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COURT OF APPEAL, FOURTH APPELLATE DISTRICT

DIVISION ONE

STATE OF CALIFORNIA

THE PEOPLE, Plaintiff and Respondent, v. JOHNSON & JOHNSON et al., Defendants and Appellants.	D077945 (Super. Ct. No. 37-2016-00017229-CU-MC-CTL)

APPEAL from a judgment of the Superior Court of San Diego County, Eddie C. Sturgeon, Judge. Affirmed as modified.

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

Horvitz & Levy, David M. Axelrad, 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 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, 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 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.

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.

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

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 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 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.

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[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.

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.

At the outset of the statement of decision, the court found there were serious, long-term risks and complications associated with Ethicon's pelvic

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[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.

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

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[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.) To the extent Ethicon suggests the court erred by admitting these materials, Ethicon has waived its argument. (*Id.* at pp. 419–420.)

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, 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. Then, after the FDA issued its update finding

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[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."

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 "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

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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.

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 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.

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[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.

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 competition in commercial markets for goods and services.' " (*Abbott Laboratories v. Superior Court* (2020) 9 Cal.5th 642, 651 (*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.) "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

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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.

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 (*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 (*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.)

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, 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 (*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 (*Nationwide*), quoting § 17500.) The FAL is " 'designed to protect consumers from false or deceptive advertising.' " (*Id.* at p. 305; see *Kwikset Corp. v. Superior Court* (2011) 51 Cal.4th 310, 331 ["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.) "[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 [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 (*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; see also *Chapman v. Skype Inc.* (2013) 220 Cal.App.4th 217, 226 [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.) 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 (*Vioxx*), quoting *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 509–510 (*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 (*Overstock.com*); *Brockey v. Moore* (2003) 107

Cal.App.4th 86, 100.) 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 (*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 [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, 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.) 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 (*J.H.*); see *Committee for Responsible Planning v. City of Indian Wells* (1989) 209 Cal.App.3d 1005, 1011 [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

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

rational explanations for why the trial court could have found 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. (See *Cahill v. San Diego Gas & Electric Co.* (2011) 194 Cal.App.4th 939, 956 [" ' "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 [failure to develop legal argument waives appellate challenge].)

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.) 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.)

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; see *Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249, 255 (*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. 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; see *Collins, supra*, 202 Cal.App.4th at p. 255 [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.) 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; see *Prata v. Superior Court* (2001) 91 Cal.App.4th 1128, 1137 ["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 assert a claim. (See, e.g., *Chapman, supra*, 220 Cal.App.4th at pp. 228–230.) A class representative in a private action must prove he or she actually relied on the deceptive advertising to have standing under the UCL.[10] (*Tobacco II, supra*, 46 Cal.4th at pp. 326–328.) Within this context, " 'a presumption, or at 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.)

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 ["[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

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[10] 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.)

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 [" '[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 [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; *Keep Our Mountains Quiet, supra*, 236 Cal.App.4th at p. 741.) 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; *People ex rel. Bill Lockyer v. Fremont Life Ins. Co.* (2002) 104 Cal.App.4th 508, 520 (*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.) " '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.)

"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.) "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.)

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.) 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.) 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.) 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.)

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.) 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 ["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 (*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.[11] 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."

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

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11 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.

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.[12] In the latter category, we include sales representative detailing; Ethicon-sponsored meals between sales representatives and doctors; and one field marketing activity—health fairs.

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.[13]

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

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12 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.

13 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.

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.

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 [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.[14]

4

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

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[14] 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.

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, quoting *Cobbs v. Grant* (1972) 8 Cal.3d 229, 244–245.) 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.) 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 ["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 [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; *Klein v. Chevron U.S.A., Inc.* (2012) 202 Cal.App.4th 1342, 1379 ["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; 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; see *De La Torre, supra*, 5 Cal.5th at p. 987 [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 (*Kasky*); *McIntyre v. Ohio Elections Comm'n* (1995) 514 U.S. 334, 336, fn. 1.)

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 (*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 (*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.)

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.) 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, 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.) 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 (*J.C. Penney*); accord *In re Morse* (1995) 11 Cal.4th 184, 200, fn. 4 ["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.)[15]

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; see *Thompson v. Western States Medical Center* (2002) 535 U.S. 357, 367 [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.)

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15 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 ….' "

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 [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 [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 (*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.)

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; see *First Federal, supra*, 104 Cal.App.4th at p. 729 [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; see *First Federal*, at p. 732 ["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 (*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.' " (*Francheschi v. Franchise Tax Bd.* (2016) 1 Cal.App.5th 247, 256–257.) " '[T]he trial court's discretion in setting civil penalties generally will be upheld.' " (*Overstock.com, supra*, 12 Cal.App.5th at p. 1088.)

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.[16]

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 of reoperation for women who received pelvic mesh implants. Relying on *People v. Superior Court (Olson)* (1979) 96 Cal.App.3d 181 (*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.) The District Attorney filed an action against

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16 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.

the agent alleging UCL and FAL violations, and seeking civil penalties. (*Id.* at pp. 184–185.) 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.)

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.) 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.) 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.) 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 (*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.) 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.) 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.)

In *JTH, supra*, 212 Cal.App.4th 1219, 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.) The Court of Appeal concluded the trial court did not abuse its discretion when calculating the number of violations. (*Id.* at pp. 1249–1255.) 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.) 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.) 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.[17] (*JTH, supra*, 212 Cal.App.4th at pp. 1249–1255; *Morse, supra*, 21 Cal.App.4th at pp. 273–274.)

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17 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 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.

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 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 [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.) 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 [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.)

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; *Lent v. Cal. Coastal Com.* (2021) 62 Cal.App.5th 812, 857 [" ' "[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.) 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.

McCONNELL, P. J.

WE CONCUR:

HALLER, J.

IRION, J.