.2d 1.) In other words, Ethicon claims its communications were not likely to deceive patients because doctors have a legal duty to disclose the risks associated with

implantation of Ethicon's products and to obtain their patients' informed consent in connection with this disclosure.

Substantial evidence supported the court's finding that Ethicon's marketing communications were likely to deceive patients, notwithstanding the legal duties owed by doctors. Obviously, doctors must be adequately informed of the risks of a medical device to effectively disclose those risks to patients. As Ethicon sales manager Michelle Garrison testified, "if [Ethicon is] not communicating [the product complications] to the doctor, the doctor may not be able to communicate that to the patient. … The doctor needs to be properly informed."

However, as previously discussed, Ethicon willfully and intentionally promulgated deceptive messages to doctors about the risks and complications associated with its products. Because doctors themselves were likely to be deceived by Ethicon's IFUs and marketing communications, the trial court reasonably found Ethicon's marketing communications were likely to deceive patients notwithstanding the legal duties doctors owe to their patients.

D

The Safe Harbor Defense Does Not Apply

Ethicon asserts the FDA authorized, or at minimum permitted, certain IFUs and marketing communications upon which the People's claims were based. According to Ethicon, the FDA's conduct established a safe harbor that barred the Attorney's

General's claims. For reasons we will explain, no such safe harbor existed.

1

Overview of the Safe Harbor Defense

Under the safe harbor defense, "[s]pecific legislation may limit the judiciary's power to declare conduct unfair [under the UCL]. If the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination. When specific legislation provides a 'safe harbor,' plaintiffs may not use the general unfair competition law to assault that harbor." (*Cel-Tech*, *supra*, 20 Cal.4th at p. 182, 83 Cal.Rptr.2d 548, 973 P.2d 527.) Stated another way, the Attorney General or another UCL plaintiff may "not 'plead around' an 'absolute bar to relief' simply 'by recasting the cause of action as one for unfair competition.'" (*Ibid.*)

There is some disagreement among courts as to whether legislation alone can create a safe harbor or whether executive action can give rise to a safe harbor as well. (*Compare Krumme v. Mercury Ins. Co.* (2004) 123 Cal.App.4th 924, 940, fn. 5, 20 Cal.Rptr.3d 485 ["only statutes can create a safe harbor"], with *Davis v. HSBC Bank Nevada, N.A.* (9th Cir. 2012) 691 F.3d 1152, 1165–1167 [regulations can create safe harbor].) We assume for purposes of this appeal, without deciding, that executive conduct can create a safe harbor. We also assume, without deciding, that the safe harbor concept applies to UCL claims based on FAL violations and fraudulent or unlawful business

practices, not merely claims based on unfair business practices. (*See De La Torre v. CashCall, Inc.* (2018) 5 Cal.5th 966, 986, 236 Cal.Rptr.3d 353, 422 P.3d 1004 [assuming without deciding that safe harbor defense applied to unlawful business practice claims] (*De La Torre*).)

2

The FDA Did Not Create a Safe Harbor for Communications Related to the POP Products

i

The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (MDA) "directs the FDA to divide medical devices into three classes based on the level of risk they present, and it provides for different regulation of each class. [Citation.] Class I, the lowest-risk category, comprises products such as bandages and tongue depressors. Class I devices are subject to 'general controls' such as labeling requirements. [Citation.] Class II devices are those for which general controls 'are insufficient to provide reasonable assurance of … safety and effectiveness.' [Citation.] In addition to being subject to general controls, Class II devices are subject to 'special controls' such as "performance standards, postmarket surveillance, … recommendations, and other appropriate actions as the [FDA] deems necessary' to ensure safety and effectiveness. [Citation.] Class III devices, the highest-risk category, are devices that cannot be determined to provide a 'reasonable assurance of … safety and effectiveness' under Class I or II controls, and that either are marketed as life-supporting

devices or pose an unreasonable risk of illness or injury." (*In re Bard IVC Filters Product Liability Litigation* (9th Cir. 2020) 969 F.3d 1067, 1070 (*Bard*).)

"Class III devices are generally subject to premarket approval by the FDA. [Citation.] Premarket approval is a rigorous process that requires the manufacturer to submit a detailed application including studies of the device's safety and effectiveness. [Citations.] The FDA may approve the device only if has 'reasonable assurance' that the device is safe and effective. [Citation.] [¶] By contrast, Class I and II devices are generally subject to a far less rigorous process referred to as section '510(k) approval,' [citation], which requires the manufacturer to show only that the device is 'substantially equivalent' to an existing Class I or Class II device. [Citations.] To grant approval, the FDA must find that the device 'has the same technological characteristics as the predicate device,' or, if the device has different technological characteristics, that it 'is as safe and effective as a legally marketed device, and … does not raise different questions of safety and effectiveness than the predicate device.'" (*Bard*, *supra*, 969 F.3d at p. 1070.)

The SUI and POP products are medical devices. They went through the section 510(k) clearance process and, during the relevant timeframe, they were designated as Class II devices. During the clearance process for the Prolift and Prolift+M devices, the FDA informed Ethicon it was unable to determine whether the devices were substantially equivalent to an existing legally marketed predicate device due to certain "deficiencies" in Ethicon's submissions to the FDA.

The FDA also noted that the draft IFUs for Prolift and Prolift+M did "not adequately address issues of usability and potential adverse events," and it ordered Ethicon to add adverse events to the IFUs, including "hematoma, urinary incontinence, urinary retention/obstruction, void dysfunction, pain, infection, adhesions, wound dehiscence, nerve damage, recurrent prolapse, contracture, and procedure failure." It also ordered Ethicon to develop a patient brochure addressing the risks and benefits of POP treatment options. Thereafter, Ethicon added most of the adverse events identified by the FDA into the IFUs for Prolift and Prolift+M.

ii

On appeal, Ethicon contends the FDA effectively wrote and approved the IFUs for the Prolift and Prolift+M devices. According to Ethicon, the FDA's alleged drafting and approval of the IFUs created a safe harbor that shielded Ethicon from liability for the content of the IFUs.

The FDA's limited review of the draft Prolift and Prolift +M IFUs—a review undertaken as part of the section 510(k) clearance process—did not create a safe harbor. "To forestall an action under the unfair competition law, another provision [or executive action, per our stated assumptions] must actually 'bar' the action or clearly permit the conduct." (*Cel-Tech*, *supra*, 20 Cal.4th at p. 183, 83 Cal.Rptr.2d 548, 973 P.2d 527; *Klein v. Chevron U.S.A., Inc.* (2012) 202 Cal.App.4th 1342, 1379, 137 Cal.Rptr.3d 293 ["to qualify for the 'safe harbor' rule, the defendant must

show that a statute 'explicitly prohibit[s] liability for the defendant's acts or omissions' [citation] or 'expressly precludes an action based on the conduct'"].)

The FDA's conduct during the clearance process did not clearly sanction or approve the final IFUs for non-510(k) purposes. "'[T]he 510(k) process is focused on *equivalence*, not safety.' … These determinations simply compare a post–1976 device to a pre–1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device.'" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 493, 116 S.Ct. 2240, 135 L.Ed.2d 700; *accord Kaiser*, *supra*, 947 F.3d at p. 1018 [in products liability case, trial court properly excluded evidence that FDA cleared Prolift because the section 510(k) clearance process and FDA safety review serve different purposes].)

Indeed, former FDA Commissioner Dr. Kessler testified the FDA's "clearance [of Ethicon's] pelvic mesh devices [was] not a finding that the labeling [was] complete, accurate and not misleading." As Dr. Kessler explained, the FDA "did not authorize [Ethicon] to exclude certain adverse events from [its] labeling." In fact, the FDA even instructed Ethicon its "substantial equivalence determination [did] not mean that [the] FDA ha[d] made a determination that [its] device[s] complie[d] with other requirements of the [Food, Drug, and Cosmetic] Act or any Federal statutes and regulations administered by other Federal agencies." The FDA also advised Ethicon it "must comply with all the [Food, Drug, and Cosmetic] Act's requirements, including … labeling" requirements.

Because product safety and labeling were not the focus of the FDA's section 510(k) clearance process, we conclude the FDA did not clearly sanction Ethicon's IFUs as lawful for all purposes when it cleared the Prolift and Prolift+M devices, or when it requested that Ethicon supplement its deficient draft IFUs as part of the section 510(k) clearance process.

3

The FDA Did Not Create a Safe Harbor for Communications Related to the SUI Products

Ethicon asserts a safe harbor defense regarding the IFUs and patient brochures for its SUI devices as well. It claims that, in September 2011, the FDA convened an advisory committee to consider issues relating to the use of surgical mesh for the treatment of SUI and POP. An executive summary prepared in advance of the meeting stated the advisory committee would consider, among other subjects, whether special controls were needed for SUI mesh products such as improvements in physician and patient labeling. After the meeting, the FDA did not order additional special controls. According to Ethicon, the FDA's inaction established a safe harbor for the SUI device labeling.

Ethicon is mistaken. At most, the FDA failed to declare Ethicon's conduct unlawful. But "[t]here is a difference between (1) not making an activity unlawful, and (2) making that activity lawful. … Acts that the Legislature [or agency] has determined to be lawful may not form the basis for an action under the unfair competition law, but acts may, if otherwise

unfair, be challenged under the unfair competition law even if the Legislature [or agency] failed to proscribe them in some other provision." (*Cel-Tech*, *supra*, 20 Cal.4th at p. 183, 83 Cal.Rptr.2d 548, 973 P.2d 527; *see De La Torre*, *supra*, 5 Cal.5th at p. 987, 236 Cal.Rptr.3d 353, 422 P.3d 1004 [a "lack of proscription is not enough" for a safe harbor].) Because the FDA's mere inaction did not clearly permit the IFUs and brochures at issue, Ethicon has failed to establish a safe harbor defense for those communications.

E

Ethicon Has Not Proven Violations of its Speech Rights

Next, Ethicon argues the trial court "punished" it for engaging in speech protected by the free speech clauses of the federal and state constitutions. According to Ethicon, the "court's holding that *all* of Ethicon's communications about its pelvic-mesh devices violated California law cannot withstand First Amendment scrutiny."

The First Amendment states, "Congress shall make no law … abridging the freedom of speech...." (U.S. Const., 1st Amend.) "Although by its terms this provision limits only Congress, the United States Supreme Court has held that the Fourteenth Amendment's due process clause makes the freedom of speech provision operate to limit the authority of state and local governments as well." (*Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 951, 119 Cal.Rptr.2d 296, 45 P.3d 243 (*Kasky*); *McIntyre v. Ohio Elections*

Comm'n (1995) 514 U.S. 334, 336, fn. 1, 115 S.Ct. 1511, 131 L.Ed.2d 426.)

It is undisputed Ethicon's IFUs and advertisements were commercial speech. "Under the First Amendment, commercial speech is entitled to less protection from governmental regulation than other forms of expression." (*People ex rel. Gascon v. HomeAdvisor, Inc.* (2020) 49 Cal.App.5th 1073, 1085, 263 Cal.Rptr.3d 438 (*HomeAdvisor*).) Generally, it is subject to scrutiny under a test articulated in *Central Hudson Gas & Elec. v. Public Serv. Comm'n* (1980) 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (*Central Hudson*). Under the *Central Hudson* test, regulation of speech is permissible if it: (1) seeks to implement a substantial governmental interest; (2) directly advances the asserted governmental interest; and (3) is not more extensive than is necessary to serve that interest. (*Id.* at pp. 564–566, 100 S.Ct. 2343.)

Although commercial speech is generally protected under the First Amendment, "commercial speech that is false or misleading is not entitled to First Amendment protection and 'may be prohibited entirely.'" (*Kasky*, *supra*, 27 Cal.4th at p. 953, 119 Cal.Rptr.2d 296, 45 P.3d 243.) Indeed, "'[i]t is well settled that *false* commercial speech is not protected by the First Amendment and may be banned entirely.'" (*Osmose, Inc. v. Viance, LLC* (11th Cir. 2010) 612 F.3d 1298, 1323, italics added; *see Castrol Inc. v. Pennzoil Co.* (3d Cir. 1993) 987 F.2d 939, 949 ["false commercial speech is not protected by the First Amendment"].) "'With regard to misleading commercial speech, the United States Supreme Court has

drawn a distinction between, on the one hand, speech that is actually or inherently misleading, and, on the other hand, speech that is only potentially *misleading*. Actually or inherently misleading commercial speech is treated the same as false commercial speech, which the state may prohibit entirely. [Citations.] By comparison, "[s]tates may not completely ban potentially misleading speech if narrower limitations can ensure that the information is presented in a nonmisleading manner."'" (*HomeAdvisor*, *supra*, 49 Cal.App.5th at p. 1085, 263 Cal.Rptr.3d 438, italics added.)

Article I, section 2, subdivision (a) of the state constitution contains a constitutional free speech guarantee as well, stating: "Every person may freely speak, write and publish his or her sentiments on all subjects, being responsible for the abuse of this right. A law may not restrain or abridge liberty of speech or press." (Cal. Const., art. I, § 2, subd. (a).) "The state Constitution's free speech provision is 'at least as broad' as [citation] and in some ways is broader than [citations] the comparable provision of the federal Constitution's First Amendment." (*Kasky*, *supra*, 27 Cal.4th at pp. 958–959, 119 Cal.Rptr.2d 296, 45 P.3d 243.) But, "[i]n construing the free speech provision [of the state constitution], California courts have usually drawn the boundaries between noncommercial speech and commercial speech, and between protected and nonprotected commercial speech, with an eye to the analogous boundaries under the First Amendment." (*People v. Superior Court (J.C. Penney Corp., Inc.)* (2019) 34 Cal.App.5th 376, 391, 246 Cal.Rptr.3d 128 (*J.C. Penney*); *accord In re Morse*

(1995) 11 Cal.4th 184, 200, fn. 4, 44 Cal.Rptr.2d 620, 900 P.2d 1170 ["we see no reason why … misleading advertisements would be protected commercial speech under the California Constitution"].)

As noted, Ethicon contends the court "punished" it for engaging in speech protected by the free speech clauses of the state and federal constitutions. Ethicon claims certain statements the court found deceptive were supported by credible scientific evidence and subject to legitimate scientific debate; therefore, the speech was merely potentially misleading—not actually or inherently misleading. According to Ethicon, such potentially misleading speech falls within the purview of the federal and state free speech clauses.

Although Ethicon contends that certain statements in its IFUs and advertisements were merely potentially misleading, Ethicon overlooks a key aspect of the statement of decision. The court rendered express factual findings that the IFUs and marketing materials included *literal falsehoods*—findings Ethicon has not challenged on appeal for lack of substantial evidence. (*See Transgo, Inc. v. Ajac Transmission Parts Corp.* (9th Cir. 1985) 768 F.2d 1001, 1022 [applying substantial evidence review to finding that defendants' speech was misleading for First Amendment purposes]; *POM Wonderful, LLC v. F.T.C.* (D.C. Cir. 2015) 777 F.3d 478, 499–500 [same].)

For example, the court found the "IFUs contained false statements about mesh's properties," including a statement the mesh possessed a bi-directional elastic property allowing adaptation to various stresses

encountered in the body. It found the IFUs included "false statements" that mesh does not degrade. And it found the marketing materials included literal falsehoods because they referred to incomplete product information as a complete description of risks. Because the trial court rendered unchallenged factual findings that the IFUs and marketing materials contained false statements, the IFUs and marketing materials at issue were not subject to constitutional free speech protections. (*Kasky*, *supra*, 27 Cal.4th at p. 953, 119 Cal.Rptr.2d 296, 45 P.3d 243.)[16]

Ethicon's free speech argument fails for another reason. Even if we were to conclude Ethicon's statements were subject to constitutional protection, that is the beginning–not the end–of the analysis. If commercial speech is lawful and not misleading, the constitutionality of any restraint on such speech must then be assessed under the multi-step *Central Hudson* inquiry. Under that test, we must consider the purpose for the speech restriction, as well as the closeness of the fit between the means used and the goal sought to be achieved by the restriction. (*Central Hudson*, *supra*, 447 U.S. at pp. 564–566, 100 S.Ct.

---

[16] In its briefs, Ethicon *implies* that some of the court's falsity findings may be incorrect. For example, it states there is "scientific dispute" and "debate" concerning whether its mesh degrades. But we do not construe this vague and passing statement—or others like it—as a substantial evidence challenge to the court's express findings that "mesh does degrade," Ethicon "knew of this surface degradation six years before the 1998 launch of their first TVT product," and, therefore, Ethicon's IFUs were false insofar as they stated the mesh "is not 'subject to degradation or weakening by the action of tissue enzymes ….'"

2343; *see Thompson v. Western States Medical Center* (2002) 535 U.S. 357, 367, 122 S.Ct. 1497, 152 L.Ed.2d 563 [a court asks "*as a threshold matter* whether the commercial speech concerns unlawful activity or is misleading. … If the speech concerns lawful activity and is not misleading … [it] next ask[s] 'whether the asserted governmental interest is substantial.'"], italics added.)

Ethicon does not try to apply this analysis to the statements the court found deceptive. It does not discuss the government's ostensible interests in regulating its speech, whether the restriction promotes those interests, or whether the restriction is more extensive than is necessary to serve those interests. By failing to provide legal analysis on these issues, Ethicon has waived its free speech arguments. (*Vo v. City of Garden Grove* (2004) 115 Cal.App.4th 425, 447–448, 9 Cal.Rptr.3d 257 [plaintiffs waived claim that ordinance violated customers' right to privacy by failing to discuss why, "if the privacy interest both exist[ed] and [was] invaded, the governmental interest sought to be advanced [did] not make the [ordinance] constitutionally permissible"]; *accord J.C. Penney*, *supra*, 34 Cal.App.5th at pp. 398–399, 246 Cal.Rptr.3d 128 [although FAL regulated defendants' protected commercial speech, demurrer based on free speech defense was improper given that the record did not permit an evaluation of the validity of the regulation under the *Central Hudson* test].)

F

The Trial Court Did Not Err in Calculating the Civil Penalty Award

Ethicon contends the trial court abused its discretion in calculating the civil penalty award in several respects. For reasons we will explain, we discern no abuse of discretion in the calculation of the award.

1

Legal Standards Governing Civil Penalties

The UCL and FAL each contain an identical provision regarding the assessment of civil penalties. Both statutes state as follows:

> "The court shall impose a civil penalty for each violation of this chapter. 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." (§§ 17206, subd. (b), 17536, subd. (b).)

"The amount of the penalty depends in the first instance on the number of violations committed." (*People ex rel. Kennedy v. Beaumont Investment, Ltd.*

(2003) 111 Cal.App.4th 102, 127, 3 Cal.Rptr.3d 429 (*Beaumont*).) The UCL and FAL do not specify what constitutes a single violation, so courts must decide what amounts to a violation on a case-by-case basis. (*Id.* at p. 128, 3 Cal.Rptr.3d 429.)

The trial court has "broad discretion" when it determines the appropriate civil penalty in a given case. (*Nationwide*, *supra*, 9 Cal.5th at p. 326, 261 Cal.Rptr.3d 713, 462 P.3d 461; *see First Federal*, *supra*, 104 Cal.App.4th at p. 729, 128 Cal.Rptr.2d 542 [the UCL and FAL set forth "six relevant factors a court may consider in determining an appropriate penalty, and the court is authorized to impose a penalty based on evidence as to *any one or more* of the enumerated factors"].) "[A]lthough the civil penalties under the UCL and the FAL 'may have a punitive or deterrent aspect, their primary purpose is to secure obedience to statutes and regulations imposed to assure important public policy objectives. … The focus of [both] statutory scheme[s] is *preventative*.'" (*Nationwide*, at p. 326, 261 Cal.Rptr.3d 713, 462 P.3d 461; *see First Federal*, at p. 732, 128 Cal.Rptr.2d 542 ["Civil penalties, like punitive damages, are intended to punish the wrongdoer and to deter future misconduct."].)

"We review the trial court's imposition of … civil penalties under an abuse of discretion standard. [Citation.] Under this standard, '[w]e do not reweigh the evidence or substitute our notions of fairness for the trial court's. [Citations.] "To merit reversal, both an abuse of discretion by the trial court must be 'clear' and the demonstration of it on appeal 'strong[.]"'"'

(*People v. JTH Tax, Inc.* (2013) 212 Cal.App.4th 1219, 1250, 151 Cal.Rptr.3d 728 (*JTH*).) An abuse of discretion exists when a trial court rules "'in an arbitrary, capricious or patently absurd manner that result[s] in a manifest miscarriage of justice.'" (*Franceschi v. Franchise Tax Bd.* (2016) 1 Cal.App.5th 247, 256–257, 205 Cal.Rptr.3d 75.) "'[T]he trial court's discretion in setting civil penalties generally will be upheld.'" (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1088, 219 Cal.Rptr.3d 65.)

2

Calculation of Violations

The trial court counted each deceptive IFU and marketing communication as a separate violation of the UCL and FAL. In adopting this methodology, the court reasoned each IFU and marketing communication was "designed to drive future sales of the product, and thus relate[d] to [Ethicon's] opportunity for gain." The court also noted its calculation was likely an undercount of the deceptive communications Ethicon circulated during the liability period.[17]

On appeal, Ethicon argues the trial court should have calculated the violations by using a per-day violation count or, alternatively, a figure tied to the rate

[17] The court found its calculation was likely an undercount because, for certain gaps of time, Ethicon did not have internal company data necessary for the Attorney General's forensic accountant to calculate the number of deceptive IFUs and marketing communications that Ethicon disseminated. These gaps of time were omitted from the violations count.

of reoperation for women who received pelvic mesh implants. Relying on *People v. Superior Court (Olson)* (1979) 96 Cal.App.3d 181, 157 Cal.Rptr. 628 (*Olson*), Ethicon contends the court abused its discretion by adopting a per-communication methodology to calculate the total number of violations. *Olson* and its progeny do not support Ethicon's argument.

In *Olson*, a real estate agent placed an advertisement containing misstatements in Southern California newspapers on eight occasions. (*Olson*, *supra*, 96 Cal.App.3d at p. 196, 157 Cal.Rptr. 628.) The District Attorney filed an action against the agent alleging UCL and FAL violations, and seeking civil penalties. (*Id.* at pp. 184–185, 157 Cal.Rptr. 628.) The trial court found both statutes were unconstitutional (either facially or as applied to the agent), granted summary judgment for the agent, and ordered that, in the event of an appellate reversal, the agent could be liable only for one statutory violation for each day the advertisement appeared in a single edition of a newspaper. (*Id.* at pp. 186–188, 157 Cal.Rptr. 628.)

In a writ proceeding, the Court of Appeal concluded the trial court's constitutional rulings were erroneous and ordered vacatur of the summary judgment ruling. (*Olson*, *supra*, 96 Cal.App.3d at pp. 195, 199, 157 Cal.Rptr. 628.) With respect to the number of statutory violations, the court rejected the People's claim that the number of violations must be based on "the number of persons to whom the representations were made so that the number of violations resulting from a false advertisement in a newspaper may theoretically be equated with the circulation of the paper."

(*Id.* at p. 198, 157 Cal.Rptr. 628.) It reasoned the circulation of the advertisement in just one newspaper (the Los Angeles Times) could result in a civil penalty exceeding two and a half billion dollars per statute—an outcome that would violate due process. (*Ibid.*)

On the other hand, the Court of Appeal rejected the trial court's bright line rule that "dissemination of a false or deceptive advertisement through a single edition of a newspaper can constitute but one violation of each statute as a matter of law." (*Olson*, *supra*, 96 Cal.App.3d at p. 198, 157 Cal.Rptr. 628.) Instead, it determined "a reasonable interpretation of the statute in the context of a newspaper advertisement would be that a single publication constitutes a *minimum* of one violation with as many additional violations as there are persons who read the advertisement or who responded to the advertisement by purchasing the advertised product or service or by making inquiries concerning such product or service. Violations so calculated would be reasonably related to the gain or the opportunity for gain achieved by the dissemination of the untruthful or deceptive advertisement." (*Ibid.*)

Subsequent decisions interpreting *Olson* have concluded that, in appropriate circumstances, total circulation can be a reasonable method to determine the number of statutory violations. In *People v. Morse* (1993) 21 Cal.App.4th 259, 25 Cal.Rptr.2d 816 (*Morse*), the People filed a civil enforcement action against an attorney who mailed false and misleading solicitations to homeowners offering to assist them in the recording of homestead declarations. The trial

court granted summary adjudication for the People and ordered the attorney to pay civil penalties based on the number of solicitations he mailed, rather than the number of people who received them or responded to them. (*Id.* at pp. 272–273, 25 Cal.Rptr.2d 816.) The Court of Appeal approved the trial court's methodology for calculating violations, reasoning that—unlike the "mass appeal at issue with the newspaper advertising in *Olson*"—the attorney targeted his individualized mail campaign to homeowners and designed his solicitations to be noticed and read. (*Id.* at pp. 273, 274, 25 Cal.Rptr.2d 816.) The court opined that "[u]nder these circumstances, it is reasonable to assume that the Legislature contemplated a penalty for each direct mailing." (*Id.* at p. 274, 25 Cal.Rptr.2d 816.)

In *JTH*, *supra*, 212 Cal.App.4th 1219, 151 Cal.Rptr.3d 728, the People filed a UCL and FAL action against a tax preparation and loan service company based, in part, on the company's false and misleading television and newspaper advertisements. The trial court found the company liable, ordered it to pay civil penalties, and determined the number of violations based on a percentage of the gross circulation figures for the advertisements (using Nielsen ratings for the television advertisements). (*Id.* at pp. 1226, 1252, 151 Cal.Rptr.3d 728.) The Court of Appeal concluded the trial court did not abuse its discretion when calculating the number of violations. (*Id.* at pp. 1249–1255, 151 Cal.Rptr.3d 728.) It noted, among other things, that the company directly mailed its advertisements to customers and viewed its advertisements as "a particularly effective outlet for

reaching its target audience." (*Id.* at p. 1255, 151 Cal.Rptr.3d 728.) Further, the court noted that *Olson* itself suggested the People's burden of proof should not "'be so onerous as to undermine the effectiveness of the civil monetary penalty as an enforcement tool.'" (*Id.* at p. 1251, 151 Cal.Rptr.3d 728.) On these bases, the Court of Appeal rejected the company's argument that the number of violations must be tied to the number of persons who actually saw the advertisements.

In accordance with these authorities, we conclude the trial court did not abuse its discretion by calculating the number of violations based on the number of IFUs or marketing communications that contained a false or misleading statement. Like the deceptive statements at issue in *Morse* and *JTH*, and unlike those in *Olson*, Ethicon's deceptive IFUs and marketing communications were substantively targeted to well-defined groups of people. The IFUs were specifically directed to doctors who were considering whether to implant Ethicon's device or were preparing to do so—often, though not always, to urogynecologists and surgical specialists. And Ethicon's marketing communications were explicitly written to appeal to those same doctors, or to prospective patients who were suffering from SUI or POP.

Further, Ethicon's IFUs and marketing communications were sent, displayed, or made available only to those same limited audiences, not the broader general public. For example, Ethicon purposefully disseminated its marketing communications in mediums designed to reach the eyes of doctors, including by sponsoring presentations at specialized medical

conferences attended by doctors and placing advertisements in medical journals read predominately by doctors. Similarly, Ethicon steered its marketing communications directly to prospective patients who were likely to be receptive to such communications (and Ethicon's products more generally). Ethicon provided patient brochures to doctors who were already implanting or likely to implant its products—all with the aim that those brochures would be left in doctors' office waiting rooms for patients to read them or take them home. Further, Ethicon even relied on Internet users' individualized online search histories to send them online advertisements about its products.

Given the highly-targeted nature of Ethicon's communications, we conclude the trial court reasonably found each IFU and marketing communication represented a gain or opportunity to gain for Ethicon. For the same reason, we conclude the court did not exceed the bounds of its discretion when determining the number of violations.[18] (*JTH*, *supra*, 212

---

[18] One category of violations that received considerable attention in the parties' briefs and at oral argument was printed marketing communications such as product brochures. The trial court adopted the methodology of the People's forensic accountant to calculate the number of violations arising from such materials. The forensic accountant, in turn, calculated the number of violations based on an estimate of the total number of printed marketing materials that were ordered by Ethicon sales representatives and sent into the state to be distributed to health care providers and ultimately patients.
On appeal, Ethicon complains the forensic accountant's calculations were inflated because he extrapolated one salesperson's history to the entire sales staff and failed to account for brochures that were ordered but not distributed, and he never took

Cal.App.4th at pp. 1249–1255, 151 Cal.Rptr.3d 728; *Morse*, *supra*, 21 Cal.App.4th at pp. 273–274, 25 Cal.Rptr.2d 816.)

3

Amount of Penalties Per Violation

The trial court assessed a civil penalty of $1,250 per violation. It considered and rendered findings pertaining to the factors set forth in the UCL (§ 17206, subd. (b)) and FAL (§ 17536, subd. (b)) when setting $1,250 as the per-violation penalty. In particular, it found: the nature and seriousness of the misconduct was "grave" because Ethicon misrepresented the benefits and risks of pelvic mesh products that can cause debilitating, chronic pain for patients and destroy (sometimes permanently) their sexual, urinary, and defecatory functions; Ethicon circulated "hundreds of thousands" of deceptive communications; Ethicon knowingly persisted in its misconduct despite internal and external calls for change; Ethicon's misconduct spanned 17 years; and the total award

---

these factors into account in calculating the number of violations associated with the brochures.

We agree it would have been desirable for the expert to have made an effort to have calculated this differential, but on this record, we find no abuse of discretion. In discovery responses, Ethicon itself admitted it had no "way to determine how many such items were actually distributed," and it had not been able to determine the "exact number of copies of printed materials that had been sent to California." Additionally, Ethicon has never suggested a method to discount the expert's calculation in either the trial court or on appeal, and in the statement of decision there was no factual finding that Ethicon's printed materials went undistributed.

was less than one percent of defendant-parent company Johnson & Johnson's $70.4 billion net worth.

Ethicon challenges the amount imposed for each civil penalty on grounds that each IFU and marketing communication "was different–in what was said, in what context, to whom, etc.–and each had a different capacity for harm." Due to these purported differences, Ethicon claims the court abused its discretion by imposing the same civil penalty per violation. We disagree.

Although the IFUs and marketing communications at issue may have differed in their particulars, all of them (with the exception of those specified above, *ante* Part III.C.3.) shared the same defining features: each contained misstatements, half-truths, and/or omissions regarding the risks of Ethicon's pelvic mesh products, and each was likely to deceive California doctors and/or patients. As the trial court put it, there was a "common theme that [ran] throughout all of [Ethicon's] marketing …[.] [T]he company concealed from consumers the most serious and long-term risks resulting from the device." Given that all of the IFUs and marketing communications pertained to the same products, shared the same or similar deceptive traits, and were likely to deceive their target audiences, the court did not exceed its discretion by imposing the same civil penalty amount for each violation.

Ethicon also asserts the trial court abused its discretion because $1,250 was too much to impose for each violation. According to Ethicon, $1,250 was too

large because Ethicon's communications—not its pelvic mesh products—were the focus of the lawsuit, and Ethicon's communications themselves did not harm patients. Further, Ethicon claims a lower penalty was warranted because Ethicon "vetted its warnings internally and externally," and, according to Ethicon, the court found that Ethicon violated only one prong of the UCL (the fraudulent prong). Once again, we disagree with Ethicon.

Ethicon's effort to distinguish between its communications, on the one hand, and its pelvic mesh products, on the other hand, is mere semantics. The communications were made for the purpose of marketing and/or providing information about Ethicon's products, and they misrepresented the safety and risks associated with Ethicon's products. The products discussed therein were implanted into patients and, in many cases, resulted in medical, physical, and emotional turmoil that lasted years or for the rest of patients' lives. The court did not abuse its discretion in considering the subject matter of Ethicon's communications, or the dire harm flowing from those deceptive communications, when assessing the nature and seriousness of Ethicon's misconduct. (*See Fremont*, *supra*, 104 Cal.App.4th at p. 529, 128 Cal.Rptr.2d 463 [court did not abuse its discretion when imposing civil penalties because "[t]he offenses were serious in that they impacted the financial security" of the victims].)

The other considerations raised by Ethicon do not suggest an abuse of discretion either. On the contrary, the fact Ethicon internally vetted its IFUs and

marketing communications tends to support the trial court's finding that Ethicon's deceptive misstatements and omissions were knowing and intentional, not the product of mere negligence. That factor weighs in favor of a higher per-violation award, as opposed to a lower per-violation award.

Further, Ethicon did not violate the UCL in just one way, as it claims. Rather, Ethicon violated the UCL in at least two ways—first, it committed fraudulent business acts; and second, it violated the FAL. Although the same conduct gave rise to the trial court's findings of UCL liability, there were at least two independent statutory bases for the court's finding of UCL liability.

These considerations aside, the trial court carefully considered each of the nonexclusive statutory factors guiding its exercise of discretion. It weighed the seriousness, severity, duration, and persistence of Ethicon's misconduct, as well as Ethicon's culpability, the number of statutory violations committed, and the financial condition of Ethicon's parent company. Based on *all* these factors, the court assessed civil penalties of $1,250 per violation—half the amount requested by the Attorney General. In doing so, the court acted within the bounds of its broad discretion.

G

The Civil Penalties Did Not Violate Ethicon's Due Process Rights

Ethicon contends the trial court violated its due process rights by imposing a civil penalty award of

$344 million (which we have reduced to approximately $302 million). Ethicon argues its due process rights were violated because it did not have fair notice that its conduct would be punishable or fair notice of the potential severity of the civil penalty award.

Ethicon's contention that it did not have notice of the potential for punishment is based on arguments we have previously found to be without merit. For instance, Ethicon repeats its claim that the trial court interpreted the UCL and FAL in an unprecedented way—*e.g.*, by requiring Ethicon to warn consumers of all risks associated with its products regardless of consumers' existing knowledge or consideration of whether Ethicon's communications would deceive consumers. Ethicon also repeats its claim that the FDA authorized certain of the IFUs at issue, such that Ethicon did not have notice its conduct could lead to liability. However, we have already rejected these assertions. (*See ante* Parts III.B.1 and III.D.2.) Ethicon's due process argument fails for the same reasons.

Ethicon's due process argument fares no better to the extent Ethicon contends it lacked fair notice of the severity of the punishment. Ethicon claims—with no additional analysis—that it lacked notice of the potential severity of the punishment because the civil penalties imposed here were larger than any other civil penalty that has been imposed under the UCL or FAL and upheld on appeal in a reported decision.

Ethicon may well be correct that the civil penalties imposed here are the largest to date under the UCL and FAL, at least among those penalties

discussed in reported appellate decisions. Nonetheless, that fact alone does not mean that Ethicon was deprived of notice regarding the potential severity of its punishment. Certainly, none of the other appellate decisions upholding civil penalty awards under the UCL and FAL "suggest that the amounts awarded [in those cases] were somehow in the outer limit of penalties that may properly be imposed." (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1090, 219 Cal.Rptr.3d 65.) Additionally, the size of the civil penalty award here is, in no small part, due to Ethicon's dissemination of thousands of deceptive statements for years on end. (*Ibid.* [rejecting claim that civil penalties awarded under UCL and FAL were excessive merely because they were larger than penalties upheld in other cases]; *Sweeney v. San Francisco Bay Conservation and Development Commission* (2021) 62 Cal.App.5th 1, 20–21, 276 Cal.Rptr.3d 482 [rejecting claim that penalty was excessive "simply because it represented [the government entity's] 'highest penalty ever'"]; *see United States v. Dish Network L.L.C.* (7th Cir. 2020) 954 F.3d 970, 980 ["Someone whose maximum penalty reaches the mesosphere only because the number of violations reaches the stratosphere can't complain about the consequences of its own extensive misconduct."].)

Several additional factors undermine Ethicon's argument that it was deprived of notice regarding the potential severity of its punishment. The UCL and FAL expressly define the maximum amounts a violator can be punished per violation—$2,500. (§§ 17206, subd. (a); 17536, subd. (a).) The Legislature enacted these provisions decades ago, giving Ethicon clear notice of the possible per-violation punishment of each

statute. (*See* Stats. 1965, ch. 827, § 1, pp. 2419–2420 [adding section 17536 to the FAL]; Stats. 1972, ch. 1084, § 2, p. 2021 [adding predecessor to section 17206].) And, as discussed, judicial authorities have long discussed the broad discretion courts possess when it comes to defining and calculating the number of UCL and FAL violations. (*E.g.*, *Beaumont*, *supra*, 111 Cal.App.4th at pp. 127–128, 3 Cal.Rptr.3d 429.)

The Attorney General even gave Ethicon direct notice of the potential punishment it faced—long before the statutory liability terminated in 2018. During the Attorney General's investigation of Ethicon, the Attorney General and Ethicon entered into a tolling agreement effective October 17, 2012. At least as of this date, Ethicon was on direct notice that it could be held liable for its communications and practices. At that time, Ethicon could have altered its communications and practices to avoid this outcome or, at least, to minimize the amount of the potential civil penalty award. It did not do so.

For all these reasons, we conclude Ethicon had notice of the punishment it could face for circulating false or misleading communications.

H

The Civil Penalties Did Not Violate the Excessive Fines Clauses

Ethicon's final argument is that the civil penalties violate the prohibitions against excessive fines enshrined in the Eighth Amendment to the federal

constitution and article I, section 17 of the state constitution.

When we consider whether a fine is excessive, "we accept the trial court's factual findings unless clearly erroneous and determine de novo whether the fine is excessive." (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1091, 219 Cal.Rptr.3d 65; *Lent v. Cal. Coastal Com.* (2021) 62 Cal.App.5th 812, 857, 277 Cal.Rptr.3d 106 ["' "[F]actual findings made by the [trial court] in conducting the excessiveness inquiry, of course, must be accepted unless clearly erroneous."'"].) "To decide whether the fine [is] constitutionally disproportionate, we consider: '(1) the defendant's culpability; (2) the relationship between the harm and the penalty; (3) the penalties imposed in similar statutes; and (4) the defendant's ability to pay.'" (*Overstock.com*, at p. 1091, 219 Cal.Rptr.3d 65.) Consideration of these factors compels a conclusion that the award, as we have amended it on appeal, is not excessive.

With regard to the first factor, Ethicon argues it was not particularly culpable because it believed in good faith that its labeling and marketing were not misleading, and that it was complying with the law. But the trial court found to the contrary. It found Ethicon took "active, willful measures for nearly twenty years to suppress information and conceal serious risk and complication information from physicians and patients." Further, it found Ethicon knowingly and willfully abused the trust of consumers, as Ethicon's misconduct "depriv[ed] 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 depriv[ed] patients of the ability to make informed decisions about their own care." Worse still, the court found that even after Ethicon amended its IFUs, the IFUs "still misleadingly omitted, and omit to this day, a number of risks associated with [Ethicon's] pelvic mesh products …." According to the trial court, Ethicon's misconduct was "egregious." These findings—which are not clearly erroneous—suggest Ethicon's culpability was extremely high.

The second factor, which considers the relationship between the harm and the penalty, also weighs against a finding of excessiveness. Ethicon claims the award was excessive because Ethicon's products worked for many patients and product complications were typically "minor and easily addressed." However, Ethicon harmed *all* consumers by depriving their doctors of material information necessary to counsel patients and forcing patients to make potentially life-altering decisions about their health and well-being based on this same false or incomplete information. Further, an especially unlucky subset of patients experienced more severe harm. After electing to receive a surgical implantation of Ethicon's products based on false or incomplete information, these patients suffered debilitating and chronic complications that, according to the trial court, "literally cannot be undone." These findings are not clearly erroneous.

Regarding the third factor, the parties refer us to just one other supposedly similar statute—21 U.S.C. § 333, subd. (f)(1)(A), which limits the civil penalties

available for violations of federal statutes and regulations governing medical devices to $1 million. To the extent this lone statute is relevant to the analysis, it counsels in favor of a finding of excessiveness. On the other hand, we note that the civil penalty imposed here is just half of what the trial court could have levied under the UCL and FAL (§§ 17206, subd. (a); 17536, subd. (a))—and half of what the Attorney General requested.

The final factor in assessing excessiveness is the defendant's ability to pay. This factor weighs strongly against a finding of excessiveness. Per the parties' stipulation, the trial court found that defendant-parent company Johnson & Johnson had a net worth of more than $70.4 billion. The civil penalty imposed by the trial court ($343,993,750) and the amended civil penalty award ($302,037,500) each constitute less than one half of one percent of Johnson & Johnson's net worth. Given these figures, it is apparent that Ethicon has ample ability to pay the civil penalty award.

Not all of the excessiveness factors point in the same direction. But the totality of the factors—namely, Ethicon's extremely high degree of culpability, the severe harm resulting from Ethicon's misconduct, and Ethicon's undisputed ability to pay—demonstrate that the amended civil penalty award is not excessive. Based on these factors, we conclude the amended civil penalty award is constitutionally permissible.

IV

DISPOSITION

The judgment is modified as follows: the civil penalties awarded to the People are reduced from $343,993,750 to $302,037,500. The judgment is affirmed as modified. The parties are to bear their own appellate costs.

WE CONCUR:

HALLER, J.

IRION, J.

APPENDIX B

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN DIEGO, CENTRAL BRANCH

Case No. 37-2016-00017229-CU-MC-CTL

[Stamp: Electronically Filed 08/06/2020 at 11:28:00 AM Clerk of the Superior Court by Tamara Parra, Deputy Clerk]

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

v.

~~[PROPOSED]~~JUDGMENT

Dept: C-67
Judge: The Honorable Eddie C. Sturgeon

Trial Date: July 12, 2019
Action Filed: May 24, 2016

JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation, and DOES 1 through 100, inclusive,

Defendants.

This equitable action pursuant to Business and Professions Code sections 17200 *et seq.* and 17500 *et seq.* was tried before the Honorable Eddie C. Sturgeon in Department 67 of the above-entitled Court from July 15 through August 29, 2019 and September 16 through September 26, 2019. Plaintiff, the People of the State of California (the "People") appeared and were represented by Attorney General Xavier Becerra through Jinsook Ohta, Supervising Deputy Attorney General, and Deputy Attorneys General Tina Charoenpong, Monica Zi, Adelina Acuña, Devin Mauney, Gabriel Schaeffer, and Daniel Osborn. Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (collectively, "Defendants") appeared and were represented by O'Melveny & Myers LLP, Covington & Burling LLP, and Butler Snow LLP.

The Court considered the evidence, both oral and documentary, briefing from the parties, argument, and proposed statements of decision and objections thereto. The Court filed a Statement of Decision on January 30, 2020, and, after requesting and receiving additional briefing and oral argument from the parties, entered an Order denying the People's request for an injunction on June 30, 2020.

IT IS ORDERED, ADJUDGED, AND DECREED that:

1. Judgment is entered in favor of Plaintiff, the People of the State of California;

2. Defendants violated Business and Professions Code section 17200 *et seq.* and 17500 *et seq.*, as set

forth in the Statement of Decision, filed on January 30, 2020;

3. Defendants shall pay civil penalties to the People pursuant to Business and Professions Code sections 17206 and 17536 in the amount of $343,993,750.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that Defendants' Motion for New Trial, filed on February 14, 2020 and heard on April 28, 2020, is denied.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the People's Motion to Correct Clerical Errors, filed on February 28, 2020 and heard on June 12, 2020 is granted. The following errata are made to the Statement of Decision, filed on January 30, 2020:

1. Page 67, line 8: "Sept. 2015" is changed to "Feb. 2018"

2. Page 67, line 9: "Sept. 2015" is changed to "Feb. 2018"

3. Page 67, line 13: "September 2015" is changed to "February 2017"

4. Page 67, footnote 36, line 26: "2015" is changed to "2018"

5. Page 68, line 1: "September 2015" is changed to "February 2017"

6. Page 68, line 3: "Sept. 2015" is changed to "Feb. 2017"

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the People's request for injunctive relief is denied.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that should they still be the prevailing party after all appeals, the People shall recover their costs from Defendants as provided by Code of Civil Procedure section 1032 *et seq*. By stipulation dated July 20, 2020, the parties agree that $509,661.75 is the amount of costs incurred in this action as of this date and awardable to the People should they still be the prevailing party under C.C.P. § 1032 *et seq.* after all appeals.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that, pursuant to Government Code section 6103.5, any filing fee or other fee for any official service rendered by the Clerk of the Court that was not paid by the People as a result of Government Code section 6103 shall be paid by Defendants to the San Diego County Superior Court Clerk of Court in the amount of $2,755.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that, pursuant to C.C.P. § 918(b) and the consent of the People as set out in the parties' Stipulation dated July 20, 2020, enforcement of this Judgment shall be stayed until final resolution of any appeal through the California Court of Appeal without the undertaking otherwise required pursuant to C.C.P. § 917(a)(1); and that the stay of enforcement

may be extended following resolution of appeal through the California Court of Appeal either upon consent of the parties or upon satisfaction of the undertaking requirement at that later time.

IT IS SO ORDERED.

Dated: 08/06/2020

Eddie C. Sturgeon

The Honorable Eddie C. Sturgeon Judge of the Superior Court

APPENDIX C

SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN DIEGO CENTRAL

MINUTE ORDER

DATE: 06/30/2020 TIME: 02:07:00 PM DEPT: C-67

JUDICIAL OFFICER PRESIDING: Eddie C Sturgeon
CLERK: Patricia Ashworth
REPORTER/ERM: Not Reported
BAILIFF/COURT ATTENDANT:

CASE NO: **37-2016-00017229-CU-MC-CTL**
CASE INIT.DATE: 05/24/2016
CASE TITLE: **The People of the State of California vs. Johnson & Johnson [IMAGED] [E-FILE]**
CASE CATEGORY: Civil - Unlimited
CASE TYPE: Misc Complaints - Other

APPEARANCES

The Court, having taken the above-entitled matter under submission on 06/12/2020 and having fully considered the arguments of all parties, both written and oral, as well as the evidence presented, now rules as follows:

FINAL RULING

Plaintiff The People of the State of California's ("People") motion for injunctive relief is denied.

An injunction is not necessary at this time to correct defendants Johnson & Johnson, Ethicon, Inc. and Ethicon US, LLC's violations of Business and Professions Code section 17200 and 17500. First, many of defendants' violations were corrected in 2015.

Second, defendants are in the process of revising its labeling. Plaintiff references the 42-State Injunction in support that this court should enter injunctive relief. Plaintiff acknowledged in the June 12, 2020 hearing defendants plan to obtain FDA clearance on those stipulated, court ordered labeling corrections. (6/22/20 supplemental briefing 2-8; Tr. 21:14-20.) The order required Ethicon[1] to disclose many of the same items at issue here to the FDA. For example, Ethicon would include disclosures of the "relevant hazards, contraindications, side effects and precautions" to ensure the IFUs for its Surgical Mesh devices, "Do not represent that the Surgical Mesh will remain soft, supple, or pliable after implantation." This court exercises its discretion to deny injunctive relief based upon this prior *stipulated* order requiring defendants to comply with the 42-State injunction order. (P's Ex. C.)

Third, the evidence supports there is sufficient current information in the public domain to inform

[1] Reference in the order is only to "Ethicon".

physicians of the current risks of defendants' products. Thus, there is little likelihood that consumers or physicians will be misled in the future.

More importantly, issuance of an injunction will lead to severe hardship to defendants. Although disputed by plaintiff, there is a strong risk the mesh products may not be sold in California because defendants may withdraw the products in an attempt to comply with plaintiffs' proposed court order. The court cannot ignore the letter from over 70 physicians lauding defendants' mesh products and stating their grounds for supporting the right to access them.

Defendants also face a strong risk of contempt proceedings notwithstanding the FDA had previously approved the labeling of the products. Defendants are correct they will be placed in the untenable position of attempting to comply with California law while violating federal law by updating the labeling before the FDA has a chance to clear it. Defendants are at risk of fines from both the FDA and The People. The court is not convinced defendants' non-IFU marketing is not labeling, as plaintiff urges.

Although the court may have the jurisdiction to issue an injunction, the court declines to order defendants to initiate a review of whatever labeling changes that defendants reasonably believe require it. (P's 3rd supp. Briefing, 5:7-8.) The FDA has the ability to review the evidence from the trial and initiate a further examination of the labeling to ensure there is no future misleading information. Additionally, nothing

prevents plaintiff from contacting the FDA regarding this court's judgment.

Accordingly, plaintiff's motion for injunction relief is denied.

Plaintiff is ordered to prepare a judgment consistent with the court's ruling denying injunctive relief and correcting the dates as set forth in the order granting plaintiff's motion to correct clerical errors.

Eddie C. Sturgeon

Judge Eddie C Sturgeon

APPENDIX D

SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF SAN DIEGO, CENTRAL BRANCH

[Stamp: Filed Clerk of the Superior Court
Jan. 30 2020]

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 Plaintiffs 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],

[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 501(k) clearance.

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-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.)

(JX10052.6.) J&J did not stop selling Prolift at any time. (8/8/19 Tr. 151:16-153:28 [Dr. Hinoul].)

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;

---

[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.

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 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 Ca1.3d 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	• 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	• 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].)

8/7/19 Tr. 38:12-39:14, 40:28-41:3, 41:21-42:1-5, 44:25-45:12 [Dr. Hinoul].)	and dyspareunia (8/7/19 Tr. 68:1-10, 70:2-11, 79:28-80:4, 81:15-82:8 [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	10

Severe contraction → *Dyspareunia → sexual function↓* *Tension response ↓* *= ↓ Sexual pain?* *No folding of mesh* *No rigidity*	
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].)

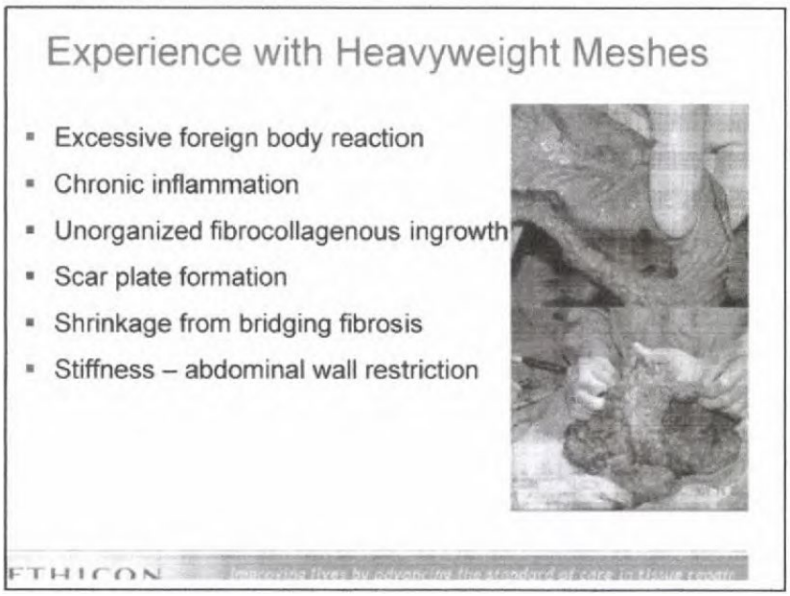
The following internal company documents further demonstrate J&J's knowledge of the ways in which the dangerous properties of mesh can cause complications:

- 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 <u>*not*</u> 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

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.)

---

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. 12:28-27 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, 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"].

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 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. 155:204, 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	Company Knowledge

[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 [TT 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

		Family IFUs[5]	**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.) • ***Life-long/recurrent*** risk of vaginal exposures • ***Life-long/recurrent*** risk of erosion into other organs

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 1FU in use 7/1/15-9/15/15].

[5] JX10186 [TVT IFU in use 9/18/15-present]; JX10184 [TVT-0 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.

			(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, 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.) • Neuromuscular problems, including acute

[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).

			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"	• 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.)

		• **NO** mention of mesh contraction	• 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	• "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]

	TVT procedure]/[a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System/GYNECARE TVT ABBREVO device]. To minimize this risk, make sure to place the tape tension free in the mid-urethral position"[8]		at 323:1-324:15)
Removal	• **NO** mention of removal • **NO** mention of serious complication that would require a significant removal	• "One or more revision surgeries may be necessary to treat these	• Need for mesh removal for serious complications, including chronic pain or

[8] Not included in JX10176 [TVT IFU in use 9/8/00-11/26/03].

	• **NO** mention of irreversibility of complications	adverse reactions" • "In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required"	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].)

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,	**2015 Gynemesh PS IFU[10]**	**Company Knowledge From the Time of Launch**

[10] JX10185 [Gynemesh PS IFU in use 4/3/1 5-present].

	Prosima IFUs[9]		
Erosion/ Exposure	• Erosion, extrusion	• "mesh extrusion, exposure, or erosion into the vagina or other structures or organs"	• ***Life-long/recurrent*** risk of vaginal exposure • ***Life-long/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.)

[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 12/8108-4/14/14]; 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].

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.)
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"	• "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	• 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,

	– **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"	the mesh, vaginal scarring, tightening and/or shortening may occur"	141:7 142:3, 142:14 143:9.)
Removal	• **NO** mention of removal • **NO** mention of	– "one or more revision surgeries may be necessary to treat	– Need for mesh removal for serious complications,

	serious complications that would require a significant removal	these complications" – "In cases in which GYNECARE GYNEMESH needs to be removed in part or whole, significant dissection may be required"	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.)
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

[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

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 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

---

12/12/08-1/13/11]; and JX10174 [Prolift +M in use 2/4/11-discontinuance].

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	• "***transitory*** foreign body	• **NO** mention of chronic foreign	• Histologically well tolerated, inert	• Chronic foreign body reaction • Inflammation

[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").

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]**	
and chronic inflammation	response"[16] • "***minimal*** inflammatory reaction" (Emphasis added)	body response • "***minimal*** inflammatory reaction"/ "minimum to mild inflammatory reaction" (Emphasis added)	• Healthy tissue incorporation	• Not inert (8/7/19 Tr. 82:14-24, 85:5-17)

[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]**	
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.)

[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.

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]**	
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 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

[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 WU in use 12/8/08-4/14/14]; JX10172 [Gynemesh

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

---

PS 1FU 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 1FU 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]; 24 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].

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:

(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.*);

---

[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 28 for further explanation.)

(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

[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.)

[Dr. Hinoul testimony re: chronic foreign body reaction and mesh is not inert]);[22]

(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

---

[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 scenarios" 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.

[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

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].)

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.)

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 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,

---

[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 [UCIA 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: "It is immaterial … whether a consumer has been actually misled by an advertiser's representations." (*Day v. AT&T Corp*., 63 Cal.AppAth 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

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]

---

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

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. (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

---

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.)

[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.

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 [same]; JX11621 [same]; JX11347

---

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

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.

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

[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.)

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. *Dentsply* 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]

---

[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

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

---

complications was in hernia literature. (7/18/19 Tr. 73:7-17 [Dr. Rosenzweig]; 8/1/19 Tr. 18:20-192 [Dr. Iakovlev]; PX4761 11/15/12 Tr. 58:2-14 [Dr. Arnaud].)

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. 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]

---

[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

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

(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.

- **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, Plaintiffs 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 healthcare providers

[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.)

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]

[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

    - **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:
    - **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].)

---

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.

- 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

---

[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.

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

---

[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.

- **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

---

[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 PX0004-01I & -013) + 1,563 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,938 violations.

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 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

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

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 presentations, the number of attendees listed (8/6/2019 Tr. 80:15-24) provides a reasonable lower-bound of the number of

[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.)

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,

[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.

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:

Sales Representative Detailing Violations		
Year	**UCL Violations**	**FAL Violations**
Post-Oct. 17, 2008	312[54]	-

[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.

[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.

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.)

[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.

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):

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)

[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.

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]:

[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].)

Total Field Marketing UCL & FAL Violations: 2009-2011		
Violation	**FAL**	**UCL**
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-

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

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 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

[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.

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 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*

[63] Additionally, a Court may appropriately increase the penalty amount where the restitution provided for by the UCL and FAL

Rent-A-Car Systems, supra, 211 Cal.App.3d at 132 [penalties are cumulative].)

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

---

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].)

> 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]

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

---

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

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

[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.

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 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]

---

[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

Dated: January 30, 2020 *Eddie C. Sturgeon*
EDDIE C. STURGEON

Judge of the Superior Court

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

---

[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].)

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

[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.)

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 3/4)]	
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 Sill and POP mesh.

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;

[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

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

---

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

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 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	3	12	-	185

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.

Marketing				
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]

[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

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 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.)

---

patient brochures (83%), followed by doctor sales aids (9%), while only a relatively small portion were in-office marketing materials (5%) and mailers (3%).

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

[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)

	579	-	-	2717	16,300	-	6,992	6,992	9,298	9,298
Total	**52,176 UCL and FAL Violations**									

III. <u>Online Advertising and Website Visits</u>

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 products. (See, e.g., PX4668; PX4657 at 25-30, 3742, 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 Count: 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

[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.)

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 lime period out of his calculations. (8/6 Tr. 132:22-28.)

IV. <u>Sales Representative Detailing</u>

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

---

[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"].)

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]								
No. Mesh-Related Visits	**22/Week**		**5/Week** [Alternate Count]		**10/Week** [Alternate Count]		**15/Week** [Alternate Count]	
Violation Type	UCL	PAL	UCL	PAL	UCL	PAL	UCL	PAL
Year								
Post-Oct. 17, 2008[13]	1,374	-	312	-	625	-	937	-

[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.)

Post-Oct. 17, 2009 [14]	-	1,595	-	362	-	725	-	1,087
2009	9,568	-	2,175	-	4,349	-	6,524	-
2010	11,412	11,412	2,594	2,594	5,187	5,187	7,781	7,781
2011	8,104	8,104	1,842	1,842	3,684	3,684	5,526	5,526
2012	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

[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.)

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].)

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. 159:911, 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]

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

Sales Rep % Time Spent on Mesh	**100%**		**66% [2/3 Bench-mark]**		**15%**[16] [Alternate Count]	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL
Year						
Post-Oct. 17, 2008[17]	571	-	377	-	86	-
Post-Oct. 17, 2009[18]	-	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

[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.)

[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.)

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 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 Sul 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:

---

[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.)

Total Field Marketing UCL & FAL Violations: 2009-2011[20]		
Year	**Total**	
Violation Type	**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**

[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. <u>Patient/PCP-directed marketing:</u>

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 Stead 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. <u>Doctor-directed marketing and sales rep training/materials</u>:

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

				proce-dure" at page JX11343.22
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 GYNECA

				RE'IVT Retropubic Tension-Free Support 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.whatshappening-downthere.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.whatshappening-downthere.com/pdf/TVT_EssentialProductlnformation.pdf" at page JX11618.23
JX10420	GYNECARE TVT Tensian-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. Exempts 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	ETH.MESH.00163582	5/30/2007	1. Includes a misleading/incomplete risks discussion at page JX10206.14

	including TVT SECUR)			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	ETH.MESH.00163644	5/30/2007	1. Includes a misleading/incomplete risks

	Incontinence Patient Brochure (including TVT SECUR)			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 at 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 (TVT016 R1) - 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 (TVT016 R3)	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
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. Exempts misleadingly incomplete adverse events information from the IFU at page JX11599.15
JX10597	GYNECARE TVT Tension-free Support for Incontinence Patient Brochure	ETH.MESH.08003181	3/3/2004	1 Includes a misleading / incomplete risks discussion at page

	(TVT016 R3)			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.0869238	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 JX 10227.7 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 its 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	ETH.MESH.13753847	8/24/2011	1. Includes a misleading / incomplete risks discussion at page

	English Patient Brochure			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 (TVT016 R1) - 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
PX2543	www.pelvichealthsolutions.com – 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	WA-AG-JJETH-00003082	1/3/2013	1. Includes a misleading/incomplete risks

	(01/03/2013) (WA-AG-JJETH-00003082-83)			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. 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,

				precaution; 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	Pelvi-chealthsolutions.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 In formation" 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 Exempts 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 PX4802.62. States, "Please read Risk Information for important information about intended uses as well as relevant risks, warnings, precautions, adverse events and

				contrain-dications for the Ethicon products featured on this page" at pages PX4802.53-66
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	ETH.MESH.03458515	5/21/2008	1. Includes a misleading/incomplete

	Summary Sheet			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 FAOs	ETH.MESH.02619360	5/24/2006	1. Includes a misleading/incomplete risks discussion at page JX10778.6
JX10782	Prolapse & GYNECARE PROLIFT* Pelvic Floor	ETH.MESH.00144997	6/7/2006	1. Includes a misleading/incomplete risks discussion at

	Repair System FAQs			pages JX10782.3-JX10782.4 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	ETH.MESH.00147654	1/17/2007	1. Includes a misleading/incomplete

	Repair System Print Ad			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	GYNECAPP 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 Coop Ads	ETH.MESH.00145218	2/14/2007	1. Includes a misleading/incomplete risks discussion at pages JX10831.1 and JX10831.2
JX10856	GYNECARE PROLIFT	ETH.MESH.02619294	7/11/2007	1. Excerpts

	Patient Mailer			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	SUl 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	ETH.MESH.02236762	6/28/2012	1. Excerpts misleadingly

	Screening Aid - 2010			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 intonation" 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
JX1206	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
JX1207	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
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 an 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 M Obturator-Mesh Placement for Patient	ETH.MESH.09744870	5/3/2013	1. Excerpts misleadingly incomplete adverse

	Consult TVTO-345-12			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.13683360	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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.00166789	8/23/2007	1. Advertising sells benefits while omitting known risks 2. States, "For more

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Prof Ed Pilot Program			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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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.

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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"

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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/

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				technique and important clinical information" at pages JX10941.1-JX10941.20
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,

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.00575093	8/20/2010	1. Advertising sells benefits while omitting

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Education Slides			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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				3. Misleadingly states, "large pore size optimizes tissue in-growth" without disclosing known risk of contracture, at page JX11169.18 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of contracture/shrin

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				kage, 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.

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				56 3. Misleadingly states, "Large pore size optimizes tissue ingrowth" without disclosing known risk of contracture, at page JXI 1184.20 4. Misleadingly states, "More clastic" and "Low Stiffness," without disclosing known risk of contracture/shrin

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				kage, 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.

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				42 3. Misleadingly states, "Large pore size optimizes tissue in-growth" without disclosing known risk of contracture, at page JX11197. 15 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known risk of

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				contracture/shrinkage, which can result in stiffness and hardening, at page JX11197.15
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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				page JX11221.48 3. Misleadingly states, "Large pore size optimizes tissue in-growth" without disclosing known risk of contracture, at page JX11221.25 4. Misleadingly states, "More elastic" and "Low Stiffness," without disclosing known

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.06584713	6/14/2011	1. Advertising sells

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Deck 2011			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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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	ETH.MESH.13704630	6/25/2013	1. Advertising sells benefits while omitting known risks

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Female Stress Urinary Incontinence (SUI) - Retropubic			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,

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				adverse reactions, see full prescribing information" at page PX4809.73. 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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED PRESENTATIONS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				studies to paint misleadingly positive picture at pages PX4810.8 and PX4810.19-0810.20

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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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,

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				which can result in stiffness and hardening, at page JX10538.3 6. Uses Ulmsten/Niisson 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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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,"

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				and "Acts as a scaffold for tissue-in-growth 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,

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				known risk of contracture/shrinkage, which can result in stiffness and hardening, at page JX10741.6
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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 JX10791.6 and JX10791.7

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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
JX10806	New GYNECARE PROLIFT * Pelvic Floor	ETH.MESH.00161467	12/6/2006	1. Advertising sells benefits while omitting known

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Systems Sales Aid			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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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 contraindication, warnings, precautions, and adverse reactions, see Instructions for Use" at pages JX10978.

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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"

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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**	GYNECARETVT-O Slim Jim	ETH.MESH,02232349	9/16/2010	1. Advertising sells benefits while

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				serious leg pain
7X11227***	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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				Instructions for Use" at page JX11227.4
JX1228**	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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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 J3X11241.5 3. States, "For complete indications, contraindications, warnings,

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				precautions, and adverse reactions, please reference full Instructions for Use" at page JX11241.5
JX11396**	TVT Exact Saks 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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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.

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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.

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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
JX11553*	Prosima Launch Sales Aid	ETH.MESH.02233634	12/23/2009	1. Advertising sells benefits while omitting

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				misleadingly incomplete adverse events information from the IFU at page JX11622.6 3. Misleadingly states, "Resists wound contraction (shrinkage)," "Softer, more supple tissue," and "Bidirectional properties,"

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				information including warnings precautions and adverse reactions" at page PX0104.13. Uses Ulmsten/ Nilsson studies to paint misleadingly positive picture at page PX0104.1
PX0127	Gynecare TVT - 5 years of Proven Performance - Lasting freedom for your	ETH.MESH.00339437	Copyright: 2012	1. Advertising sells benefits while omitting known risks 2. Excerpts

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	SUI patients			misleadingly incomplete adverse events information from the IFU at page PX0127.63. Misleadingly states, "porous structure of mesh allows for rapid tissue ingrowth," without disclosing known risk or contracture, at page PX0127.3

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED SALES AIDS				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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 (85/13/2010)	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, precaution and adverse reactions, click Prescribing Information" at page PX2444 3. Uses Ulmaten/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 mis-leadingly 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	ethi-con360.com (ETH.ME	ETH.MESH.19809660	3/12/2009	1. Advertising sells benefits

	SH.19809660)			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

				incom- plete adverse events in- formation from the IFU at pages PX4665.8 and PX4665.7 9-80 3. Uses Ulmsten/ Nilsson studies to paint mis- leadingly positive picture at pane 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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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.

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.03458285	4/9/2008	1. Advertising sells benefits while omitting

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Incontinence Ad for AUA			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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.00143568	2/1/2006	1. Advertising sells benefits while omitting

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Panel and Journal Ad			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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				fosters proper tissue incorporation," without disclosing known risk of contracture, at page JX10803.1 5. Misleadingly slates, "Lightweight, soft, and supple," without disclosing known risk of contracture/shrinkage, which can

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				result in stiffness and hardening, at page JX10803.1
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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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,"

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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"

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				product information, including warnings, precautions, and adverse events, sec reverse at page JX10928.1
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,

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				JX11150.25
JX11158*	GYNECARE TVT ABBREVO Sell Sheet	ETH.MESH.02238119	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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				JX11224.2
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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.13739531	12/5/2012	1. Advertising sells

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	Incontinence			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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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"

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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,"

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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	ETH.MESH.03459106	8/20/2008	1. Advertising sells benefits

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
	and 11.5 Year Data AUGS Insertion Card			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

DOCTOR-DIRECTED MATERIALS - OTHER ADVERTISING				
Exhibit	**Document Name**	**Bates number**	**Date**	**Violations**
				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

APPENDIX E

California Supreme Court

S274680

IN THE SUPREME COURT OF CALIFORNIA

En Banc

[Stamp: Supreme Court Filed July 13, 2022 Jorge Navarrete Clerk]

Court of Appeal, Fourth Appellate District, Division One - No. D077945

THE PEOPLE, Plaintiff and Respondent,

v.

JOHNSON & JOHNSON et al., Defendants and Appellants.

The petition for review is denied.

/s/ Cantil-Sakauye
Chief Justice

APPENDIX F

Cal. Bus. & Prof. Code § 17200

§ 17200. Unfair competition; prohibited activities

As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code.

APPENDIX G

Cal. Bus. & Prof. Code§ 17206

§ 17206. Civil Penalty for Violation of Chapter[1]

(a) Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General, by any district attorney, by any county counsel authorized by agreement with the district attorney in actions involving violation of a county ordinance, by any city attorney of a city having a population in excess of 750,000, or by a county counsel of any county within which a city has a population in excess of 750,000, by any city attorney of any city and county, or, with the consent of the district attorney, by a city prosecutor in any city having a full-time city prosecutor, in any court of competent jurisdiction.

(b) The court shall impose a civil penalty for each violation of this chapter. 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

---

[1] Section caption supplied by Stats.2021, c. 140 (S.B.461).

misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth.

(c)(1) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half to the General Fund.

(2) If the action is brought by a district attorney or county counsel, the penalty collected shall be paid to the treasurer of the county in which the judgment was entered.

(3)(A) Except as provided in subparagraph (B) and subdivision (e), if the action is brought by a city attorney or city prosecutor, one-half of the penalty collected shall be paid to the treasurer of the city in which the judgment was entered, and one-half to the treasurer of the county in which the judgment was entered.

(B) If the action is brought by the City Attorney of San Diego, the penalty collected shall be paid to the treasurer of the City of San Diego.

(4) The aforementioned funds shall be for the exclusive use by the Attorney General, the district attorney, the county counsel, and the city attorney for the enforcement of consumer protection laws.

(d) The Unfair Competition Law Fund is hereby created as a special account within the General Fund in the State Treasury. The portion of penalties that is

payable to the General Fund or to the Treasurer recovered by the Attorney General from an action or settlement of a claim made by the Attorney General pursuant to this chapter or Chapter 1 (commencing with Section 17500) of Part 3 shall be deposited into this fund. Moneys in this fund, upon appropriation by the Legislature, shall be used by the Attorney General to support investigations and prosecutions of California's consumer protection laws, including implementation of judgments obtained from such prosecutions or investigations and other activities which are in furtherance of this chapter or Chapter 1 (commencing with Section 17500) of Part 3. Notwithstanding Section 13340 of the Government Code, any civil penalties deposited in the fund pursuant to the National Mortgage Settlement, as provided in Section 12531 of the Government Code, are continuously appropriated to the Department of Justice for the purpose of offsetting General Fund costs incurred by the Department of Justice.

(e) If the action is brought at the request of a board within the Department of Consumer Affairs or a local consumer affairs agency, the court shall determine the reasonable expenses incurred by the board or local agency in the investigation and prosecution of the action.

Before any penalty collected is paid out pursuant to subdivision (c), the amount of any reasonable expenses incurred by the board shall be paid to the Treasurer for deposit in the special fund of the board described in Section 205. If the board has no such special fund, the moneys shall be paid to the Treasurer.

The amount of any reasonable expenses incurred by a local consumer affairs agency shall be paid to the general fund of the municipality or county that funds the local agency.

(f) If the action is brought by a city attorney of a city and county, the entire amount of the penalty collected shall be paid to the treasurer of the city and county in which the judgment was entered for the exclusive use by the city attorney for the enforcement of consumer protection laws. However, if the action is brought by a city attorney of a city and county for the purposes of civil enforcement pursuant to Section 17980 of the Health and Safety Code or Article 3 (commencing with Section 11570) of Chapter 10 of Division 10 of the Health and Safety Code, either the penalty collected shall be paid entirely to the treasurer of the city and county in which the judgment was entered or, upon the request of the city attorney, the court may order that up to one-half of the penalty, under court supervision and approval, be paid for the purpose of restoring, maintaining, or enhancing the premises that were the subject of the action, and that the balance of the penalty be paid to the treasurer of the city and county.

APPENDIX H

Cal. Bus. Prof. Code § 17500

§ 17500. False or misleading statements; penalty

It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, 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, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor

punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both that imprisonment and fine.

APPENDIX I

Cal. Bus. & Prof.Code § 17536

§ 17536. Penalty for Violations of Chapter; Proceedings; Disposition of Proceeds[1]

(a) Any person who violates any provision of this chapter shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction.

(b) The court shall impose a civil penalty for each violation of this chapter. 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.

(c) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to

---

[1] Section caption supplied by Prop. 64.

the treasurer of the county in which the judgment was entered, and one-half to the State Treasurer.

If brought by a district attorney or county counsel, the entire amount of penalty collected shall be paid to the treasurer of the county in which the judgment was entered. If brought by a city attorney or city prosecutor, one-half of the penalty shall be paid to the treasurer of the county and one-half to the city. The aforementioned funds shall be for the exclusive use by the Attorney General, district attorney, county counsel, and city attorney for the enforcement of consumer protection laws.

(d) If the action is brought at the request of a board within the Department of Consumer Affairs or a local consumer affairs agency, the court shall determine the reasonable expenses incurred by the board or local agency in the investigation and prosecution of the action.

Before any penalty collected is paid out pursuant to subdivision (c), the amount of such reasonable expenses incurred by the board shall be paid to the State Treasurer for deposit in the special fund of the board described in Section 205. If the board has no such special fund the moneys shall be paid to the State Treasurer. The amount of such reasonable expenses incurred by a local consumer affairs agency shall be paid to the general fund of the municipality which funds the local agency.

(e) As applied to the penalties for acts in violation of Section 17530, the remedies provided by this section and Section 17534 are mutually exclusive.