No. 24-2766

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LUDMILA GULKAROV, et al.,
Plaintiffs-Appellants,

v.

PLUM, PBC,
Defendant-Appellee.

On Appeal from the United States District Court
Northern District of California
The Honorable Yvonne Gonzalez Rogers
Case No. 4:21-cv-913-YGR

BRIEF OF AMICI CURIAE THE CONSUMER BRANDS ASSOCIATION, THE COUNCIL FOR RESPONSIBLE NUTRITION, AND FMI – THE FOOD INDUSTRY ASSOCIATION IN SUPPORT OF DEFENDANT-APPELLEE PLUM, PBC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, amici curiae Consumer Brands Association, Council for Responsible Nutrition, and FMI – The Food Industry Association state that they are not publicly held corporations, that they have no parent corporations, and that no publicly held company owns 10% or more of their stock.

Dated: October 25, 2024

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STATEMENT REGARDING CONSENT

All parties have consented to the filing of this amicus brief. *See* Fed. R. App. P. 29(a)(2).[1]

IDENTITY AND INTEREST OF AMICI CURIAE

The Consumer Brands Association ("CBA") represents the world's leading consumer packaged goods companies, as well as local and neighborhood businesses. The consumer packaged goods industry is the largest U.S. manufacturing employment sector, delivering products vital to consumers' quality of life. It contributes $2 trillion to U.S. gross domestic product and supports more than 20 million American jobs.

The Council for Responsible Nutrition ("CRN") is the leading trade association for the dietary supplement industry. CRN represents more than 180 companies worldwide selling products such as multivitamins, single ingredient vitamins and minerals (such as vitamin C and calcium), prenatal vitamins and folic acid supplements, omega-3, and probiotics, among many others. CRN works with its members to ensure compliance

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), amici state that no party's counsel authored this brief in whole or in part. Amici further state that no party, counsel for any party, or any person other than amici (including their members and counsel) contributed money that was intended to fund the preparation or submission of this brief.

with federal and state laws governing marketing, manufacturing, and safety. CRN's work promotes and protects responsible industry, while also ensuring that consumers receive high quality nutritional products.

FMI – The Food Industry Association ("FMI") proudly advocates on behalf of a wide range of members across the value chain—from retailers who sell to consumers, to producers who supply the food, as well as the wide variety of companies providing critical services—to amplify the collective work of the food industry. Its collective membership represents a $1 trillion industry with nearly 6 million employees and includes approximately 1,000 food retail and wholesale companies encompassing 33,000 retail store locations in all 50 states. These members serve more than 100 million American households with the foods and other items they need every single day. FMI's retailer membership also includes nearly 12,000 supermarket pharmacy locations that provide critical health care products and services for communities across the nation.

Amici submit this brief to address Plaintiffs' effort to have the California Supreme Court revisit the standard this Court articulated in *Hodsdon v. Mars, Inc.*, 891 F.3d 857 (9th Cir. 2018), which each amicus's respective members rely on to label their products.

INTRODUCTION AND SUMMARY OF ARGUMENT

There is no dispute that the District Court applied the governing legal standard that this Court articulated in *Hodsdon v. Mars, Inc.*, 891 F.3d 857 (9th Cir. 2018), when it granted Plum's motion for summary judgment.[2] Because *Hodsdon* dooms their claims, Plaintiffs want this Court to ask the California Supreme Court to clarify the "legal standard [that] applies to a claim of deception by omission under the Consumer [sic] Legal Remedies Act and the Unfair Competition Law," which Plaintiffs assert is "currently in flux." Mot. for Certification at 4. This is not the case. The California Supreme Court has repeatedly refused to review this precise question because California appellate courts agree that an omission-based claim is not viable absent a duty to disclose.

In *Hodsdon*, this Court exhaustively surveyed and synthesized the canon of California case law involving UCL and CLRA claims arising from alleged omissions. It confirmed that a plaintiff cannot prevail on an

[2] This brief refers to Plaintiffs-Appellants as "Plaintiffs," refers to Defendant-Appellee Plum, PBC as "Plum," and refers to the Attorney General of California as the "Attorney General" or the "AG." It refers to the Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*, as the "UCL," and it refers to the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, as the "CLRA."

omission-based claim unless the omission is "contrary to a representation actually made by the defendant" or is "an omission a of fact that the defendant was obliged to disclose." 891 F.3d at 865.[3] *Hodsdon* clarified that a duty to disclose arises only if the omitted information relates to an "unreasonable safety hazard" or concerns a feature "central to the product's function." *Id.* at 861, 863–64. If (but only if) the plaintiff establishes a duty to disclose under one of these two criteria, *Hodsdon* directs the court to consider whether the plaintiff has *also* satisfied "one of the four factors" set forth in *LiMandri v. Judkins*, 52 Cal. App. 4th 326 (1997).[4] *Hodsdon*, 891 F.3d at 864. The District Court straightforwardly applied *Hodsdon* when it found that Plaintiffs failed to adduce evidence sufficient to satisfy *any* of these requirements. *See* 1-ER-10–15.

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[3] Unless noted, all internal citations, quotation marks, and alterations are omitted.

[4] The *LiMandri* factors require a plaintiff to establish: (1) that "the defendant is the plaintiff's fiduciary"; (2) that "the defendant has exclusive knowledge of material facts not known or reasonably accessible to the plaintiff"; (3) that the defendant "actively conceal[ed] a material fact from the plaintiff"; or (4) that the defendant made "partial representations that are misleading because some other material fact has not been disclosed." *Hodsdon*, 891 F.3d at 862; *accord LiMandri*, 52 Cal. App. 4th at 336.

Plaintiffs, supported by the Attorney General, ask this Court to request that the California Supreme Court reconsider whether a plaintiff must establish a duty to disclose to prevail on an omission-based claim under the CLRA or UCL. But the California Supreme Court has repeatedly declined review in cases where the parties (or the Attorney General) have asked for this precise relief. For good reason: California appellate courts are in accord that an omission-based claim under the UCL or CLRA is not viable absent a duty to disclose.

Plaintiffs and the Attorney General have not identified a single case in which a California appellate court has permitted an omission-based claim under the UCL or CLRA to proceed without requiring the plaintiff to establish a duty to disclose or contrary affirmative representations. And manufacturers (including many of amici's members) rely on *Hodsdon* in shaping their expectations about what they must—and conversely need not—disclose to consumers on product labels. The California Supreme Court has repeatedly deemed this question unworthy of review. This Court should decline to certify this question.

ARGUMENT

It is a significant undertaking for a state supreme court to resolve a question certified by a federal appellate court. For that reason, this Court should certify a question to the California Supreme Court "only after careful consideration" and should not make this decision "lightly." *U.S. Bank, N.A. v. White Horse Estates Homeowners Ass'n*, 987 F.3d 858, 867 (9th Cir. 2021).

Certification of a "question of California law" is proper only in those rare situations where the California Supreme Court's decision "could determine the outcome of a matter pending in the requesting court" and "[t]here is no controlling precedent." Cal. R. Ct. 8.548(a); *see Guevarra v. Seton Med. Ctr.*, 642 F. App'x 683, 687 (9th Cir. 2016) (declining to certify question that failed to meet this standard). Certification is not a vehicle to relitigate settled legal questions governed by controlling precedent. In other words, a party who has already lost on an issue of state law "[o]rdinarily . . . should not be allowed a second chance at victory" if "the district court employed a reasonable interpretation of state law." *In re McLinn*, 744 F.2d 677, 681 (9th Cir. 1984).

In addition to assessing whether a legal question is unsettled and outcome-determinative, this Court considers a number of prudential factors that guide its decision to grant or deny certification. Those factors include: "(1) whether the question presents important public policy ramifications yet unresolved by the state court; (2) whether the issue is new, substantial, and of broad application; (3) the state court's caseload; and (4) the spirit of comity and federalism." *White Horse Estates*, 987 F.3d at 867. As explained below, the issue Plaintiffs seek to certify to the California Supreme Court is well-settled. Many courts have cited *Hodsdon* in ruling on similar claims, and the California Supreme Court has repeatedly refused similar invitations to reconsider the standard governing UCL and CLRA claims premised on alleged omissions.

Indeed, when California Supreme Court recently denied review in *Nalick v. Seagate Technologies LLC*, it declined a similar invitation to consider whether the UCL and CLRA "impose a duty on manufacturers to disclose to consumers facts related to potential . . . product failures, regardless of whether there is a safety hazard, a product defect, or the warranty has run." Ex. 1, at 5; Ex. 2. That question is still unworthy of review, and it is therefore unworthy of certification.

I. *Hodsdon* Is in Accord with Controlling California Authority.

A. California courts agree that the law imposes a duty-to-disclose requirement, as this Court held in *Hodsdon*.

California courts have long agreed, as this Court recognized in *Hodsdon*, that an omission is not actionable under the UCL or CLRA unless it is contrary to an affirmative representation by the defendant or concerns a fact that the defendant has a duty to disclose.

Nearly fifty years ago, the California Court of Appeal noted that "[f]raud or deceit may consist of the suppression of a fact by one who is bound to disclose it or who gives information of other facts which are likely to mislead for want of communication of that fact." *Outboard Marine Corp. v. Superior Court*, 52 Cal. App. 3d 30, 36–37 (1975). That is the same standard that this Court articulated in *Hodsdon*, which holds that an omission is actionable only if it is "contrary to a representation actually made by the defendant" or is "an omission of a fact that the defendant was obliged to disclose." 891 F.3d at 865.

The California Court of Appeal has subsequently applied that principle in cases arising under the UCL and CLRA, holding that alleged omissions are actionable only if they are contrary to a defendant's affirmative representations or relate to a fact that the defendant is

"obliged to disclose" to its consumers. *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 835 (2006); *see also Bardin v. DaimlerChrysler Corp.*, 136 Cal. App. 4th 1255, 1276 (2006) (affirming order sustaining demurrer to CLRA claim where the plaintiff did not allege "facts showing [the defendant] was 'bound to disclose' . . . nor . . . facts showing [the defendant] ever gave any information of other facts which could have the likely effect of misleading the public 'for want of communication'").

In reaching this conclusion, the *Daugherty* court acknowledged that the UCL—unlike the common law of fraud—does not require "actual deception," "reasonable reliance," or "damage." 144 Cal. App. 4th at 838. But it nonetheless concluded that the "failure to disclose a fact one has no affirmative duty to disclose" is not "likely to deceive anyone within the meaning of the UCL." *Id.* Because Honda's consumers did not have any specific expectation regarding the allegedly omitted automotive defect, the *Daugherty* court found that Honda's failure to disclose this alleged defect was not likely to deceive consumers. Instead, the court explained, "[t]he only expectations buyers could have had about the . . . engine was that it would function properly for the length of Honda's express

warranty, and it did." *Id.* As a result, Honda "did nothing that was likely to deceive the general public by failing to disclose" the alleged defect. *Id.*

Many California appellate opinions are in accord.[5] For example, in *Rubenstein v. Gap, Inc.*, the plaintiff alleged that Gap misled consumers by failing to "disclose that its factory store clothing was not previously for sale at traditional Gap stores." 14 Cal. App. 5th 870, 877 (2017). After the trial court sustained Gap's demurrer, the Attorney General filed an amicus brief in the Court of Appeal and took the position that "a defendant may be liable for a fraudulent business practice under the UCL," even "absent a false or misleading representation or a duty to disclose." *Id.* at 879. The Court of Appeal "decline[d] to adopt the Attorney General's position" and rejected it as "contrary to a good deal of Court of Appeal precedent on the importance of a duty to disclose." *Id.*

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[5] *E.g.*, *Berryman v. Merit Prop. Mgmt., Inc.* 152 Cal. App. 4th 1544, 1556–57 (2007) (applying *Daughtery* and affirming dismissal of UCL claim because the plaintiff failed to allege a duty to disclose); *Lopez v. Nissan N. Am., Inc.*, 201 Cal. App. 4th 572, 595 (2011) (affirming dismissal of CLRA claim because the defendant had no duty disclose odometers were slightly inaccurate); *Brakke v. Econ. Concepts, Inc.*, 213 Cal. App. 4th 761, 772 (2013) ("California cases have recognized . . . absent a duty to disclose, the failure to do so does not support a claim under the fraudulent prong of the UCL.") *Graham v. Bank of Am., N.A.*, 226 Cal. App. 4th 594, 613–14 (2014) (holding that the plaintiff failed to state an omission-based UCL claim where the defendant did not owe a duty to disclose).

It is easy to see why California law imposes a duty-to-disclose requirement in cases arising under the UCL and CLRA: it properly limits the scope of liability under the UCL while simultaneously protecting consumers against fraud. In cases where an omission is contrary to a defendant's voluntary and affirmative representations, the UCL and CLRA continue to impose liability. But in cases involving pure omissions not contrary to the defendant's affirmative representations, dispensing with a duty-to-disclose requirement would make "liability under the UCL or CLRA . . . limitless." *Hall v. Sea World Entm't, Inc.*, 2015 WL 9659911, at *7 (S.D. Cal. Dec. 23, 2015).

Under that standard, a plaintiff could survive dismissal by simply alleging that he or she was "likely to be deceived" by an omission—which is a question that courts deem "best left for a jury." *Asis Internet Serv. v. Subscriberbase Inc.*, 2010 WL 1267763 at *3 (N.D. Cal. Apr. 1, 2010). Such a standard would leave defendants no way to know *ex ante* which information they must disclose to consumers, which is why California law has required a duty to disclose in pure omissions cases. *Cf. Kreisher v. Mobil Oil Corp.*, 198 Cal. App. 3d 389, 402 (1988) ("One of the fundamental purposes of law is to provide stability. The announcement

of a legal principle, whether by the Legislature or by the courts, furnishes notice of what is either allowed or prohibited.").

In short, the question of whether an omissions-based claim under the UCL or the CLRA requires a duty to disclose is well-settled under California law. That is why the California Supreme Court has declined numerous requests to revisit this question. *See infra* at 23–24. It is not necessary to certify this question to the California Supreme Court.

B. The cases the Attorney General cites do not suggest that California law eschews any duty-to-disclose test.

The Attorney General, which submitted an amicus brief in support of certification, argues that an omissions-based claim under the UCL does not require an underlying duty to disclose. *See* AG Amicus Br. at 6. But none of the cases the Attorney General cites support this argument—or even suggest that the law is unsettled.

For example, the Attorney General (and Plaintiffs) cite *Ford Dealers Association v. Department of Motor Vehicles*, which addressed whether the California Vehicle Code authorized the DMV to require the "affirmative disclosure of a vehicle's history." 32 Cal. 3d 347, 363 (1982). But the California Supreme Court's interpretation of the DMV's statutory authority under the Vehicle Code has no bearing on the

applicable standard under the UCL or CLRA. Nothing in *Ford Dealers Association* suggests that an omission-based claim under these two statutes is viable absent a duty to disclose.

Nor does *Committee on Children's Television, Inc. v. General Foods Corp.*, 35 Cal. 3d 197 (1983), suggest that the UCL and CLRA do not require a duty to disclose in a case premised on pure omissions. Rather, that case involved omissions that, "when joined with . . . affirmative misrepresentations . . . render[ed] the advertisements misleading and deceptive." *Id.* at 206–07.[6] Because California law proscribes omissions that are contrary to a defendant's affirmative representations, *Committee on Children's Television* is not apposite to this case, which concerns pure omissions not contrary to any affirmative representations. It therefore does not address the relevant issue—whether the UCL and CLRA impose a duty-to-disclose requirement in a case based on pure omissions.

Finally, relying on *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163 (1999), the Attorney General argues that California law does not impose a duty-to-disclose

[6] The same is true of *Chern v. Bank of America*, which involved affirmative representations that were contrary to the allegedly omitted information. 15 Cal. 3d 866, 876 (1976).

requirement in UCL claims premised on omissions because the "parallel" FTC Act does not impose such a requirement. *See* AG Amicus Br. at 13–14. But *Cel-Tech* discusses the "parallel" nature of the FTC Act only in the context of the UCL's "unfair" prong, which is distinct from the "fraudulent" prong of the UCL on which Plaintiffs' claims principally rely and is inapplicable to omission claims. *See* 20 Cal. 4th at 185 (noting that the court could "turn for guidance to the jurisprudence . . . under the parallel" FTC Act to "devise a more precise test for determining *what is unfair* under the unfair competition law") (emphasis added); *see also Hodsdon*, 891 F.3d at 865 (explaining that the UCL "establishes three varieties of unfair competition—acts or practices which are unlawful, *or* unfair, *or* fraudulent") (emphasis added).

Moreover, even on its own terms, *Cel-Tech* does not suggest that the UCL imposes no threshold duty-to-disclose requirement in cases based on pure omissions. It stands instead for the unremarkable proposition that the FTC Act is "more than ordinarily persuasive" in interpreting the scope of the UCL. *Cel-Tech*, 20 Cal. 4th at 185. The Attorney General does not cite a single case in which a California court relied on the FTC Act to interpret the UCL in a case based on pure omissions. The notion

that the FTC's guidance is "more than ordinarily persuasive" does not suggest that this Court should disregard voluminous state and federal court precedent holding that the UCL and CLRA impose a duty-to-disclose requirement in pure omissions cases like Plaintiffs' lawsuit here.

In short, none of the cases the Attorney General cites conflicts with *Hodsdon*'s holding that the UCL and CLRA require a duty-to-disclose requirement in order to establish liability for pure omissions. To the contrary, the California Court of Appeal—whose decisions are ordinarily binding in cases arising under state law—has consistently agreed that the UCL and CLRA impose a threshold duty to disclose in pure omissions cases. *See Bliss Sequoia Ins. & Risk Advisors, Inc. v. Allied Prop. & Cas. Ins. Co.*, 52 F.4th 417, 419 (9th Cir. 2022) (noting that federal courts applying state law are "obligated to follow the decisions of the state's intermediate appellate courts unless there is convincing evidence that the state supreme court would decide differently").

"[C]ontrolling precedent" resolves the question Plaintiffs seek to certify, which is why the California Supreme Court has repeatedly declined review in cases that pose this question. Cal. Ct. R. 8.548(a)(2). This Court should therefore deny Plaintiffs' motion for certification. *See*

Bliss Sequoia, 52 F.4th at 423 ("When there is little reason to doubt the answer to a state-law question, we ought not outsource our work to a state court simply because we find the burden of decision unwelcome.").

C. *Hodsdon* correctly synthesizes California case law regarding the *scope* of the duty to disclose.

Leaving aside their mistaken assertion that California law does not impose a duty-to-disclose requirement at all, Plaintiffs and the Attorney General double down by arguing that the *scope* of the duty to disclose is unsettled. *See* Appellants' Opening Br. at 7; AG Amicus Br. at 8–12. It is not. *Hodsdon* represents a careful and comprehensive synthesis of settled California law, and there is no reason to ask the California Supreme Court to re-do this Court's work. *See McLinn*, 744 F.2d at 681; *Alliance for Prop. Rights & Fiscal Responsibility v. City of Idaho Falls*, 742 F.3d 1100, 1108–09 (9th Cir. 2013).

In *Hodsdon*, this Court clarified that that a plaintiff can state a claim arising out of alleged omissions by alleging a duty to disclose—which requires either (1) that the omission relates to an "unreasonable safety hazard" or (2) that "the omission is material" and that the defect is "central to the product's function." *Hodsdon*, 891 F.3d at 861, 863–64. If (but only if) the plaintiff makes a threshold showing of one of these two

criteria, the court must separately consider whether the plaintiff has satisfied at least one of the four *LiMandri* factors. *See id.*

This Court did not invent this standard out of whole cloth. To the contrary, it flows directly from the Court of Appeal's decisions in *Collins v. eMachines, Inc.*, 202 Cal. App. 4th 249 (2011) and *Rutledge v. Hewlett-Packard Co.*, 238 Cal. App. 4th 1164 (2015).

In *Collins*, the plaintiffs asserted claims under the UCL and CLRA premised on alleged defects in computer floppy disks. *See Collins*, 202 Cal. App. 4th at 253. Because floppy disks "provided the primary means of storing and transporting computer data," and because the purported defects allegedly "could and did corrupt computer data," the Court of Appeal found that a reasonable consumer would "certainly attach importance to the disclosure" of this purported defect. *Id.* at 256.

As the Court of Appeal explained, the floppy disk "was integral to the storage, access, and transport of accurate computer data" and was therefore "*central to the function of a computer as a computer*." *Id.* at 258 (emphasis added). In light of this finding, as well as its finding that the plaintiff satisfied two of the four *LiMandri* factors, the Court of Appeal

found that alleged omissions relating to this "critical hardware" were actionable under the UCL and CLRA. *See id.* at 256–58.

Rutledge similarly involved defects in the display of notebook computers. The *Rutledge* court first observed that the UCL and CLRA require a duty to disclose to prevail on a claim premised on pure omissions. *See Rutledge*, 238 Cal. App. 4th at 1173. In assessing whether that duty existed, the court emphasized the plaintiffs' allegations that a notebook computer requires a functioning display. Without that "critical . . . function," the court noted, "the computer would not be portable and would require the connection of an outside monitor." *Id.* at 1175.

The *Rutledge* court determined that the defendant was not entitled to summary judgment on the plaintiff's UCL and CLRA claims because the plaintiff had adduced evidence of a defect that affected the computer's central function, which was "sufficient to create a triable issue of fact as to the nature of HP's representations, and whether that triggered a *duty to disclose* the defect." *Id.* at 1176 (emphasis added). The *Rutledge* court further reasoned that there remained "triable issue[s] of fact as to whether HP knew about the defect in the TDK inverters" and whether it "concealed this fact from the consumers who purchased notebooks

containing the TDK inverters." *Id.* at 1179. Notably, these "triable issues of fact" correlate with two of the four *LiMandri* factors—whether the defendant has "exclusive knowledge of material facts not known or reasonably accessible to the plaintiff" and whether it "actively conceals a material fact from the plaintiff." *LiMandri*, 52 Cal. App. 4th at 336.

The *Rutledge* court also noted that, while it was not *necessary* for a plaintiff to allege that the omitted defect relates to an unreasonable safety hazard, such an allegation would be *sufficient* to establish a duty to disclose. *See Rutledge*, 238 Cal. App. 4th at 1174; *see also Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1143 (9th Cir. 2012) (holding that it was not erroneous to "require[e] Plaintiffs to allege that the design defect caused an unreasonable safety hazard"). Consistent with *Rutledge*, the *Hodsdon* court clarified that, even though the "safety hazard pleading requirement" is not strictly necessary, that fact did "not deprive *Wilson* of all vitality." *Hodsdon*, 891 F.3d at 864. Instead, the *Hodsdon* court explained, a safety hazard may provide yet *another* basis to prove a defendant had a duty to disclose in cases where the "defect in question does not go to the central functionality of the product." *Id.*

The standard that this Court articulated in *Hodsdon* follows directly from the Court of Appeal's decisions in *Collins* and *Rutledge*. And the Court of Appeal has cited approvingly to *Hodsdon* in assessing omissions-based claims brought under the UCL and CLRA. *See, e.g.*, *People v. Johnson & Johnson*, 77 Cal. App. 5th 295, 325 (2022) (relying on *Hodsdon* and noting that it correctly "synthesiz[ed] state law"); *Nalick v. Seagate Tech, LLC*, 2021 WL 1135226, at *9 (Cal. Ct. App. Mar. 25, 2021) ("We follow *Collins*, *Rutledge*, and *Hodsdon* in concluding omission claims are viable provided they relate to the product's central functionality.").[7]

In short, *Hodsdon* sets forth a comprehensive and accurate synthesis of California law governing the duty to disclose in cases premised on alleged omissions. This weighs strongly against asking the

[7] Although *Nalick* is an unpublished case, California's prohibition on citing unpublished opinions of the California Court of Appeal does not prohibit this Court from considering *Nalick* as persuasive authority and as a data point about how California state courts have applied *Hodsdon*. *See White Horse Estates*, 987 F.3d at 863 (noting that a federal court can consider unpublished state court decisions to analyze state law "because they may lend support to a conclusion as to what the [state supreme court] would hold in a published decision").

California Supreme Court to revisit this question. *See McLinn*, 744 F.2d at 681; *City of Idaho Falls*, 742 F.3d at 1108–09.

II. Certification Is Inappropriate Because the Question Is Well-Settled and There Is No Indication That the California Supreme Court Would Decide This Issue Differently.

In determining whether to grant certification, this Court considers: "(1) whether the question presents important public policy ramifications yet unresolved by the state court; (2) whether the issue is new, substantial, and of broad application; (3) the state court's caseload; and (4) the spirit of comity and federalism." *White Horse Estates*, 987 F.3d at 867. These factors uniformly weigh against certification.

As explained above, the California Court of Appeal has extensively considered the proper standard governing omissions-based claims under the UCL and CLRA. It is irrelevant whether the scope of liability under those statutes implicates "public policy" issues; even if that were true, there is no serious argument that those issues are "yet unresolved." *Id.*

To the contrary, certifying this question to the California Supreme Court would upend nearly two decades of California and federal precedent interpreting the UCL. *See* AG Amicus Br. at 15 ("In the past year alone, federal courts have issued decisions citing *LiMandri* in at

least seventeen other cases involving omissions under the UCL, FAL, or CLRA."). Indeed, since this Court decided *Hodsdon* in 2018, over 100 federal decisions have cited or relied on it in adjudicating UCL and CLRA claims premised on alleged omissions. *See* Ex. 3 (chart of cases). Given that *Hodsdon* is the law of the land, it would be profoundly destabilizing to revisit the standard that this Court carefully and correctly distilled from the California case law.

This Court should therefore decline Plaintiffs' invitation to certify this question to the California Supreme Court, as "there is no sharp split of authority between the California Courts of Appeal and the Ninth Circuit regarding the proper interpretation of state law." *Herrera v. Zumiez, Inc.*, 953 F.3d 1063, 1070 (9th Cir. 2020) (denying request for certification). Declining certification would not only avoid the unnecessary burden that certification will impose on the California Supreme Court, but also respect the "important doctrine of *stare decisis*, the means by which we ensure that the law will not merely change erratically, but will develop in a principled and intelligible fashion." *Vasquez v. Hillery*, 474 U.S. 254, 265 (1986); *accord Miranda v. Selig*, 860 F.3d 1237, 1243 (9th Cir. 2017) ("[E]ven at the Supreme Court, '*stare*

decisis is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process.'") (quoting *Payne v. Tennessee*, 501 U.S. 808, 827 (1991)).

The remaining three *White Horse Estates* factors also weigh against certification. The question Plaintiffs pose for certification is not novel. Nor is there any indication that the California Supreme Court would answer the question differently than this Court did in *Hodsdon*. Indeed, even though private plaintiffs and the Attorney General have repeatedly asked the California Supreme Court to address this issue, the California Supreme Court has repeatedly refused that invitation.

For example, in *Nalick*, the plaintiffs filed a petition for review in 2021, in which they asked the California Supreme Court to decide whether the UCL and CLRA "impose a duty on manufacturers to disclose to consumers facts related to potential furniture product failures, regardless of whether there is a safety hazard, a product defect, or the warranty has run." Ex. 1, at 5. The California Supreme Court denied review. Ex. 2. The next year, in *Johnson & Johnson*, the Attorney

General submitted an amicus brief in which he urged the California Supreme Court to clarify "[w]hether, under the Unfair Competition Law (UCL) and False Advertising Law (FAL), a communication may be held 'likely to deceive' its target audience when it omits information that the target audience would not expect it to include." Ex. 4, at 7. The California Supreme Court denied review once again. *See* Ex. 5.

There is no reason to think that the California Supreme Court would deem this question any more worthy of review today. *See Anderson v. Deutsche Bank Nat. Trust Co. Am.*, 649 F. App'x 550, 552 n.1 (9th Cir. 2016) (declining to certify question because "it seems clear that the California Supreme Court is aware of the emergence of this issue, but has not indicated a readiness to address it"); *Smith v. Ford Motor Co.*, 462 F. App'x 660, 665 (9th Cir. 2011) (declining to certify question to the California Supreme Court because "sufficient controlling precedent exists from the California appellate courts to address the questions posed, and there is no indication that the California Supreme Court would decide these issues differently"). That fact weighs heavily against certifying this question to the California Supreme Court.

The Attorney General notes that the California Supreme Court recently granted review in *Capito v. San Jose Healthcare System LP*, Case No. S280018. *See* AG Amicus Br. at 4. The California Supreme Court agreed to address whether, under the UCL and CLRA, a "hospital [has] a 'duty to disclose' to emergency room consumers its intention (exclusively known by hospital) to charge a substantial Visitation Fee to each and every emergency room patient simply for being seen in the emergency room." Ex. 6, at 4. Although the issue presented is distinct from the one posed here, the Attorney General filed an amicus brief in *Capito* in which he took the position—as he does here—that "plaintiffs who allege deception by omission under the UCL must only allege conduct that was 'likely to deceive' the public, and need not additionally satisfy *LiMandri* or any other standard requiring a 'duty to disclose' as a threshold consideration." AG Amicus Br. at 4.

The California Supreme Court's decision to accept review in *Capito* does not suggest that the law is "in flux" or that this Court should certify this case to the California Supreme Court. The California Supreme Court's formulation of the question presented—whether a hospital has a duty to disclose its intention to charge a fee to emergency room patients

in specific factual circumstances—implicitly recognizes that the UCL and CLRA require a threshold showing of a duty to disclose. And in any event, if the California Supreme Court wanted to use *Capito* as a vehicle to clarify the general standard governing omissions-based claims under the UCL and CLRA, the Attorney General has already asked it to do so. There is no need for this Court to pile on here.

CONCLUSION

This Court should deny Plaintiffs' motion for certification and affirm the judgment below.

Dated: October 25, 2024

/s/ Dean N. Panos

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CERTIFICATE OF COMPLIANCE

I, Dean N. Panos, hereby certify as follows:

1. The foregoing brief complies with Federal Rule of Appellate Procedure 29(a)(5) because the brief's word count of 5,403 words does not exceed half the word limit of a principal brief, excluding the portions identified in Federal Rule of Appellate Procedure 32(f).

2. The foregoing brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in 14 point Century Schoolbook font.

Dated: October 25, 2024

/s/ Dean N. Panos
Dean N. Panos

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on October 25, 2024, that all participants in the case are registered CM/ECF filers, and that service will be effected using the appellate CM/ECF system.

Dated: October 25, 2024

/s/ Dean N. Panos
Dean N. Panos

EXHIBIT 1

Supreme Court of California
Jorge E. Navarrete, Clerk and Executive Officer of the Court

S268227

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

SCOTT NALICK,
Plaintiff and Appellant,
v.
SEAGATE TECHNOLOGY LLC
Defendant and Respondent

On Review From The Court Of Appeal For the State of California
First Appellate District, Division 1 No. A158237

PETITION FOR REVIEW

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ISSUE PRESENTED FOR REVIEW

Whether California's Consumers Legal Remedies Act (CLRA) and Unfair Competition Law (UCL) impose a duty on manufacturers to disclose to consumers facts related to potential future product failures, regardless of whether there is a safety hazard, a product defect, or the warranty has run.

INTRODUCTION

This petition invites the Court to resolve an important question of California law that even the First District Court of Appeal acknowledged is one on which the "[c]ourts are split . . . ." (See Slip Opinion ("Slip op.") (attached as Exhibit A to this Petition) at 16.) The underlying appellate court's decision laid out in no uncertain terms the unresolved split between the Second and Fourth Districts' approach on the one hand, and the Third and Sixth Districts' on the other.

Within just a few weeks of the First District's opinion, Judge Chen of the United States District Court for the Northern District of California remarked that "caselaw on the scope of a defendant's duty to disclose in omission-based consumer protection cases is marked by 'general disarray.'" (See *In re Toyota Rav4 Hybrid Fuel Tank Litig.* (N.D. Cal. Apr. 9, 2021, No. 20-cv-00337-EMC) 2021 WL 1338949, at *19 (*In re Toyota*).)

Indeed, litigants have asked the Ninth Circuit to certify the question to this Court on more than one occasion. (See *Hodsdon v. Mars, Inc.* (9th Cir. 2017) 891 F.3d 857, 865, fn. 7 (*Hodsdon*); *Smith v. Ford Motor Co.* (9th Cir. 2011) 462 Fed.Appx. 660, 665.)

If the Court does not resolve this question, companies and consumers will continue to face inconsistent and unpredictable results in connection with CLRA and UCL suits premised on omissions-only claims. This lack of consistency can only undermine faith in the judicial system as an institution where similar cases should yield similar results. It will virtually guarantee appellate litigation in any consumer products case involving an alleged duty to disclose, regardless of which side prevails in the lower court. Thus, the Court should grant Seagate's petition so that the lack of uniformity among the courts regarding this important issue of California law can be resolved once and for all.

Clarifying the scope of a manufacturer's duty to disclose will significantly benefit the relationship between sellers and consumers, both inside and outside California. Specifically, it will provide companies much-needed direction regarding what they must disclose regarding potential post-warranty product failures. Without guidance from this Court, companies will continue to struggle to find workable and objective standards for their disclosure obligations.

Additionally, resolving the issue presented will help both manufacturers and consumers by clarifying what, if any, legal significance remains of warranties under California law. Under the First District's post-warranty disclosure rule, California's well-established and longstanding warranty jurisprudence would effectively be rendered a nullity, as consumers would be able to bring CLRA and UCL claims, as the Ninth Circuit warned, for "[f]ailure of a product to last forever . . . ." (*Wilson v. Hewlett-Packard Co.* (9th Cir. 2012) 668 F.3d 1136, 1141-1142 (*Wilson*).)

That risk is demonstrated by the facts at issue here, where the named plaintiff has claimed merely a "diminution in value" injury to consumers, not any safety risk. Nor did he convince the trial court of the existence of a discernible physical defect, instead premising his claim on alleged hard drive failure rates that purportedly exceeded those disclosed to consumers, whether inside or outside Seagate's warranty period.

If, on the other hand, the Court adopts the Second and Fourth Districts' position, which aligns with the Ninth Circuit's holding in *Wilson*, manufacturers will continue to be able to issue meaningful warranties, and consumers will benefit by having clear, definitive, and straightforward assurances regarding their purchases.

Should companies remain at risk of liability for omissions-only claims like this one, they will have no choice but to spread such potential costs through the prices charged to consumers, leaving the public in the

undesirable position of insuring against potential, non-hazardous product failures long into the future by paying higher prices at the outset. Resolving this important question by limiting such claims to situations where consumers' safety has actually been put at risk by undisclosed defects will ultimately benefit consumers.

BACKGROUND

I. PROCEEDINGS IN THE TRIAL COURT

Nalick purchased a particular model of Seagate external hard disk drive. According to Nalick, that specific drive failed approximately one year after purchase. He filed a class action alleging that the drive model contained a latent defect that caused an unacceptably high failure rate, and that Seagate made misrepresentations and omissions about the drives' reliability and failure rates that violated the CLRA (Civ. Code § 1750, et seq.), the UCL (Bus. & Prof. Code § 17200, et seq.), California's False Advertising Law (Bus. & Prof. Code, § 17500, et seq.), and the Song-Beverly Consumer Warranty Act (Civ. Code, § 1790, et seq.).

Following discovery, Nalick moved for class certification under several different theories. (Slip op. at 3.) The trial court granted class certification "limited to CLRA and UCL (but not the illegal prong) claims based on omissions. The motion [wa]s otherwise denied." (Order Granting in Part Plaintiffs' Motion for Class Certif., *Pozar v. Seagate Technology LLC* (Super. Ct. S.F. City and County, 2017, No. CGC-15-547787) 2017

WL 6812218, at *16.) The trial court found that "after all the discovery we have had in this case, plaintiffs do not even have a theory as to what the latent defect is and why the Drives failed. Nor is there any study done, or any study offered or described, which would provide a statistical analysis of the failure rate." (*Id.* at p. *13.) Thereafter, Nalick proceeded solely on an "omissions only" theory.

Seagate later moved for summary judgment and summary adjudication in the alternative. With respect to the class claims, Seagate argued that Nalick's omissions claims were barred by *Daugherty v. American Honda Motor Co., Inc.* (2006) 144 Cal.App.4th 824, 834 (*Daugherty*), in which the Second District Court of Appeal held that omissions-only CLRA and UCL claims based on failures that arose after the manufacturer's warranty expired could only be based on safety-related defects. Seagate argued that Nalick failed to establish either (1) a duty to disclose based on a materially higher failure rate or (2) that Seagate had exclusive knowledge of or concealed any material information regarding the drives' failure rate.

The trial court initially denied Seagate's motion for summary judgment, concluding that *Daugherty* did not completely bar Nalick's claims because it only excluded product claims that arose post-warranty. On reconsideration, however, the trial court granted Seagate's motion for summary adjudication of the class claims, finding there was no disputed

issue of material fact regarding the products' purportedly heightened failure rates or Seagate's knowledge of such rates. Nalick appealed.

II. THE COURT OF APPEAL'S DECISION

The Court of Appeal reversed, concluding that Nalick raised triable issues of material fact regarding Seagate's duty to disclose allegedly heightened failure rates for the hard drives at issue. (Slip op. at 10.) In reaching its conclusion, the Court of Appeal devoted considerable attention to the duty to disclose in omissions claims under the CLRA and the UCL.

The Court of Appeal identified two areas where courts have disagreed: (1) whether a duty to disclose predicated solely on omissions requires a "safety hazard" (Slip op. at 16); and (2) if not, whether such a duty to disclose should be applied to claims arising after expiration of the warranty period (Slip op. at 15, fn. 6).

On the first question, the court followed a line of post-*Daugherty* cases holding that omission claims are viable without a safety hazard, provided they relate to a product's "central functionality." In doing so, the court recognized concerns about undermining warranties, and thus "emphasize[d] the necessary limits in assessing whether a defect is central to functionality." (Slip op. at 20.) On the second question, the court agreed with Nalick's contention that "the trial court improperly concluded Seagate's duty to disclose did not apply to postwarranty claims under the CLRA and UCL[,]" thus rejecting the trial court's conclusion that

Daugherty bars omissions liability for (non-safety-related) product claims arising after the warranty period. (Slip op. at 2, 7, 13.)

ARGUMENT

I. THE COURT SHOULD GRANT REVIEW TO SECURE UNIFORMITY OF DECISION IN OMISSIONS CLAIMS UNDER THE CLRA AND UCL.

A. Review Is Necessary to Resolve the Conflict Over Whether the CLRA and UCL Authorize an Omissions Claim in Product Cases Involving No Safety Hazard.

As previously noted, the case law on omissions-based claims is "marked by general disarray." (*In re Toyota*, *supra*, 2021 WL 1338949, at p. *19, internal quotation marks omitted.) As a result, courts are struggling both to decide between competing standards and to apply them.

The principal split relates to whether a plaintiff must establish a safety hazard in order to pursue an omissions-based product liability claim under the CLRA or UCL. The Second and Fourth District require a safety hazard in order to assert such claims. (See *Daugherty*, *supra*, 144 Cal.App.4th at p. 836.)

Other districts, however, do not require a safety defect. The Sixth District, for example, holds a physical defect central to the function of the product is enough, irrespective of whether it poses a safety risk to the consumer. (See *Rutledge v. Hewlett-Packard Co.* (2015) 238 Cal.App.4th 1164, 1175 (*Rutledge*).) The Third District adopted common law fraud

elements called the *LiMandri* factors[1] and required a physical defect central to the product's function. (See *Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249, 255 (*Collins*).) The Fifth Appellate District holds that there is no independent duty to disclose safety concerns, but a duty may arise if any of the *LiMandri* factors are satisfied. (*Gutierrez v. Carmax Auto Superstores California* (2018) 19 Cal.App.5th 1234, 1260; see also *id.* at pp. 1267-1270 (Poochigian, A.P.J., dissenting) ("Though the majority assures us that '[n]ot every omission or nondisclosure of fact is actionable' . . . its limitations on omission liability are illusory").)

Federal courts considering nondisclosure cases under California law are asking for help. Such courts have concluded that California law on omission-based liability is "not well established" and in "disarray." (*Blissard v. FCA US LLC* (C.D. Cal. Nov. 9, 2018, No. LACV1802765-JAKJEMX) 2018 WL 6177295, at *11 (Kronstadt, J.); *In re Apple Inc.*

[1] *Falk v. General Motors Corp.* (N.D. Cal. 2007) 496 F.Supp.2d 1088, 1094-1095, was the first case to apply these factors to a product liability claim under the UCL and the CLRA. Plaintiffs there alleged no safety concerns with their allegedly defective speedometers, and they all experienced problems *after* the expiration of the warranty. *Ibid.* The court recognized a duty to disclose under four circumstances:

> (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 fact.

(*Id.* at 1095, quoting *LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 337.)

Device Performance Litigation (N.D. Cal. 2019) 386 F.Supp.3d 1155, 1168 (Davila, J.); *In re Toyota*, *supra*, 2021 WL 1338949, at p. *19.)

In the absence of controlling California authority, the Ninth Circuit has tried to fill in the gaps, but has only added to the confusion. Two rulings hold that a safety defect is required in products cases involving non-disclosure. (*Wilson*, *supra*, 668 F.3d at p. 1138; *Williams v. Yamaha Motor Co. Ltd.* (9th Cir. 2017) 851 F.3d 1015, 1028-1029 (*Williams*).) Another holds that non-disclosure cases may proceed without a safety defect where the omission was material, the defect was central to the product's function, and one of the four *LiMandri* factors is met. (*Hodsdon*, *supra*, 891 F.3d at p. 863.)

The Request for Publication submitted by the Center for Consumer Law & Economic Justice (CCLEJ) asked for publication of the First District's decision because CCLEJ believed publication was necessary in order to resolve the "disagreement among state and federal courts about whether an omissions-only theory of liability must be accompanied by a defect, safety risk, or affirmative misrepresentation." (Request for Pub. at 2.) Without resolution of this significant and ongoing disagreement on California law, courts, parties, and the public will continue to suffer from the resulting unpredictability in defining a manufacturer's obligation to make disclosures.

B. Review Is Necessary to Resolve the Conflict Over Whether the CLRA and UCL Authorize an Omissions Claim Arising After the Warranty Period.

Even if there were uniformity regarding whether consumers were permitted to pursue omissions-based claims in the absence of a safety concern, the division between courts on whether to permit such claims for issues that arise after the expiration of a product warranty would still remain. As several courts have expressed, allowing products claims based on alleged post-warranty risks "raises concerns about the use of consumer fraud statutes to impermissibly extend a product's warranty period." (*Williams*, *supra*, 851 F.3d at p. 1029.) That is what is happening here.

Again, state and federal courts applying California law have produced conflicting opinions. *Daugherty*, for example, rejected an omissions-based claim under the CLRA where there was no safety defect and "*[a]ll of plaintiff's automobiles functioned as represented throughout their warranty periods*, and indeed many still have experienced no malfunction." (144 Cal.App.4th at p. 834, emphasis added.) In *Collins*, however, the court allowed a CLRA claim based on omissions about a product without any discernible safety hazard, and distinguished *Daugherty*, noting that the alleged defect in *Daugherty* was latent and did not manifest until after expiration of the warranty. (202 Cal.App.4th at p. 256.) "To allow a CLRA claim in these circumstances would be to supplant warranty law; failure of a product to last forever would become a

'defect' and a manufacturer would no longer be able to issue limited warranties." (*Id.* at pp. 256-257.)

In *Rutledge*, the court allowed an omissions claim for notebook computers that contained inverters the defendant knew would likely cause display screens to dim and darken "at some point before the end of the notebook's useful life." (238 Cal.App.4th at p. 1168.) The court rejected HP's argument that plaintiff did not have a claim under the CLRA and UCL because the computers functioned for the duration of the warranty period, noting "appellants' theory is that the inverters were defective in manufacturing and installation *at the time the notebooks were sold.*" (*Id.* at 1175, emphasis added.) The court adopted the "central functionality" test, reasoning that "the defect in the inverters occurred in its manufacturing and installation and was material, because it affected the performance of the display screens of notebook computers." (*Ibid*.)

As the Court of Appeal noted in the case at bar, "[s]ome federal courts have disagreed amongst themselves on whether the [duty to disclose] should be applied to claims arising after the expiration of a warranty period." (Slip op. at 15, fn. 6, comparing *Daniel v. Ford Motor Co*. (E.D. Cal. May 18, 2016, Civ. No. 2:11-02890 WBS EFB) 2016 WL 2899026, at *2 (duty applies to safety defects that manifest after expiration of warranty period), with *Williams*, *supra*, 851 F.3d at p. 1029 ("the fact that the alleged defect concerns premature, but usually post-warranty, onset of a natural

condition raises concerns about the use of consumer fraud statutes to impermissibly extend a product's warranty period").)

As discussed above, the court in *Collins* distinguished *Daugherty* because the defect in *Daugherty* manifested after the expiration of a warranty. (202 Cal.App.4th at p. 257.) And in *Rutledge*, the court allowed non-safety omission claims to proceed, even though the product problems arose post-warranty. (238 Cal.App.4th at p. 1175.) Notably, both *Collins* and *Rutledge* involved product defects, something Nalick never established in the instant case. This means that yet another approach to post-warranty claims may be emerging: omissions claims based neither on an affirmative misrepresentation nor any kind of defect, but rather failure rates, whether during the warranty or thereafter, alleged to diminish the product's value.

While federal courts interpreting California law have generally limited plaintiffs from bringing such claims after a warranty expires, the disparate nature of these decisions confirms the need for this Court to establish clarity. For example, a number of federal courts have "expressly distinguished the *Daugherty* line of cases as those cases involved defects which 'manifested after the warranty period expired.'" (*Rasmussen v. Apple, Inc.* (N.D. Cal. 2014) 27 F.Supp.3d 1027, 1037-1038, citation omitted; see also *Decker v. Mazda Motor of America, Inc.* (C.D. Cal. Oct. 24, 2011, No. SACV 11-0873 AG) 2011 WL 5101705, at *4.)

Likewise, in *Wilson*, the court stated that "California federal courts have generally interpreted *Daugherty* as holding that a manufacturer's duty to consumers is limited to its warranty obligations absent either an affirmative misrepresentation or a safety issue." (668 F.3d at p. 1141, internal quotation marks and citation omitted.) *Wilson* involved a defect arising after expiration of the warranty, and the court distinguished cases where the defect instead manifested during the warranty period. (*Id.* at p. 1142 & fn. 1.) The court in *Wilson*, quoting *Daugherty*, commented that unless liability for failure to disclose a defect is limited to safety risks, "the '[f]ailure of a product to last forever would become a 'defect,' a manufacturer would no longer be able to issue limited warranties, and product defect litigation would become as widespread as manufacturing itself.'" (*Id.* at pp. 1141-1142; see also Slip op. at 16 (quoting *Wilson*).)

Here, the Court of Appeal recognized the existence of "points of distinction between the present case and *Rutledge* and *Collins*," including that the computers in *Collins* "were never complete and operational due to the alleged microchip defect at the time they were sold." (Slip op. 19.) It also cited *Collins* approvingly for that court's recognition that *Daugherty* does not sanction "an end-around the warranty laws." (Slip op. at 21, fn. 9.) Nevertheless, while accepting the trial court's determination that "the record could not support a finding that the hard drives contained a latent defect" (Slip op. at 4), the court allowed Nalick to pursue post-warranty

claims (Slip op. at 20-21). In doing so, the court permitted Nalick to circumvent warranty laws just as it worried would happen and other courts have disapproved. Without guidance from this Court, state and federal courts will continue to issue inconsistent rulings about whether the CLRA and UCL permit "pure omissions" claims arising after the warranty period in the absence of a safety hazard or latent defect.

II. THIS COURT SHOULD GRANT REVIEW TO SETTLE IMPORTANT QUESTIONS OF CONSUMER LAW.

A. The Emerging Subjective and Unpredictable Legal Standards Harm Both Consumers and Companies.

Under the First District's non-defect, post-warranty omission theory, companies will be hard-pressed to determine what needs to be disclosed to consumers and when. Manufacturers' understanding of consumer experience with their products evolves in real time, as factory testing, product development, and consumer returns continue. Here, Nalick argued that the value of all the drives was diminished by elevated failure rates in factory testing at particular points in time. It is unclear who would need to be notified of such internal test results and how any notification would be feasible for most consumer products purchased at retail. Among other things, manufacturers cannot know in advance what return rates will be for products not yet sold.

This is why manufacturers have limited warranties: to provide a remedy for consumers while limiting their exposure to future claims based

on products that are constantly evolving and have a finite useful life. As one district court cautioned, broad and ambiguous legal standards about product disclosures would permit a plaintiff to "only allege disappointed expectations to survive a motion to dismiss claims under the CLRA . . . ." (*In re Sony Grand Wega KDF-E A10/A20 Series Rear Projection HDTV Television Litigation* (S.D. Cal. 2010) 758 F.Supp.2d 1077, 1095, fn. 7.)

As another district court judge explained, in criticizing the unworkability of legal standards like the standard offered by the First District:

> This rationale applies with even greater force to the component parts of laptop computers where consumer expectations are even more subjective and likely unreliable, and where usage will greatly vary from consumer to consumer.

(*Oestreicher v. Alienware Corp.* (N.D. Cal. 2008) 544 F.Supp.2d 964, 972, aff'd. (9th Cir. 2009) 322 Fed.Appx. 489 (*Oestreicher*).) Holding companies to such unpredictable standards is both unfair and unjust. Without clearly defined disclosure standards, companies may be forced to pass the cost of such risks on to consumers, harming both buyers and sellers of products in the process.

B. The Emerging Subjective and Unpredictable Legal Standards Must Be Clarified Because California Consumers and Businesses Depend on Clear Warranty Protections.

Under the standard adopted by the First District Court of Appeal, consumers may be permitted to state claims against manufacturers based on

product malfunctions that occur long after the pertinent warranty expires. As the Ninth Circuit recognized, allowing such claims "'would eliminate term limits on warranties, effectively making them perpetual or at least for the 'useful life' of the product.'" (See *Wilson*, *supra*, 668 F.3d at pp. 1141-1142, quoting *Oestreicher*, *supra*, 544 F.Supp.2d at p. 972.)

The impact of this legal standard on the consumer-manufacturer relationship is significant. As one federal court observed in analyzing California law on this issue, "the purpose of a warranty is to contractually mark the point in time during the useful life of a product when the risk of paying for repairs shifts from the manufacturer to the consumer." (*Oestreicher*, *supra*, 544 F.Supp.2d at p. 972.) Imposing liability for claims like these would lead to a world in which "a manufacturer would no longer be able to issue limited warranties" whatsoever. (*Daugherty*, *supra*, 144 Cal.App.4th at p. 829.)

Removing the "limited" nature of a warranty also disrupts manufacturers' ability to price their products fairly. Providing a definite endpoint to a manufacturer's obligation to guarantee functionality allows manufacturers to provide consumers products at prices that reflect their true risks and costs. (See generally *Abraham v. Volkswagen of America, Inc.* (2d Cir. 1986) 795 F.2d 238, 250 (explaining relationship between "predict[ed] rates of failure" with pricing, including of warranties).)

The reason for time limitations on a manufacturer's duty to disclose is sound: every product is bound to eventually fail. (See *Daugherty*, *supra*, 144 Cal.App.4th at p. 830, quotation and citation omitted ("All parts will wear out sooner or later and thus have a limited effective life.").) Warranties provide certainty by preventing a manufacturer from facing perpetual liability for such inevitable wear and tear. Because of this, courts applying California law have long recognized the importance of preserving the legal significance of warranties (see, e.g., *Oestreicher*, *supra*, 544 F.Supp.2d at p. 973): they facilitate predictability in the consumer-manufacturer relationship and permit manufacturers to fairly and accurately price products. Without clarity from California's highest court, warranties may be rendered meaningless in California due to decisions like the First District's in this case.

CONCLUSION

The relationship between companies and the public is built around certainty and predictability. California law on what manufacturers must disclose about their products to customers is plagued by inconsistency and subjectivity. California courts, including the First District Court of Appeal, are applying vastly different legal standards. Many are holding that only safety defects need to be disclosed. Others are finding that latent non-safety-related defects about a product's "central functionality" require

disclosure. Courts in both camps disagree about whether lawsuits about failures to disclose can be brought after the warranty period.

Without intervention from this Court, the situation will only get worse. To secure uniformity of decision and settle important questions of law raised by the First District's opinion and this petition, the Court should grant review.

DATED: May 4, 2021

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CERTIFICATION OF WORD COUNT

I certify that the text of this brief consists of 3,934 words (excluding tables, and this certificate) as counted by the word processing program used to generate this brief.

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PROOF OF SERVICE

Scott Nalick vs. Seagate Technology LLC

STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO

At the time of service, I was over 18 years of age and **not a party to this action**. I am employed in the County of San Francisco, State of California. My business address is Four Embarcadero Center, 17th Floor, San Francisco, CA 94111-4109.

On May 4, 2021, I served true copies of the following document(s) described as **PETITION FOR REVIEW** on the interested parties in this action as follows:

SEE ATTACHED SERVICE LIST

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on May 4, 2021, at San Francisco, California.

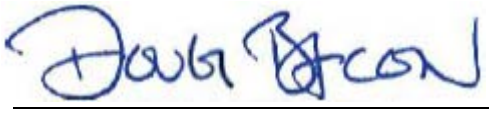

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EXHIBIT A

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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION ONE

SCOTT NALICK, Plaintiff and Appellant, v. SEAGATE TECHNOLOGY LLC, Defendant and Respondent.	A158237 (San Francisco City & County Super. Ct. No. CGC-15-547787)

Following class certification of plaintiff Scott Nalick's causes of action for violations of the California Consumer Legal Remedies Act (Civ. Code, § 1750 et seq.; CLRA) and California's unfair competition law (Bus. & Prof. Code, § 17200 et seq.; UCL), pursuant to an omissions-based theory of liability, defendant Seagate Technology LLC (Seagate) moved for summary judgment. The trial court initially denied the motion in its entirety, concluding operative law authorized Nalick to pursue the claims at issue, and triable issues of material fact existed as to the threshold of materiality for a hard drive's annual failure rate (AFR) and Seagate's knowledge of such AFR's.

The trial court subsequently reconsidered and reversed its prior decision. The court affirmed its prior conclusion that prewarranty CLRA and UCL class claims could be pursued based on Seagate's alleged failure to disclose high AFR's for its hard drives. However, it concluded on

reconsideration that the evidence only indicated a 3 percent AFR would be material to consumers, and Nalick failed to demonstrate Seagate had exclusive knowledge of such an AFR in connection with its hard drives.

On appeal, Nalick contends the trial court improperly concluded Seagate's duty to disclose did not apply to postwarranty claims under the CLRA and UCL. He further contends the record demonstrates AFR's as low as 1 percent are material, and Seagate had knowledge of significantly higher AFR's for its drives. We agree and reverse the order granting summary adjudication.

I. BACKGROUND

A. Factual Background

Seagate manufactures certain internal and external hard disk drives identified as "ST3000DM001." Seagate stated its internal drive provided "trusted performance, reliability, simplicity and capacity." Seagate's website highlighted the drives' "Proven quality and performance," and it disseminated reliability specifications that claimed its annual failure rate (AFR) was less than 1 percent. Regarding its external drives, Seagate claimed the drives would "protect" and keep "safe from loss" a user's digital life and memories.

Nalick purchased a Seagate Backup Plus Drive, which contains a ST3000DM001 drive. Nalick asserts the drive failed approximately one year after his purchase, and he could not retrieve his data.

B. Procedural Background

Nalick filed a class action complaint, alleging the ST3000DM001 drives contained a latent defect that caused them to fail at high rates resulting in

data loss.[1] The operative second amended complaint asserted Seagate's misrepresentations and omissions about the drives' reliability and failure rates violated the CLRA, the UCL, California's false advertising law (Bus. & Prof. Code, § 17500 et seq.; FAL), and the Song-Beverly Consumer Warranty Act (Civ. Code, § 1790 et seq.; Song-Beverly Act).

1. Class Certification

Following discovery, Nalick filed a motion for class certification. The motion asserted the class[2] should be certified for the alleged violation of the Song-Beverly Act, the "fraudulent" prong of the UCL based on representations regarding the drives' reliability and omissions regarding the drives' failure rates, the CLRA based on concealing the drives' failure rates, the "unfair" prong of the UCL, and the "unlawful" prong of the UCL based on the Song-Beverly Act and CLRA violations. Seagate opposed the motion.

The trial court granted the class certification motion in part, "limited to CLRA and UCL (but not the illegal prong) claims based on omissions." The trial court explained the Song-Beverly Act only applied if title passes in California, which created individualized issues and thus was not appropriate for certification. In limiting certification to claims "based on omissions," the

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[1] The complaint was also brought by another individual plaintiff, Tim Pozar. However, as part of its ruling on the class certification motion, discussed in part I.B.1., *post*, the trial court found Pozar's claims atypical and he could not serve as a class representative. Pozar was dismissed from the case and is not part of this appeal.

[2] The motion identified the class as "All citizens of California who purchased a Seagate hard disk drive with model number ST3000DM001, or who purchased an external drive that contained an ST3000DM001 drive, on or after September 4, 2011." It also identified a "Consumer Subclass." The trial court noted the class definition was both under- and over-inclusive, but could be revised to address these issues. The class definition is not at issue in this appeal.

court also concluded the record could not support a finding that the hard drives contained a latent defect or that common questions predominate as to any affirmative misrepresentations.

2. Seagate's Motion for Summary Judgment

Seagate subsequently filed a motion for summary judgment or, in the alternative, summary adjudication. In connection with the class claims at issue in this appeal, it argued Nalick failed to demonstrate either a latent defect or any affirmative misrepresentations, and his remaining omissions claims were barred by *Daugherty v. American Honda Motor Co., Inc.* (2006) 144 Cal.App.4th 824, 834 (*Daugherty*). Next, Seagate argued Nalick failed to establish a duty to disclose because there was no evidence of a sufficiently high AFR that would trigger any disclosure obligation. Likewise, Seagate argued there is no evidence of what level of AFR would be required to trigger a disclosure obligation. Seagate further asserted there is no evidence it was aware of or actively concealed any material information regarding a heightened AFR.

In support of its motion, Seagate submitted three declarations from various employees: Glen Almgren, the engineering director for Seagate's reliability group; Sek Nam "Allen" Ng, Seagate's director of customer technical support for the Americas Channel and Original Equipment Manufacturers; and David Trane, Seagate's executive engineering director of released products.

Almgren discussed the reliability demonstration testing (RDT) Seagate uses to qualify a drive for production and sale. Almgren explained the RDT process involved subjecting the drives to high stress, such as maximum workloads and increased temperatures. The data from the RDT was then used to calculate the mean time between/before failure (MTBF) and the AFR.

He asserted the drives at issue were all at or below a 1 percent AFR at the time of their release.

Ng recounted a recall issued by Apple for ST3000DM001 drives based on a cumulative return rate of around 5 or 6 percent, which would correspond to an annual return rate of "less than" 3 percent.

Trane's declaration discussed his role in reviewing and investigating return rate information on products, including the drives at issue. He summarized the cumulative return rates on the drives at issue at both 12 and 24 months, and noted many returned drives were marked as " 'no trouble found' " following postreturn testing. For the retail products, Trane noted the total retail returns over 12 months was slightly less than 4 percent, which decreased to a 2.22 percent return rate when Seagate removed the " 'no trouble found' " and " 'could not duplicate' " returns. He opined these were normal return rates for consumer products.

Seagate also submitted an expert declaration from Dr. Itamar Simonson, a professor of marketing at Stanford University. He conducted a marketing survey to determine the impact of an AFR of less than 8 percent as opposed to less than 1 percent. Participants were provided data sheets for two hypothetical hard drives with only the AFR changed. They were then asked to indicate the likelihood of buying each hard drive. Simonson stated the survey results indicated participants shown the higher AFR were not less or more likely to purchase the hard drive, and the participants' main focus was on other attributes such as capacity, ease of use, size, and brand.

Nalick opposed the motion. He argued *Daugherty* did not bar the class's omissions-based claims arising after a warranty period provided plaintiffs can prove a duty to disclose. Nalick asserted Seagate had such a duty to disclose because high AFR's were material to a reasonable consumer,

the drives' AFR's were consistently above 1 percent, and consumer demand decreases as the AFR rises above 1 percent. Nalick further asserted Seagate was aware the AFR was above 1 percent because it utilized improper methodology in its ongoing reliability testing (ORT) and provided overly optimistic projections on the impact of " 'fixes' " to known problems. He also contended the evidence demonstrated Seagate had a duty to disclose the high AFR's because of representations made by Seagate regarding the drives' reliability.

In support of his opposition, Nalick submitted three expert declarations. First, Nalick submitted a declaration by Robert L. Klein, cofounder of a market research and consulting firm. Klein critiqued the survey and report prepared by Simonson, noting it changed a single number on a two-page document without explaining the significance of that change, hid the nature of the omission by stating a failure rate of less than 8 percent, and failed to assess whether survey respondents noticed the changed AFR. Klein argued it "strains credulity under any common-sense test" that consumers would be equally likely to buy a hard drive with an AFR of 1 percent versus 8 percent.

Next, Nalick submitted an expert declaration from Stefan Boedeker, a statistician and economist employed as a managing director at the Berkeley Research Group. Boedeker developed an economic loss model to quantify the damages incurred by the class attributable to the purchase of hard drives with a higher AFR than 1 percent. He concluded, based on an empirical consumer study he conducted, an AFR above 10 percent would "quickly approach[ ] the sales price of the product and even exceed[ ] the sales price," while lower AFR's would result in economic loss at a lower rate. Boedeker calculated the estimated loss for AFR's of 3, 5, 8, and 10 percent,

corresponding to economic losses ranging from 16.9 percent to 75.4 percent, and noted "the model can be further refined to enable to quantification of economic losses for different interim AFR's."

Finally, Nalick submitted a declaration by Dr. Jon Garrett Elerath, a mechanical engineer with experience developing and evaluating reliability activities for hard disk drives. He opined the product AFR's at issue in this matter were substantially higher than 1 percent; Seagate employed flawed methodology in calculating the AFR's; the assumptions Seagate employed regarding the effectiveness of " 'fixes' " to known problems were flawed and resulted in erroneous recalculations of the product AFR's; the combination of the above issues resulted in AFR's that were actually 5 to 10 times greater than the values shown in prerelease testing; postrelease ORT resulted in AFR's regularly above 1 percent; Seagate accepted failure rates from ORT of up to 3 percent AFR and sometimes higher; Seagate employed flawed methodology to calculate postrelease AFR's and flawed analyses of ORT results; Seagate's prerelease test results were not consistent with postrelease ORT testing; and Seagate knew or should have known the true AFR's of the products were well above generally accepted industry standards.

The trial court initially denied the motion for summary judgment. In relevant part, the court concluded *Daugherty* did not completely bar Nalick's theory of liability because it only excluded claims for defects arising after the warranty period.

Next, the trial court addressed whether Seagate had knowledge of a materially heightened AFR. The court explained the evidence presented by Seagate—specifically Simonson's declaration—demonstrated the AFR's fell within the spectrum of consumer expectations.

The trial court next assessed Nalick's evidence and concluded he raised a dispute of fact as to whether an AFR higher than 1 percent would meet a reasonable consumer's expectations and whether Seagate knew its products exceeded that threshold. Specifically, the court found Klein's declaration sufficiently disputed Simonson's survey results and raised a factual dispute regarding the materiality of AFR's in excess of 1 percent. The court then noted, when applying the 1 percent AFR rate, Seagate's evidence raised triable issues of material fact by indicating at least some of the products had AFR's in excess of 1 percent. The court did not rely upon Elerath's and Boedeker's declarations and thus did not rule upon Seagate's objections to them.[3]

3. Seagate's Request for Reconsideration

Seagate subsequently requested that the court, sua sponte, reconsider its ruling on the summary judgment motion. As relevant to this appeal, Seagate argued Klein's declaration failed to create a triable issue of material fact because Klein only disputed Seagate's expert report, and Nalick presented no admissible evidence to indicate a 1 percent AFR was material to consumers. Nalick opposed the request.

The court agreed to reconsider its ruling, and the parties submitted supplemental briefs. In connection with the class claims, Seagate argued Nalick presented no admissible evidence regarding consumer expectations of AFR's. It argued he merely disputed Seagate's evidence, which was insufficient to raise a triable issue. Rather, Seagate contended, Nalick was

[3] The trial court also denied Seagate's summary judgment motion as to Nalick's individual claims. However, we do not address that portion of the ruling because it is not at issue on appeal.

required to introduce evidence that consumers considered an AFR of 1 percent to be material.

Conversely, Nalick asserted Seagate had not carried its burden because it failed to reference proof of materiality or Simonson's declaration in its separate statement. Nalick further asserted Simonson's survey was problematic and did not support his conclusions, and Nalick provided sufficient evidence of materiality so as to raise a triable issue of fact.

On reconsideration, the trial court granted Seagate's motion for summary adjudication of the class claims. Specifically, the trial court reconsidered its conclusion that a dispute of material fact existed regarding the products' heightened AFR's and Seagate's knowledge of such AFR's. First, the court noted it properly exercised its discretion to consider Simonson's declaration, despite its absence from the separate statement, because it was referenced in Seagate's opening brief and Nalick directly responded to the evidence. Next, the court affirmed its prior conclusion that Seagate carried its initial burden, noting, "The fact that a jury may reject Dr. Simonson's testimony does not render his opinion inadmissible or otherwise insufficient to satisfy Seagate's initial burden." Finally, the court reversed its prior ruling that the Klein testimony was sufficient to carry Nalick's burden because Klein did not present evidence regarding what level AFR would be material to a reasonable consumer.

The trial court then assessed the Boedeker and Elerath declarations[4] to determine whether they sufficed to carry Nalick's burden. On the question of

[4] The Boedeker declaration was an exhibit to his deposition testimony, which was taken in a parallel federal case, and included in this matter via an attorney declaration. Our reference to Boedeker's declaration includes both his declaration and his deposition testimony.

materiality, the court noted Boedeker's declaration was admissible evidence that an AFR as low as 3 percent was material to a reasonable consumer. The court noted: "Boedeker used his survey data to analyze annualized failure rates between 1% and 10% through interpolation. [Citation.] Seagate has never argued or shown that Boedeker's application of interpolation was improper. Moreover, evidence that consumers would have paid less for a product if one attribute of the product were changed is evidence that the attribute is material."

Turning to the question of Seagate's heightened knowledge, the court first noted Seagate's evidence did not demonstrate knowledge of a failure rate above 3 percent. The court then determined Elerath's declaration did not carry Nalick's burden because "even construing Dr. Elerath's declarations liberally they do not contain a reasoned explanation connecting the factual predicates to the ultimate conclusions." The court thus granted summary adjudication of Nalick's class claims.

Nalick subsequently appealed from the court's order.

II. DISCUSSION

Nalick contends the trial court improperly granted summary adjudication of the class claims because he adequately raised triable issues of material fact regarding Seagate's duty to disclose allegedly higher AFR's for those hard drives at issue. We agree and reverse.

A. Standard of Review

" 'Summary adjudication motions are "procedurally identical" to summary judgment motions. [Citation.] A summary judgment motion "shall be granted if all the papers submitted show that there is no triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." [Citation.] To be entitled to judgment as a matter of law, the

moving party must show by admissible evidence that the "action has no merit or that there is no defense" thereto. [Citation.] A defendant moving for summary judgment meets this burden by presenting evidence demonstrating that one or more elements of the cause of action cannot be established or that there is a complete defense to the action. [Citations.] Once the defendant makes this showing, the burden shifts to the plaintiff to show that a triable issue of material fact exists as to that cause of action or defense. [Citations.] Material facts are those that relate to the issues in the case as framed by the pleadings. [Citation.] There is a genuine issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof.' " (*Duffey v. Tender Heart Home Care Agency, LLC* (2019) 31 Cal.App.5th 232, 240–241 (*Duffey*).)

" 'The trial court's ruling on a motion for summary adjudication, like that on a motion for summary judgment, is subject to this court's independent review.' [Citation.] 'In performing our review, we view the evidence in a light favorable to the losing party . . . , liberally construing [his] evidentiary submission while strictly scrutinizing the moving party's own showing and resolving any evidentiary doubts or ambiguities in the losing party's favor.' " (*Duffey*, *supra*, 31 Cal.App.5th at p. 241.) The court does not weigh evidence, but instead considers whether the evidence creates a triable issue of fact. (*Andrews v. Foster Wheeler LLC* (2006) 138 Cal.App.4th 96, 113.)

B. Expert Declarations

" '[A]n expert declaration is admissible to support or defeat summary judgment if the expert's testimony would be admissible at trial in accordance with Evidence Code section 720. An expert may testify to an opinion on a

subject "that is sufficiently beyond common experience that the opinion of an expert would assist the trier of fact." (Evid. Code, § 801, subd. (a).)' " (*Fernandez v. Alexander* (2019) 31 Cal.App.5th 770, 779 (*Fernandez*).)

" 'The same rules of evidence that apply at trial also apply to the declarations submitted in support of and in opposition to motions for summary judgment. Declarations must show the declarant's personal knowledge and competency to testify, state facts and not just conclusions, and not include inadmissible hearsay or opinion.' " (*Fernandez*, *supra*, 31 Cal.App.5th at p. 779.) Pursuant to Evidence Code section 801, a trial court acts as a gatekeeper and should exclude any expert opinion that is based upon assumptions of fact without evidentiary support, or which involve guesses or surmises. (*Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747, 770 (*Sargon*).) Evidence Code section 802 permits a court to inquire into both the type of material on which an expert relies and whether that material actually supports the expert's reasoning. (*Sargon*, at p. 771.) In exercising its role as a gatekeeper, the trial court should exclude expert opinion testimony "that is (1) based on matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or (3) speculative." (*Id*. at pp. 771–772; *Fernandez*, at p. 782 [liberal construction does not "eliminate the need for some form of 'reasoned explanation,' and it remains the case that any inferences must 'reasonably be derived from' the declaration"].) The trial court's focus should be " 'solely on principles and methodology, not on the conclusions that they generate.' " (*Sargon*, at p. 772.)

An appellate court reviews for abuse of discretion a trial court's ruling excluding or admitting expert testimony. (*Sargon*, *supra*, 55 Cal.4th at p. 773.)

C. Seagate's Motion for Summary Judgment or, Alternatively, Summary Adjudication

Nalick asserts the trial court erred in granting Seagate's motion on two grounds. First, Nalick contends the trial court improperly interpreted *Daugherty*, *supra*, 144 Cal.App.4th 824, as barring any omissions liability after the expiration of the warranty period. Second, Nalick contends his submitted evidence regarding materiality, Seagate's knowledge, and Seagate's representations regarding reliability adequately created genuine issues of material fact sufficient to defeat summary judgment.

1. Duty to Disclose Under the CLRA and UCL

Civil Code section 1770, subdivision (a) makes unlawful certain "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that results in the sale or lease of goods or services to any consumer . . . ." (See *Daugherty*, *supra*, 144 Cal.App.4th at p. 833.) A deceptive act includes the misrepresentation or omission of a material fact. (*McAdams v. Monier, Inc.* (2010) 182 Cal.App.4th 174, 185.) For an omission to be actionable under the CLRA, it must be contrary to a representation actually made by the defendant, or the defendant must have had a duty to disclose the omitted fact. (*Daugherty*, at p. 835.) Moreover, the plaintiff asserting a CLRA claim must show the misrepresentation or omission was likely to deceive a reasonable consumer. (*Consumer Advocates v. Echostar Satellite Corp.* (2003) 113 Cal.App.4th 1351, 1361–1362.)

Similarly, "[c]onduct violating the UCL includes 'any unlawful, unfair or fraudulent business act or practice . . . .' (Bus. & Prof. Code, § 17200.) By

proscribing unlawful business practices, the UCL borrows violations of other laws and treats them as independently actionable. In addition, practices may be deemed unfair or deceptive even if not proscribed by some other law." (*Daugherty*, *supra*, 144 Cal.App.4th at p. 837.) " 'A business practice is "fraudulent" within the meaning of [the UCL] if it is "likely to deceive the public. [Citations.] It may be based on representations to the public which are untrue, and ' "also those which may be accurate on some level, but will nonetheless tend to mislead or deceive. . . . A perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under" ' the UCL. [Citations.] The determination as to whether a business practice is deceptive is based on the likely effect such practice would have on a reasonable consumer." ' " (*Rubenstein v. The Gap, Inc.* (2017) 14 Cal.App.5th 870, 876–877.) " '[A] business practice is "unfair" if (1) the consumer injury is substantial; (2) the injury is not outweighed by any countervailing benefits to consumers or competition; and (3) the injury could not reasonably have been avoided by consumers themselves.' " (*Id.* at p. 880.)

Seagate contends *Daugherty* bars any omissions-only theory of liability in the absence of a defect, safety risk, or affirmative misrepresentation. In *Daugherty*, *supra*, 144 Cal.App.4th 824, the Second Appellate District addressed whether American Honda Motor Co., Inc. (Honda) had a duty to disclose an engine defect that could cause an oil leak malfunction. The court explained, "although a claim may be stated under the CLRA in terms constituting fraudulent omissions, to be actionable the omission must be contrary to a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose." (*Id.* at p. 835.) The court first noted the plaintiff did not allege any representation regarding the

engine apart from its express warranties, and the engine "functioned as warranted." (*Id.* at pp. 836, 835.) Next, the court rejected the plaintiff's argument that Honda had a duty to disclose because it knew of " 'unreasonable risk.' " (*Id.* at p. 836.) The court explained the " 'unreasonable risk' alleged is merely the risk of 'serious potential damages'—namely, the cost of repairs . . . . The complaint is devoid of factual allegations showing any instance of physical injury or any safety concerns posed by the defect."[5] (*Daugherty*, at p. 836.)

Contrary to Seagate's position, *Daugherty* did not bar omissions-only theories. Rather, *Daugherty* explained, as a general rule, a manufacturer cannot be liable for a failure to disclose unless such omission (1) is "contrary to a representation actually made by the defendant" or (2) pertains to a "fact the defendant was obliged to disclose." (*Daugherty*, *supra*, 144 Cal.App.4th at p. 835.) Courts have uniformly applied this general rule.[6] (See, e.g.,

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[5] The court also rejected the UCL claim because the alleged failure to disclose did not involve a fact Honda was required to disclose because the only expectation Honda's buyers could have was that the engine would function for the length of Honda's express warranty. (*Daugherty*, *supra*, 144 Cal.App.4th at p. 838.) It also rejected the UCL claim on the "unlawful" and "unfair" prongs because there was no underlying statutory violation and the alleged injury to consumers is not substantial. (*Daugherty*, at pp. 837, 839.)

[6] Some federal courts have disagreed amongst themselves on whether the rule should be applied to claims arising after the expiration of a warranty period. (Compare *Daniel v. Ford Motor Co.* (E.D.Cal. May 18, 2016, Civ. No. 2:11-02890 WBS EFB) 2016 WL 2899026 at p. *2 [test applies to defects that manifest after expiration of the warranty period] with *Williams v. Yamaha Motor Co. Ltd.* (9th Cir. 2017) 851 F.3d 1015, 1029 ["the fact that the alleged defect concerns premature, but usually post-warranty, onset of a natural condition raises concerns about the use of consumer fraud statutes to impermissibly extend a product's warranty period"].)

Gutierrez v. Carmax Auto Superstores California (2018) 19 Cal.App.5th 1234, 1258 (*Gutierrez*); *Rubenstein v. The Gap, Inc.*, *supra*, 14 Cal.App.5th at p. 881.) In fact, the two other cases cited by Seagate, *Bardin v. DaimlerChrysler Corp.* (2006) 136 Cal.App.4th 1255 (*Bardin*) and *Buller v. Sutter Health* (2008) 160 Cal.App.4th 981, both recognize the viability of omission-based claims when there exists a duty to disclose. In *Bardin*, however, the court rejected the UCL and CLRA claims because the complaint failed to allege facts showing defendant was " 'bound to disclose' " its use of tubular steel exhaust manifolds because customers had no expectation or assumption regarding the materials used by the defendant. (*Bardin*, at pp. 1275–1276.) Similarly, in *Buller*, the court explained the complaint did not allege the defendants had an affirmative duty to disclose the availability of a discount because patients are unlikely to expect such discounts. (*Buller*, at p. 988.)

The question before this court is thus whether Seagate had a duty to disclose the allegedly higher failure rates of its drives. Courts are split as to whether the duty to disclose requires a "safety hazard" showing. The Ninth Circuit, in *Wilson v. Hewlett-Packard Co.* (9th Cir. 2012) 668 F.3d 1136,[7] commented that unless liability for failure to disclose a defect is limited to unreasonable safety risks, "the '[f]ailure of a product to last forever would become a "defect," a manufacturer would no longer be able to issue limited warranties, and product defect litigation would become as widespread as manufacturing itself.' " (*Wilson*, at pp. 1141–1142.) *Daugherty* also implicitly adopted the safety hazard position as to claims arising from an alleged duty

[7] While federal cases interpreting state law are persuasive, they are, of course, not binding on this court. (9 Witkin, Cal. Procedure (5th ed. 2020) Appeal, § 507.)

to disclose when it noted, "The complaint is devoid of factual allegations showing any instance of physical injury or any safety concerns posed by the defect." (*Daugherty*, *supra*, 144 Cal.App.4th at p. 836.)

However, two post-*Daugherty* California Court of Appeal cases—*Rutledge v. Hewlett-Packard Co.* (2015) 238 Cal.App.4th 1164 (*Rutledge*) and *Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249 (*Collins*)—cast doubt on whether plaintiffs must identify a "safety hazard" to state a claim for failing to disclose. These cases instead focus on whether the defect is "material" and central to the product's functionality. In *Collins*, the plaintiffs filed a class action alleging the defendant failed to disclose a microchip defect, which resulted in the computers improperly writing data to, and reading data from, floppy disks and related data corruption. (*Collins*, at p. 253.) In addressing whether the complaint stated claims for violating both the CLRA and UCL, the court explained "deceptive practices . . . include the concealment or suppression of material facts" because they encompass, in part, "the suppression of a fact by one who is bound to disclose it." (*Collins*, at p. 255.) The court further explained "a fact is deemed 'material,' and obligates an exclusively knowledgeable defendant to disclose it, if a ' "reasonable [consumer]" ' would deem it important in determining how to act in the transaction at issue." (*Id.* at p. 256.) The *Collins* court concluded the plaintiffs sufficiently alleged the materiality of the microchip defect because "the floppy disk was central to the function of a computer as a computer." (*Id.* at p. 258.)

Likewise, in *Rutledge*, a class action was brought alleging Hewlett-Packard Co. (HP) manufactured certain notebook computers containing inverters that HP "knew would likely fail and cause display screens to dim and darken at some point before the end of the notebook's useful life."

(*Rutledge*, *supra*, 238 Cal.App.4th at p. 1168.) The plaintiffs argued "HP had a duty to disclose the material fact that the inverters were defective in manufacturing and installation" because "consumers expect a notebook computer to be portable, and a properly working display screen is essential to the notebook's portability." (*Id.* at p. 1173.) In response, HP argued manufacturers do not have a duty to disclose "a product defect absent an unreasonable risk of 'physical injury or safety concerns,' " which was not present. (*Id.* at pp. 1173–1174.) The court rejected HP's argument. Although the HP computers did not immediately malfunction like those in *Collins*, the plaintiffs alleged the "inverters were defective in manufacturing and installation at the time the notebooks were sold" and thus were " 'substantially certain to fail' " at some point in the future. (*Rutledge*, at p. 1175.) The plaintiffs sufficiently alleged this defect to be "material, because it affected the performance of the display screens of notebook computers." (*Ibid.*)

Both *Collins* and *Rutledge* emphasized "neither *Daugherty* nor *Bardin* preclude a duty to disclose material information known to a manufacturer and concealed from a consumer." (*Rutledge*, *supra*, 238 Cal.App.4th at p. 1174; accord *Collins*, *supra*, 202 Cal.App.4th at p. 258.) Rather, these cases found *Daugherty* and *Bardin* distinguishable as involving nonmaterial defects. They noted the engine defect in *Daugherty* was due to normal use and wear and did not manifest, if at all, until long after the warranty limits. (*Collins*, at pp. 256–257; *Rutledge*, at p. 1175.) *Collins* likewise distinguished *Bardin* by noting "the composition of the exhaust manifolds was an insignificant matter" and consumers had no expectations about the composition. (*Collins,* at p. 257; *Rutledge*, at p. 1175.)

There are certainly points of distinction between the present case and *Rutledge* and *Collins*. *Collins*, in particular, involved computers that were never complete and operational due to the alleged microchip defect at the time they were sold. (*Collins*, *supra*, 202 Cal.App.4th at p. 257.) But these cases provide important guidance on when a defendant may be subject to a duty to disclose.

In *Hodsdon v. Mars, Inc.* (9th Cir. 2018) 891 F.3d 857 (*Hodsdon*), the Ninth Circuit summarized the holdings in *Rutledge* and *Collins*, noting those cases sanctioned an "omission claim when: the plaintiff alleges that the omission was material; second, the plaintiff must plead that the defect was central to the product's function; and third, the plaintiff must allege one of the four *LiMandri*[8] factors." (*Hodsdon*, at p. 863, citing *Collins*, 202 Cal.App.4th at pp. 255–256.) The *LiMandri* factors are as follows: " '(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*, *supra*, 52 Cal.App.4th at p. 336.) The *Hodsdon* court relied on these opinions to conclude an omission only needed to relate to the central functionality of the products rather than constitute a safety hazard. (*Hodsdon*, at p. 863.) Recently, the Fifth Appellate District acknowledged omissions of material fact are actionable under the CLRA and UCL. (See *Gutierrez*, *supra*, 19 Cal.App.5th at pp. 1258, 1266.) The *Gutierrez* court considered whether the duty to disclose safety concerns constituted an additional, "*independent* duty of disclosure," but

[8] *LiMandri v. Judkins* (1997) 52 Cal.App.4th 326 (*LiMandri*).

ultimately concluded it was merely "a specific application of the duty to disclose" when one of the *LiMandri* factors are met. (*Gutierrez*, at pp. 1258, 1260.)

We follow *Collins*, *Rutledge*, and *Hodsdon* in concluding omission claims are viable provided they relate to the product's central functionality. However, we are cognizant of the concerns about undermining warranties and thus emphasize the necessary limits in assessing whether a defect is central to functionality. *Collins*, for example, allowed claims to proceed based on allegations that a chip error resulted in corrupting data on the user's floppy disk. (*Collins*, *supra*, 202 Cal.App.4th at p. 258.) In *Rutledge*, laptop screens failed entirely, thus requiring them to be connected to an external monitor and undermining the portability of laptops. (*Rutledge*, *supra*, 238 Cal.App.4th at p. 1175.) In both instances, the defects either totally or significantly impacted the product's primary use. Conversely, the Northern District of California concluded a failure to include fans and vents in certain computers, resulting in debris causing permanent dark smudging on screens, was not central to a computer's functionality. (*Ahern v. Apple Inc.* (N.D.Cal. 2019) 411 F.Supp.3d 541, 568.) Likewise, security vulnerabilities in a microprocessor did not give rise to a duty to disclose because "the allegations do not go to the central functionality of a microprocessor and do not show that the chips were incapable of use." (*In re Intel Corp. CPU Mktg., Sales Practices & Prod. Liab. Litig.* (D.Or. Mar. 27, 2020, No. 3:18-md-2828-SI) 2020 WL 1495304 at p. *17.)

Here, the alleged defect is the premature failure of the hard drives. Seagate does not appear to contend the drives that prematurely fail have any remaining functionality. Accordingly, the alleged high rate of premature failure goes to the heart of the drive's functionality. Nalick's pre- and

postwarranty claims may proceed provided he can meet the *LiMandri* test and demonstrate materiality and exclusive knowledge by Seagate.[9]

With regard to the *LiMandri* test, Nalick argues he can demonstrate a duty to disclose arising from partial representations made by Seagate. Seagate disagrees, arguing the trial court did not certify class claims based on affirmative misrepresentations. Undoubtedly, the class certification order expressly limited class claims to those "based on omissions." However, omissions claims—i.e., those based on a failure to disclose—can encompass situations "when the defendant makes partial representations that are misleading because some other material fact has not been disclosed." (*Collins*, *supra*, 202 Cal.App.4th at p. 255, citing *LiMandri*, *supra*, 52 Cal.App.4th at p. 336; see also *Gutierrez*, *supra*, 19 Cal.App.5th at p. 1260; *Hodsdon*, *supra*, 891 F.3d at p. 863.) And the trial court's class certification order acknowledged as much by restating Nalick's omission-based theory of liability as follows: " '[P]roof of liability turns on whether the average consumer purchasing the Drive would be likely to be deceived by Seagate's representations about the Drives' reliability and its omission of the Drives' failure rates. Because Seagate uniformly concealed the true failure rates of the Drive—*while prominently featuring the Drive's reliability on its website,*

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[9] Seagate also argues any claims arising during the warranty period should be barred because, unlike in *Daugherty*, Nalick did not assert any claim based on the language of Seagate's warranty. But Seagate does not cite any authority to support its position that the CLRA and UCL cannot encompass claims arising during a warranty period. To the contrary, the fact that claims occurred during the warranty period was an express factor in the *Collins* court decision. (See *Collins*, *supra*, 202 Cal.App.4th at p. 257 ["The complaint before us is unlike *Daugherty* because it does not attempt an end-around the warranty laws. In the complaint, plaintiffs allege: 'Both named Plaintiffs suffered data loss and missing files when using their floppy disk drive, during and before the warranty expired.' "].)

in its marketing, and on its boxes—the Class was exposed to the same deceptive course of conduct.' " (Italics added.) While the trial court did not certify class claims based on a latent defect or affirmative misrepresentation, nothing in its order limited how Nalick may prove his omissions-based claims.

2. Materiality and Exclusive Knowledge

We next turn to whether the record reflects a genuine issue of material fact regarding at what level AFR's become material and whether Seagate had exclusive knowledge of such AFR's.

Expert declarations opposing summary judgment must be " 'liberally construed.' " (*Fernandez*, *supra*, 31 Cal.App.5th at p. 779.) However, a liberal construction does not "eliminate the need for some form of 'reasoned explanation,' and it remains the case that any inferences must 'reasonably be derived from' the declaration." (*Id*. at p. 782.) Trial courts may inquire into both the type of material on which an expert relies and whether that material actually supports the expert's reasoning. (*Sargon*, *supra*, 55 Cal.4th at p. 771.) The trial court's focus should be " 'solely on principles and methodology, not on the conclusions that they generate.' " (*Id*. at p. 772.) An appellate court reviews for abuse of discretion a trial court's ruling excluding or admitting expert testimony. (*Id*. at p. 773.)

Nalick does not dispute the trial court's holding that Seagate met its initial burden by showing a reasonable consumer would not find any difference between an AFR of less than 1 percent and an AFR of 8 percent. Rather, Nalick asserts the evidence he presented creates a genuine issue of material fact as to whether failure rates in excess of 1 percent were material to a reasonable consumer.

Nalick first argues industry standards and Seagate's own reliability specifications for hard disk drives require an AFR of 1 percent or less. While possibly true, we agree with the trial court that evidence regarding industry standards for AFR's and Seagate's reliability specifications do not alone provide evidence of consumer expectations. Likewise, we agree with the trial court that Nalick's criticism of the methodology Seagate used in its consumer study to conclude an 8 percent AFR was immaterial to consumers does not, by itself, provide evidence of what AFR would be material to a reasonable consumer.

However, we disagree in part with the trial court's interpretation of Boedeker's declaration. The trial court noted Boedeker's opinions were based on a consumer survey, data from which was used to quantify the drop in consumer demand for hard drives with heightened AFR's. The court further noted the lowest AFR for which Boedeker offered a quantitative opinion on economic loss was 3 percent, and it thus determined his declaration demonstrated "an [AFR] of as low as 3% is material to a reasonable consumer, but is not evidence of materiality as to any lower annual failure rate." In reaching its conclusion, the trial court rejected Seagate's argument that Boedeker did not measure the materiality of AFR's. It noted Boedeker's survey addressed AFR's at various increments, Boedeker used this data to analyze AFR's "between 1% and 10% through interpolation," Boedeker's method of interpolation was appropriate, and "evidence that consumers would have paid less for a product if one attribute of the product were changed is evidence that the attribute is material."

The trial court did not abuse its discretion in concluding Boedeker's declaration was admissible and affirming his methodology to show evidence of materiality. (See *Sargon*, *supra*, 55 Cal.4th at p. 772.) Nor does Seagate

assert the trial court abused its discretion in doing so. However, the trial court exceeded its role by adopting its own interpretation of Boedeker's conclusions. (See *ibid.*) The trial court provided no explanation for its determination that only AFR's at or above 3 percent are material. Perhaps the trial court utilized 3 percent because that was the lowest AFR for which Boedeker provided a quantitative number for economic loss. However, Boedeker's declaration did not conclude an AFR of 3 percent was the first level at which consumers would experience economic loss. To the contrary, Boedeker expressly stated "the model can be further refined to enable the quantification of economic losses for different interim AFRs," including "the specification of economic losses for all incremental AFRs between 1% and 50%." Boedeker's declaration thus indicates consumers experience some degree of economic loss for AFR's above 1 percent, and—per the methodology approved by the trial court—that economic loss corresponds to a degree of materiality. Additionally, Boedeker found "the [AFR] is by far the most important attribute" for survey participants. While a jury may ultimately conclude only a certain level of economic loss evidences materiality, we must interpret Boedeker's declaration liberally. (See *Fernandez*, *supra*, 31 Cal.App.5th at p. 779.) Accordingly, Boedeker's declaration provides sufficient evidence of materiality for AFR's above 1 percent to raise a genuine issue of material fact.

Because Nalick has offered evidence to raise a genuine issue of material fact as to whether AFR's over 1 percent are material, we need not resolve the parties' dispute regarding Elerath's declaration. Putting aside Elerath's declaration, the record contains sufficient evidence to raise a factual dispute regarding whether Seagate had knowledge of hard drives with AFR's over 1 percent. As noted by the trial court in its initial order on summary

judgment, the Trane and Ng declarations submitted by Seagate "identify return rates that were in excess of 1% per year over the first two years, even, in Trane's case, when 'No Trouble Found' and 'Could Not Duplicate' returns are excluded." The trial court's initial order thus correctly determined "a trier of fact presented with Seagate's evidence could conclude that at least some of the drive families at issue here had AFR's in excess of 1% and that Seagate knew of those AFR's as a result of return data."

In sum, Boedeker's declaration sufficiently raises a triable issue as to whether AFR's over 1 percent are material to a reasonable consumer, and Seagate's own evidence raises a triable issue as to whether it had knowledge of AFR's above 1 percent. Together, Nalick has adequately disputed Seagate's motion for summary adjudication of the class claims.

III. DISPOSITION

The trial court's order granting summary adjudication is reversed, and the matter is remanded for further proceedings consistent with this opinion. Plaintiff Scott Nalick may recover his costs on appeal. (Cal. Rules of Court, rule 8.278(a)(1), (2).)

MARGULIES, J.

WE CONCUR:

HUMES, P. J.

SANCHEZ, J.

A158237
Nalick v. Seagate Technology LLC

STATE OF CALIFORNIA
Supreme Court of California

PROOF OF SERVICE

STATE OF CALIFORNIA
Supreme Court of California

Case Name: **Scott Nalick vs. Seagate Technology LLC**
Case Number: **TEMP-80129BS5**
Lower Court Case Number:

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Date

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Signature

Popovic, Neil (132403)
Last Name, First Name (PNum)

Sheppard Mullin Richter & Hampton LLP
Law Firm

EXHIBIT 2

Court of Appeal, First Appellate District, Division One - No. A158237

S268227

IN THE SUPREME COURT OF CALIFORNIA

En Banc

SCOTT NALICK, Plaintiff and Appellant,

v.

SEAGATE TECHNOLOGY LLC, Defendant and Respondent.

The petition for review is denied.
The request for an order directing publication of the opinion is denied.

CANTIL-SAKAUYE
Chief Justice

EXHIBIT 3

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
In Re Theos Dark Chocolate Litigation, 2024 WL 4336631 (N.D. Cal. Sept. 27, 2024)	X	X
J.J. v. Ashylnn Marketing Group, Inc., 2024 WL 4257646 (S.D. Cal. Sept. 20, 2024)	X	X
Castillo v. Prime Hydration LLC, --- F. Supp. 3d ----, 2024 WL 4133815 (N.D. Cal. 2024)	X	X
Forrett v. West Thomas Partners LLC, 2024 WL 3963844 (N.D. Cal. Aug. 26, 2024)	X	X
Smith v. Intel Corp., --- F. Supp. 3d ----, 2024 WL 3834706 (N.D. Cal. 2024)	X	X
Grausz v. Hershey Co., 2024 WL 3836100 (S.D. Cal. Aug. 15, 2024)	X	X
Krystofiak v. BellRing Brands, Inc., --- F. Supp. 3d ----, 2024 WL 3012801 (N.D. Cal. 2024)	X	X
Hedrick v. BSH Home Appliances Corp., 2024 WL 2190984 (C.D. Cal. May 14, 2024)	X	X
R.C. v. Walgreen Co., --- F. Supp. 3d ----, 2024 WL 2263395 (C.D. Cal. 2024)	X	X
Hayden v. Bob's Red Mill Natural Foods, Inc., 2024 WL 1643696 (N.D. Cal. Apr. 16, 2024)	X	X
Ramirez v. Bank of America, N.A., 2024 WL 3550393 (N.D. Cal. Apr. 3, 2024)	X	

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Zeller v. Optavia LLC, 2024 WL 1207461 (S.D. Cal. Mar. 14, 2024)		X
Paperno v. Whirlpool Corp., 2024 WL 1091192 (N.D. Cal. Mar. 13, 2024)	X	X
Hammerling v. Google, LLC, 2024 WL 937247 (9th Cir. Mar. 5, 2024)	X	X
B.K. v. Eisenhower Medical Center, --- F. Supp. 3d ----, 2024 WL 878100 (C.D. Cal. 2024)	X	X
Grausz v. Hershey Co., 713 F. Supp. 3d 818 (S.D. Cal. 2024)	X	X
Mendoza v. Procter and Gamble Co., 707 F. Supp. 3d 932 (C.D. Cal. 2023)	X	X
Clark v. InComm Financial Services, Inc., 2023 WL 8522952 (C.D. Cal. Dec. 1, 2023)	X	X
Rodriguez v. Mondelēz Global LLC, 703 F. Supp. 3d 1191 (S.D. Cal. 2023)	X	X
Neu v. FCA US LLC, 2023 WL 10406710 (C.D. Cal. Nov. 13, 2023)	X	X
In re Intel Corp. CPU Marketing, Sales Practices & Products Liability Litigation, 2023 WL 7211394 (9th Cir. Nov. 2, 2023)	X	X
Farmer v. BarkBox, Inc., 2023 WL 8522984 (C.D. Cal. Oct. 6, 2023)		X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
MacDougall v. American Honda Co., Inc., 2023 WL 9687349 (C.D. Cal. Oct. 3, 2023)	X	X
Sanchez v. Navy Federal Credit Union, 2023 WL 6370235 (C.D. Cal. Aug. 14, 2023)	X	
Clark v. InComm Financial Services, Inc., 2023 WL 5167364 (C.D. Cal. July 17, 2023)	X	X
Goodwin v. Walgreens Co., 2023 WL 4037175 (C.D. Cal. June 14, 2023)	X	X
McKay v. Sazerac Co., 2023 WL 3549515 (N.D. Cal. May 17, 2023)	X	X
In re Natera Prenatal Testing Litigation, 664 F. Supp. 3d 995 (N.D. Cal. 2023)	X	X
Brand v. KSF Acquisition Corp., 2023 WL 3225409 (S.D. Cal. Mar. 17, 2023)	X	X
Kravehrad v. Vizio, Inc., 2023 WL 2558535 (C.D. Cal. Jan 26, 2023)	X	X
Bazarganfard v. Club 360 LLC, 2023 WL 2376290 (C.D. Cal. Jan. 24, 2023)	X	X
Freund v. HP, Inc., 2023 WL 187506 (N.D. Cal. Jan. 13, 2023)	X	X
Rice v. Kimberly-Clark Corp., 2022 WL 16804522 (E.D. Cal. Nov. 8, 2022)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Brown v. Madison Reed, Inc., 622 F. Supp. 3d 786 (N.D. Cal. 2022)	X	X
Kravehrad v. Vizio, Inc., 2022 WL 16859975 (C.D. Cal. Aug. 11, 2022)	X	X
Spindler v. General Motors, LLC, 616 F. Supp. 3d 943 (N.D. Cal. 2022)	X	X
McKinney v. Corsair Gaming, Inc., 2022 WL 2820097 (N.D. Cal. July 19, 2022)	X	X
Hammerling v. Google LLC, 615 F. Supp. 3d 1069 (N.D. Cal. 2022)	X	X
Barrett v. Apple Inc., 2022 WL 2119131 (N.D. Cal. June 13, 2022)	X	X
Smith v. Allianz Service Co., 2022 WL 4596591 (C.D. Cal. June 10, 2022)	X	
In re Apple Processor Litigation, 2022 WL 2064975 (N.D. Cal. June 8, 2022)	X	X
Klaehn v. Cali Bamboo LLC, 2022 WL 1830685 (9th Cir. June 3, 2022)	X	X
Bettles v. Toyota Motor Corp., 2022 WL 1619337 (C.D. Cal. May 23, 2022)	X	X
Taleshpour v. Apple, Inc., 2022 WL 1577802 (9th Cir. May 19, 2022)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Antonyan v. Ford Motor Co., 2022 WL 1299964 (C.D. Cal. Mar. 30, 2022)	X	X
Flores-Mendez v. Zoosk, Inc., 2022 WL 357500 (N.D. Cal. Feb. 7, 2022)	X	
Singh v. Google LLC, 2022 WL 94985 (N.D. Cal. Jan. 10, 2022)	X	
Oddo v. United Technologies Corp., 2022 WL 577663 (C.D. Cal. Jan. 3, 2022)	X	X
Quackenbush v. American Honda Motor Co., 2021 WL 6116949 (N.D. Cal. Dec. 27, 2021)		X
Romoff v. General Motors LLC, 574 F. Supp. 3d 782 (S.D. Cal. 2021)	X	X
Sheets v. Lippert Components, Inc., 2021 WL 4951899 (E.D. Cal. Oct. 25, 2021)	X	X
Johnson v. Glock, Inc., 2021 WL 6804234 (N.D. Cal. Sept. 22, 2021)	X	X
Kelin v. Ljubljana Inter Auto d.o.o., 2021 WL 6424917 (C.D. Cal. Sept. 13, 2021)	X	X
Garlough v. FCA US LLC, 2021 WL 4033177 (E.D. Cal. Sept. 3, 2021)	X	X
Taleshpour v. Apple Inc., 549 F. Supp. 3d 1033 (N.D. Cal. 2021)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Harris v. LSP Products Group, Inc., 2021 WL 2682045 (E.D. Cal. June 30, 2021)	X	X
Klaehn v. Cali Bamboo, LLC, 2021 WL 3044166 (S.D. Cal. June 14, 2021)	X	X
Johnson v. Glock, Inc., 2021 WL 1966692 (N.D. Cal. May 17, 2021)	X	X
In re Toyota RAV4 Hybrid Fuel Tank Litigation, 534 F. Supp. 3d 1067 (N.D. Cal. 2021)	X	X
Burchfield v. Prestige Consumer Healthcare, Inc., 534 F. Supp. 3d 1192 (C.D. Cal. 2021)	X	X
Taleshpour v. Apple Inc., 2021 WL 1197494 (N.D. Cal. Mar. 30, 2021)	X	X
Eidmann v. Walgreen Co., 522 F. Supp. 3d 634 (N.D. Cal. 2021)	X	X
Johnson v. Glock, Inc., 2021 WL 428635 (N.D. Cal. Feb. 8, 2021)	X	X
Klaehn v. Cali Bamboo, LLC, 2021 WL 5549226 (S.D. Cal. Jan. 22, 2021)	X	X
In Re Samsung Galaxy Smartphone Marketing & Sales Practices Litigation, 2020 WL 7664461 (N.D. Cal. Dec. 24, 2020)	X	X
Anderson v. Apple, Inc., 500 F. Supp. 3d 993 (N.D. Cal. 2020)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
C.W. v. Epic Games, Inc., 2020 WL 5257572 (N.D. Cal. Sept. 3, 2020)		X
Rhodeman v. Ocwen Loan Servicing, LLC, 2020 WL 4727289 (C.D. Cal. July 30, 2020)	X	
Adams v. Starbucks Corp., 2020 WL 4196248 (C.D. Cal. July 9, 2020)	X	X
Carrillo v. BMW of North America, LLC, 2020 WL 12028896 (C.D. Cal. June 8, 2020)		X
Oddo v. Arocaire Air Conditioning and Heating, 2020 WL 5267917 (C.D. Cal. May 18, 2020)	X	X
Dang v. Samsung Electronics Co., 803 F. App'x 137 (9th Cir. 2020)	X	X
Sloan v. General Motors, LLC, 2020 WL 1955643 (N.D. Cal. Apr. 23, 2020)	X	
Carrillo v. BMW of North America, LLC, 2020 WL 12028895 (C.D. Cal. Mar. 25, 2020)		X
Olosoni v. HRB Tax Group, Inc., 2020 WL 11563095 (N.D. Cal. Mar. 24, 2020)	X	X
Wallace v. SharkNinja Operating, LLC, 2020 WL 1139649 (N.D. Cal. Mar. 9, 2020)	X	
Garcia v. Harley-Davidson Motor Co., 2019 WL 6050768 (N.D. Cal. Nov. 15, 2019)	X	

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Rhodeman v. Ocwen Loan Servicing, LLC, 2019 WL 5955368 (C.D. Cal. Nov. 12, 2019)	X	
Ahern v. Apple, Inc., 411 F. Supp. 3d 541 (N.D. Cal. 2019)	X	
Sosenko v. LG Elec. U.S.A., Inc., 2019 WL 6118355 (C.D. Cal. Aug. 29, 2019)	X	X
Cappello v. Walmart Inc., 394 F. Supp. 3d 1015 (N.D. Cal. 2019)	X	
Knowles v. Arris International PLC, 2019 WL 3934781 (N.D. Cal. Aug. 20, 2019)	X	X
Nava v. Kobe Steel, Ltd., 2019 WL 4729540 (N.D. Cal. July 18, 2019)	X	X
Patterson v. RW Direct, Inc., 382 F. Supp. 3d 938 (N.D. Cal. 2019)	X	X
Espineli v. Toyota Motor Sales, U.S.A., Inc., 2019 WL 2249605 (E.D. Cal. May 24, 2019)	X	X
In re Apple Inc. Device Performance Litigation, 386 F. Supp. 3d 1155 (N.D. Cal. 2019)	X	X
Grossman v. Schell & Kampeter, Inc., 2019 WL 1298997 (E.D. Cal. Mar. 21, 2019)	X	X
Browning v. Unilever United States, Inc., 2018 WL 6615064 (C.D. Cal. Dec. 17, 2018)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Barrera v. Samsung Electronics America, Inc., 2018 WL 10759180 (C.D. Cal. Dec. 7, 2018)	X	X
Dang v. Samsung Electronics Co., 2018 WL 6308738 (N.D. Cal. Dec. 3, 2018)	X	X
Blissard v. FCA US LLC, 2018 WL 6177295 (C.D. Cal. Nov. 9, 2018)	X	X
Thornton v. Micro-Star International Co., 2018 WL 5291925 (C.D. Cal. Oct. 23, 2018)	X	X
In re Apple Inc. Device Performance Litigation, 347 F. Supp. 3d 434 (N.D. Cal. 2018)	X	X
Beyer v. Symantec Corp., 333 F. Supp 3d 966 (N.D. Cal. 2018)	X	X
Hughes v. Big Heart Pet Brands, 760 F. App'x 876 (9th Cir. 2018)	X	X
Hall v. SeaWorld Entertainment, Inc., 747 F. App'x 449 (9th Cir. 2018)	X	
Sud v. Costco Wholesale Corp., 731 F. App'x 719 (9th Cir. 2018)	X	X
Wirth v. Mars, Inc., 730 F. App'x 468 (9th Cir. 2018)	X	X
De Rosa v. Tri-Union Seafoods, LLC, 730 F. App'x 466 (9th Cir. 2018)	X	X

Federal Decisions Citing *Hodsdon* in Assessing UCL and CLRA Omission Claims

Case Name	UCL Omission Claim	CLRA Omission Claim
Barber v. Nestlé USA, Inc., 730 F. App'x 464 (9th Cir. 2018)	X	X
McCoy v. Nestlé USA, Inc., 730 F. App'x 462 (9th Cir. 2018)	X	X
Dana v. Hershey Co., 730 F. App'x 460 (9th Cir. 2018)	X	X

EXHIBIT 4

S274680

S_____

IN THE SUPREME COURT OF CALIFORNIA

JOHNSON & JOHNSON et al.,
Petitioners and Appellants,

v.

THE PEOPLE,
Respondent.

AFTER A DECISION BY THE COURT OF APPEAL
FOURTH APPELLATE DISTRICT, DIVISION ONE
CASE NO. D077945

On Appeal From Superior Court of California, County of San Diego Civil Case No. 37-2016-00017229-CU-MC-CTL
THE HONORABLE EDDIE C. STURGEON, JUDGE, DEPT. 67
TEL. NO. (619) 450-7067

PETITION FOR REVIEW

SERVICE ON ATTORNEY GENERAL AND S.D.D.A. REQUIRED BY CAL. R. OF CT. 8.29 AND CAL. CIV. CODE § 17209

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ISSUES PRESENTED

1. Whether, under the Unfair Competition Law (UCL) and False Advertising Law (FAL), a communication may be held "likely to deceive" its target audience when it omits information that the target audience would not expect it to include?

2. Whether, under the UCL/FAL, a trial court may punish a defendant for statements that the target audience never saw or heard?

3. Whether due process prohibits the imposition of more than $300 million in penalties for conduct that Defendants had no notice violated the law?

INTRODUCTION

This case presents critical questions about the reach of "two of California's most prominent consumer protection statutes—the unfair competition law (UCL) and the false advertising law (FAL)." (*Nationwide Biweekly Admin., Inc. v. Superior Court* (2020) 9 Cal.5th 279, 292.) Both statutes prohibit statements that are likely to deceive their target audience, and require trial courts to impose penalties of up to $2,500 per violation. Here, the People alleged that every communication Ethicon, Inc. (a subsidiary of Johnson & Johnson) made about its FDA-cleared, prescription-only pelvic-mesh medical devices violated the UCL and FAL. The trial court agreed, and imposed nearly $350 million in civil penalties—by far the largest penalty in the reported case law. The Court of Appeal reversed one aspect of the trial court decision but otherwise affirmed a penalty of $302 million, still orders-of-magnitude larger than any previous penalty. This unprecedented

result warrants review in this Court for at least three important reasons.

First, the Court should resolve a conflict over the UCL/FAL standard for determining when an omission of information makes a communication "likely to deceive." The People alleged that Ethicon violated the UCL and FAL because it omitted certain information about the risks of pelvic-mesh devices in the devices' FDA-regulated labeling and in its marketing materials. In keeping with the statutory focus on likelihood of deception, many Courts of Appeal apply the consumer-expectations standard. (See, e.g., *Daugherty v. Am. Honda Motor Co.* (2006) 144 Cal.App.4th 824, 838.) If reasonable consumers in the target audience do not expect the information to be included, then its omission is not likely to deceive them.

Here, however, the Court of Appeal did not consider whether the target audience would have expected the omitted information to be included. Instead, it held that Ethicon's omissions violated the UCL and FAL under the test articulated for common-law claims in *LiMandri v. Judkins* (1997) 52 Cal.App.4th 326. In so doing, the Court of Appeal deepened an open and acknowledged split about the proper test for omissions under the UCL and FAL. (*See Gray v. Toyota Motor Sales, U.S.A.* (C.D. Cal. Jan. 23, 2012) 2012 WL 313703, at *4 ("[T]he California Courts of Appeal are split on whether the *LiMandri* test is properly applied to … claims based on omissions.").) This Court should grant review to resolve this important and recurring question.

Second, the $300 million penalty presents an important question about how UCL/FAL violations may be counted and punished—namely, whether a court can assess penalties for materials that were never distributed or that the target audience otherwise never saw. This Court has addressed the standard for identifying violations only once, nearly half a century ago in *People v. Superior Court (Jayhill Corp.)* (1973) 9 Cal.3d 283. The Court explained that "the Legislature intended that the number of violations is to be determined by the number of persons to whom the misrepresentations were made." (*Id.* at p. 289.) Since *Jayhill Corp.*, the Courts of Appeal have uniformly held that if a circulation-based method for identifying violations is used, it must reflect the number of people who saw or heard the deceptive communication.

Here, however, the Court of Appeal affirmed a decision counting as violations every device labeling and marketing material shipped into the State, even though undisputed evidence established that many of the materials were never distributed, let alone read or seen. The Court also affirmed tens-of-millions of dollars in penalties for communications for which no evidence established what was said. The Court's decision conflicts with settled precedent and dramatically extends the law, authorizing vast punitive overreach under the UCL and FAL. It also makes California an inhospitable place to do business, ultimately harming consumers in the State.

Finally, the penalty violates due process. Ethicon did not have fair notice that California law (unlike federal law or

instructions from the FDA) required it to include "all risks" and descriptors of those risks in its federal device labeling and marketing materials. Imposing more than $300 million in penalties on that basis is fundamentally unfair.

The petition should be granted and the decision below reversed.

STATEMENT OF THE CASE

A. Ethicon's Devices and Communications

1. Ethicon's pelvic-mesh medical devices. Ethicon manufactured prescription-only medical devices to treat two women's health conditions: 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." (Opn. 4.) POP is a pelvic-floor disorder characterized by a weakening of the muscles and tissues that hold in place pelvic organs, allowing one or more organs to "prolapse" or descend into, or even outside of, a woman's vagina. (*Ibid.*)

Since 1998, Ethicon has marketed a polypropylene mesh device called TVT to treat SUI. TVT "revolutionized" the treatment of this condition. (39.RT.6262:16-19; 26.AA.5580 [533:19-534:11].)[1] Whereas prior surgical treatments necessitated significant hospital and recovery time, TVT offered surgeons a "minimally invasive" surgical option. (41.RT.6701:4-18.) "After the release of TVT, Ethicon developed and sold additional

[1] "AA" refers to Appellants' Appendix in the Court of Appeals. "RT" refers to the reporter's transcript.

iterations of [the device]." (Opn. 5.) To this day, pelvic mesh devices remain the "gold standard" for surgical treatment of SUI. (51.RT.8726:18-21.) The success of Ethicon's SUI devices prompted surgeons to ask Ethicon to manufacture mesh devices to treat POP (24.AA.5167-5168 [86:08-88:01], including Gynemesh PS, Prolift, Prolift-M, and Prosima (Opn. 5).

2. Ethicon's communications. "During the relevant timeframe, Ethicon disseminated three categories of communications giving rise to the [claims] at issue here: (1) Instructions for Use (IFUs); (2) marketing communications directed to California doctors; and (3) marketing communications directed to California patients." (Opn. 7.)

Instructions For Use (IFUs). "IFUs are packets of information" included inside the packaging of medical devices. (Opn. 7.) They are required by FDA regulations. (21 C.F.R. § 801.109(c).) IFUs "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." (Opn. 7-8.) Many surgeons testified that IFUs are "not considered" "a source for evidence-based medicine" (54.RT.9114:1-15), and that they do not consult IFUs to learn device risks (see, e.g., 39.RT.6236:25-6237:27, 6305:21-6306:2; 40.RT.6409:7-6410:17; 41.RT.6695:4-26, 6712:19-26; 44.RT.7343:24-7344:19, 7347:13-7349:11; 54.RT.9065:22-26.) It was also undisputed that many IFUs went unread. That was because IFUs come inside packaging, and surgical staff often removed and discarded IFUs from the

device's packaging before a procedure began, sometimes before the surgeon even arrived. (25.RT.3385:6-3386:18; 26.RT.3411:14-3412:17; 34.RT.5031:1-7; 50.RT.8416:1-10 ["[The IFU] honestly goes just in the trash."].)

Doctor-Directed Communications. Ethicon marketed its devices to surgeons through oral communications at sales visits and in printed marketing materials. At trial, however, the People put on "no evidence of the actual substance of any of Ethicon's oral communications with doctors." (Opn. 55.)

Ethicon's print marketing came in different formats, ranging from traditional product brochures (see, e.g., 11.AA.2909-2914), to one-page convention fliers (25.AA.5379), literature reviews (25.AA.5384-5393), and sheets with product ordering information. (25.AA.5382-5383.) There was no evidence that surgeons expect these communications to contain all-inclusive risk disclosures. To the contrary, both sides agreed that relying on marketing materials to learn product risks is not "consistent with … evidence-based medicine." (40.RT.6409:7-6414:7; see also 39.RT.6236:25-6237:27.)

Patient-Directed Communications. Ethicon also communicated with patients through print materials. These materials likewise varied in length and content, ranging from full-length brochures (e.g., 12.AA.3315-3322) to self-diagnosis questionnaires (19.AA.4218-4219). The point of these communications was not to replace doctor-patient counseling but to prompt and facilitate conversations between women and their doctors. (33.RT.4856:2-8; 33.RT.4956:17-4962:14.) This was

especially important because many women were hesitant to seek treatment due to the sensitive nature of these conditions. (E.g., 40.RT.6380:15-6384:4.)

3. Distribution. That Ethicon shipped print marketing materials to California did not mean they were all then distributed to doctors or patients. Ethicon's corporate representative on sales-related practices testified, for example, that she "filled up two recycling bins" of undistributed marketing materials when she was a salesperson. (26.RT.3458:14-3459:2; see also 26.RT.3459:3-12; 35.RT.5357:12-19, 5358:1-14.) Nor was there any evidence showing how many of the patient marketing materials distributed to doctor's offices were then provided to patients. As explained below, the People's violation-counting expert conceded that he did not count the marketing materials actually distributed to doctors or patients, but rather identified as violations all materials shipped into the State, whether distributed or not. (*Infra* at 15.)

4. PR Kits. For another category of communications held to warrant civil penalties—public relations ("PR") kits—there was not even evidence of what the communications that were punished said. The trial court counted 45,000 violations for PR kits based on the estimated "circulation" of three independent doctor or hospital newsletters because those newsletters *might* have incorporated Ethicon-related content. (35.RT.5332:24-5334:22.) But there was no evidence that the newsletters actually incorporated any such content, let alone that they included any statements that the court found deceptive. (35.RT.5332:24-5334:22, 5337:27-5338:26, 5340:22-5342:21.)

B. The People's Case

The People alleged that *every* communication Ethicon made about its pelvic-mesh devices in a ten-year period (2008 to 2018) violated the UCL and FAL. According to the People (and later the trial court, which adopted their proposed statement of decision), "the common, overarching deception that runs through each of Defendants' marketing materials" was "Defendants' failure to communicate all the known, serious, long-term risks specific to their mesh products." (26.AA.5688.) This failure to disclose "all known risks" in every communication, the People claimed, rendered each and every one likely to deceive.

Very little evidence supported that sweeping allegation. The People did not call a single California surgeon who uses Ethicon's devices to testify that he or she was misled, or was likely to be misled, by any Ethicon communication. Nor did the People offer any evidence that the target audiences for Ethicon's communications expected any of them—even its IFUs—to contain exhaustive all-inclusive risk disclosures. To the contrary, every testifying California surgeon who uses mesh disagreed with the People's claims. So did 82 California surgeons who wrote the Attorney General that his claims have "no merit." (23.AA.4903-4906.) And the People offered no evidence that any California patient or surgeon was harmed by Ethicon's communications—e.g., that a patient agreed to surgery based on something Ethicon said or that a surgeon obtained a faulty informed consent. Only two patients testified: a California patient who said she did not see any Ethicon materials (12.AA.3202 [2680:5-9]), and an Illinois

patient who acknowledged that she used the patient brochure as intended—it prompted her "to ask her [doctor] because she's going to be the one doing the job" (23.RT.2921:6-8 ["This is a pamphlet. This isn't my doctor."]).

The People also called a forensic accountant to quantify Ethicon's in-state marketing activity. The expert did not limit his count to materials or communications containing alleged misstatements or material omissions because "[t]hat wasn't part of my task." (35.RT.5352:20-26; see also 5320:28-5321:3, 5342:13-21, 5354:14-25, 5388:19-27.) Instead, he included "all quantifiable instances of circulation or dissemination" of Ethicon's marketing. (26.AA.5649.) In many instances, he had no idea what the materials he counted actually said. (See 35.RT.5321:4-5322:1, 5326:15-18, 5331:21-5332:12, 5340:22-5341:23, 5388:8-11.) And he made no effort to determine how many of Ethicon's materials were actually distributed to surgeons, or by surgeons to their patients (35.RT.5357:12-5360:23, 5388:1-15), let alone how many of those materials were ultimately read (35.RT.5328:13-17, 5360:24-5361:3, 5388:16-18).

C. The Trial Court's Decision

The parties submitted proposed statements of decision after trial. The trial court adopted the People's proposed statement *in toto*, with two exceptions: it set the penalty at $343 million (instead of the $788 million the People requested); and it denied the People's request for injunctive relief. In adopting the People's violation count, the court adopted the People's theory that all Ethicon's communications were likely to deceive. Based on the

People's count of all marketing materials shipped into California and all oral communications made in California sales calls, the court found 275,195 violations of the UCL and FAL. (26.AA.5649.) Its judgment thus included punishment for materials that were never distributed, statements that were never read or heard, and communications about which there was no evidence.

D. The Court of Appeal's Decision

The Court of Appeal affirmed in large part but vacated $42 million in penalties, leaving in place a $302,037,500 judgment.

1. Omissions. Although the trial court never addressed the standard applicable to omissions, the Court of Appeal affirmed the trial court's holding the omission of various risks and descriptors from Ethicon's IFUs and marketing materials violated the UCL and FAL. The Court of Appeal applied the *Limandri* test, and held that the trial court had "issued findings … pertinent to the third [and] fourth *LiMandri* factors"—i.e., Ethicon "concealed material facts" and Ethicon made "partial representations." (Opn. 31-32.) But the Court of Appeal, like the trial court, never explained how the supposed presence of those *LiMandri* factors shows that the omissions were likely to deceive reasonable surgeons or patients. (*Ibid.*)[2]

2. Penalties. The Court of Appeal reversed the trial court's award of penalties for every mesh-related oral communication because there was no "evidence in the record establishing the

[2] The Court of Appeal also held *sua sponte* that petitioners waived their argument concerning the standard for omissions claims (Opn. 30), but that holding is clearly wrong for the reasons discussed *infra* Part I.B.2.

content of any of Ethicon's oral marketing communications, let alone each of the thousands of communications that were penalized." (Opn. 53.) But the Court declined to reverse penalties of $56.25 million for newsletters published by entities that received PR kits, despite an equal dearth of evidence of the contents of any such newsletter.[3] And the Court affirmed almost $250 million in additional penalties for all Ethicon's IFUs and mesh-related print marketing. In the Court's view, it did not matter that the trial court's violation count swept in undistributed materials and materials that no one otherwise saw because Ethicon's materials "were substantively targeted to well-defined groups of people." (Opn. 73.) To justify civil penalties, the Court held, it was enough that Ethicon had merely created those undistributed or unseen materials for that audience.

3. Due Process. The Court of Appeal rejected Defendants' argument "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"—"for the same reasons" it rejected Defendants' arguments on the merits. (Opn. 78.)

REASONS FOR GRANTING THE PETITION

I. THE COURT SHOULD RESOLVE A CONFLICT OVER THE PROPER STANDARD FOR DETERMINING WHEN AN OMISSION VIOLATES THE UCL AND FAL

The UCL and FAL prohibit statements that are likely to deceive reasonable consumers. (See, e.g., *Nationwide*, *supra*, 9

[3] The Court of Appeal also denied without explanation petitioners' request for rehearing on that point.

Cal.5th at p. 308.) This Court has never addressed the test for determining when reasonable consumers are likely to be deceived by an omission, and the Courts of Appeal have issued conflicting opinions. Indeed, it is widely acknowledged that the "Courts of Appeal are split on whether the *LiMandri* test is properly applied to UCL … claims based on omissions." (*Gray*, *supra*, 2012 WL 313703, at *4.)[4] The conflict is ripe for this Court's resolution, and this case presents an ideal vehicle to resolve it.

A. The Decision Below Deepens An Acknowledged Conflict Over The Proper Standard For Determining When An Omission Is Actionable

1. The *LiMandri* test. The Court below evaluated the People's claim that omissions in Ethicon's communications were likely to deceive consumers under the test set out in *LiMandri*. *LiMandri* did not address UCL or FAL claims, but rather common-law claims for failure to disclose. (52 Cal.App.4th at p. 335.) The *LiMandri* Court held that "[t]here are four circumstances in which nondisclosure or concealment may constitute actionable fraud": (1) where there is a fiduciary relationship; (2) where the defendant has exclusive knowledge of the omitted facts; (3) where the defendant conceals a material fact; and (4) where the defendant

[4] See also, e.g., *Herron v. Best Buy Co.*, (E.D. Cal. 2013)924 F. Supp. 2d 1161, 1175 [noting "split"]; *Callaway v. Mercedes-Benz USA, LLC* (C.D. Cal. May 12, 2016) 2016 WL 11756827, at *4 fn.4 [same]; *In re Fontem US, Inc. Consumer Class Action Litig.* (C.D. Cal. Apr. 22, 2016) 2016 WL 11503066, at *10 fn.11 [same]; *Doe v. SuccessfulMatch.com* (N.D. Cal. 2014) 70 F.Supp.3d 1066, 1076 [same]; *Backhaut v. Apple, Inc.* (N.D. Cal. 2014) 74 F. Supp. 3d 1033, 1049 [same]; *Herremans v. BMW of N. Am., LLC* (C.D. Cal. Oct. 3, 2014) 2014 WL 5017843, at *11-12 [same].

makes a partial representation. (*Id.* at p. 336 [quotations omitted].) In this case, applying *LiMandri* to the UCL and FAL, the Court of Appeal held that the trial court had rendered findings "pertinent to" the third and fourth *LiMandri* factors, and on that basis affirmed. (Opn. 31-32.)

As the Court of Appeal observed (see Opn. 31), it was not the first court to apply *LiMandri*'s common-law test to evaluate whether the failure to disclose information is likely to deceive under the UCL and FAL. In *Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249, 255-56, for example, the Court of Appeal applied *LiMandri* to CLRA and UCL claims based on eMachines's alleged failure to disclose defects in the hardware on its floppy disks.[5] Likewise, in *Gutierrez v. Carmax Auto Superstores California* (2018) 19 Cal.App.5th 1234, 1258, 1260, the Court of Appeal applied *LiMandri*'s factors to a CLRA claim alleging that Carmax failed to disclose a safety recall. Although the Ninth Circuit has noted that California law is "somewhat vague about the test," it reads California law to hold that "the plaintiff must allege one of the four *LiMandri* factors" to state "a UCL omission claim." (*Hodson v. Mars, Inc.* (9th Cir. 2018) 891 F.3d 857, 863.)

2. The consumer-expectations test. Other courts, however, "disagree" that *LiMandri*'s common-law test applies to claims under the UCL and FAL. (*Buller v. Sutter Health* (2008) 160 Cal.App.4th 981, 988 fn.3.) These courts focus instead on

[5] "The standard for determining whether a representation is 'fraudulent' under the UCL applies equally to claims arising under the CLRA." (*Klein v. Chevron U.S.A., Inc.* (2012) 202 Cal.App.4th 1342, 1382.)

consumer expectations. In *Daughtery*, *supra*, 144 Cal.App.4th at p. 838, for example, the Court of Appeal found that Honda's failure to warn of particular engine risks was not actionable under the UCL because buyers would not have had an expectation that information about the engine defect would be disclosed at the time of sale, and had no assumptions about the defect risk beyond the period of Honda's express warranty. (*Daugherty*, *supra*, 144 Cal.App.4th at p. 838-39.)

Likewise in *Bardin v. DaimlerChrysler Corp.*, (2006) 136 Cal.App.4th 1255, 1275, the Court of Appeal affirmed the dismissal of the plaintiff's UCL claim because the complaint did not allege that members of the public had any expectation that the challenged communications would contain information allegedly omitted from them or made any assumptions about the omitted information. And in *Klein, supra*, the Court of Appeal held that plaintiffs had alleged an actionable UCL claim because, "unlike in *Bardin*, the complaint contain[ed] allegations that the public did in fact have an expectation or assumption about" the matter in question: the public expected to receive a particular quantity of fuel "in each transaction," so Chevron's failure to disclose how its storage practices would affect that quantity was potentially deceptive. (202 Cal. App.4th at pp. 1381-82; see also, e.g., *Brakke v. Econ. Concepts, Inc.* (2013) 213 Cal.App.4th 761, 772 [following *Daugherty* and applying consumer-expectations test]; *Buller*, *supra*, 160 Cal.App.4th at pp. 986-88 [following *Daugherty* and *Bardin* and holding that an "alleged failure to reveal … discount policy is not conduct that is 'likely to deceive' patients" because

patients "are not likely to be operating under the expectation that they are entitled to a discount"].)

3. Other approaches. Compounding the confusion, some courts have applied *both* the *LiMandri* test and the consumer-expectations test to evaluate plaintiffs' claims. (*Rubenstein v. The Gap, Inc.* (2017) 14 Cal.App.5th 870, 877-79.) And still other courts have taken essentially an ad hoc approach to omissions. (See *Berryman v. Merit Prop. Mgmt., Inc.* (2007) 152 Cal.App.4th 1544, 1557 [no allegation of "affirmative duty to disclose"].) As the Ninth Circuit has observed, the "reasoning" in some Court of Appeal cases is "far from clear." (*Hodson*, *supra*, 891 F.3d at p. 863 [citing *Rutledge v. Hewlett-Packard Co.* (2015) 238 Cal.App.4th 1164 [and noting "the court did not apply the *LiMandri* factors"].)

* * *

This Court grants review "[w]hen necessary to secure uniformity of decision or to settle an important question of law." (Cal. R. Ct. 8.500, subd. (b)(1).) The first question presented satisfies both criteria. The Courts of Appeal are not uniform on the standard for determining whether omissions are actionable under the UCL and FAL, and the question of what standard courts must apply is exceptionally important, as explained next.

B. The Question Of What Standard Courts Must Apply To Determine Whether Omissions Violate The UCL And FAL Is Important, And This Case Is An Ideal Vehicle To Resolve It

1. *This issue is important and recurring*

The proper standard for determining when omissions are actionable under the UCL and FAL is self-evidently an issue of

exceptional public importance. The sheer number of decisions noting the "split" in authority (*supra* at 18 & fn.4) demonstrates both the importance of the issue and the need for this Court's guidance. And because both private and public plaintiffs can bring omissions-based UCL and FAL claims, a decision resolving that spit will have ramifications far beyond this case.

The question also goes to the touchstone of UCL/FAL liability—whether a communication is "likely to deceive" reasonable consumers in the target audience. Lost in the Court of Appeal's decision, and in the many other decisions applying *LiMandri*'s common-law factors, is an evaluation of whether the omission is in fact likely to deceive. Consider the two *LiMandri* factors that the Court of Appeal purported to apply in this case. The third factor asks whether the defendant actively concealed a material fact. But the mere fact that the defendant chose not to include some information says nothing about whether a *particular omission* in a *particular communication* is likely to deceive a reasonable consumer. If reasonable consumers in the target audience for a particular communication (e.g., trained pelvic surgeons) already know the omitted information or would not otherwise expect the communication to include it, then the omission of the information is not likely to deceive them. The same is true of the *LiMandri* factor focusing on partial representations. No one doubts that partial representations can violate the UCL and FAL in some circumstances. But the fact that a defendant disclosed some but not all information does not by itself show that a consumer, acting reasonably in the circumstances, is likely to be

deceived by the communication. Basing liability on a partial representation without more is tantamount to holding that *all* omissions are actionable under the UCL and FAL—whether *or not* they are likely to deceive.

This Court has repeatedly "reiterate[d]" that "the concept encompassed in the phrase 'likely to be deceived' has no relationship to the concept of common law fraud." (*Day v. AT & T Corp.* (1993) 63 Cal.App.4th 325, 332; see also *In re Tobacco II Cases* (2009) 46 Cal.4th 298, 312.) The *LiMandri* factors, drawn from common-law fraud principles, do not answer the relevant question for UCL and FAL liability.

The reasonable-expectations test, by contrast, does go to the relevant question under the UCL and FAL. If a communication omits material information that consumers in the target audience would reasonably expect it to include, there may be a likelihood that consumers will wrongly infer that the omitted information does not exist. (Cf. *Shaeffer v. Califia Farms, LLC* (2020) 44 Cal.App.5th 1125, 1138 ["[A]n implied representation is actionable only if a reasonable consumer is likely to infer that representation from the label's affirmative content."].) Conversely, consumers who did not expect the omitted information to be included would not likely be deceived, because they would not draw the negative inference. To take an example from this case, reasonable surgeons do not expect brief conversations with salespeople to catalogue all possible device risks, so it is unlikely for a surgeon to be deceived when a salesperson omits to mention a risk during a short conversation. Applying the consumer-expectations test ensures

that omissions liability under the UCL and FAL extends only to communications likely to deceive their target audiences, as the law requires. Selectively applying the *LiMandri* common-law fraud factors—as the Court of Appeal did here—does not.

2. *This case is an ideal vehicle for resolving the conflict in the Courts of Appeal on the standard for omissions-based liability under the UCL and FAL*

This case presents an ideal opportunity for this Court to clarify the test for omissions-based liability under the UCL and FAL and resolve the conflict in the Courts of Appeal. The People presented no evidence that the target audiences for Ethicon's communications expected all of those communications to include exhaustive all-inclusive risk disclosures. (*Supra* at 11-12.) Applying the consumer-expectations test would require reversal of the both the liability findings and the gargantuan $302 million civil penalty imposed below.

The People may argue that review of this issue is foreclosed because the Court of Appeal held that petitioners had waived it. That is wrong, for four independent reasons.

First, the omissions "test" is merely the means to determine whether an omission is likely to deceive a reasonable consumer, and there is no question that petitioners preserved the argument that Ethicon's communications were not likely to deceive.

Second, despite its *sua sponte* waiver finding, the Court of Appeal reached the merits, and its decision is now precedent applying the *LiMandri* test. (See, e.g., *Lebron v. Nat'l R.R. Passenger Corp.* (1995) 513 U.S. 374, 379 ["[E]ven if this *were* a

claim not raised by petitioner below, we would ordinarily feel free to address it, since it was addressed by the court below."].)

Third, on the record here, the Court of Appeal's waiver holding is simply untenable. In its original decision, the Court opined that petitioners "d[id] not clearly identify the legal standard [they thought] the trial court *should have* applied." (Opn. 30.) But not even the People argued that petitioners had waived the point. (Cf. *Norwood v. Vance* (9th Cir. 2010) 591 F.3d 1062, 1068.) Petitioners expressly argued that an omission is likely to deceive reasonable consumers only where the consumer-expectations test is satisfied—specifically, that a duty to disclose exists under the UCL and FAL where "members of [the target audience] have … an expectation or assumption about the matter in question." (Appellants' Opening Brief ("AOB") 39 [quoting *Daugherty*, *supra*, 144 Cal.App.4th at p. 838.]; Appellants' Reply Brief ("ARB") 22 ["focus on consumer expectations is exactly the inquiry mandated by *Daugherty* and other duty-to-disclose cases"]. Petitioners cited the leading cases and argued throughout that the relevant focus must be on consumer expectations, i.e., whether the target audience expected the communications to include the omitted information. (See AOB 13, 30-31, 40, 44-45, 51-53; ARB 8, 11, 22, 30.) Or, putting the question in the context of the communications that the trial court penalized, petitioners argued that liability should turn on whether doctors or patients expected the communications in issue to provide exhaustive all-inclusive

risk information and whether they were likely to be misled by its absence.[6]

Petitioners filed a timely petition for rehearing on the Court of Appeal's *sua sponte* waiver finding, noting all the places in their briefs where they argued for the consumer-expectations test. The court's response: "Ethicon's merits briefs purport to discuss the *circumstances* under which an omissions-based claim may be raised, but they do not set forth the proper *legal* standard a court must employ when assessing such a claim." (Order Modifying Opn. 1-2.) But there is no difference between the circumstances in which a claim is actionable and the legal standard governing a claim—here, the consumer-expectations test. Equally important, the Court did not deny that it understood petitioners' argument and the cases petitioners cited, so there was no basis for the Court to refuse to reach the merits—which it ultimately did. (See, e.g., *Gutierrez*, *supra*, 19 Cal.App.5th at p. 1245.)

Fourth, even if the waiver holding were defensible, this Court has discretion to consider "pure questions of law on

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[6] See, e.g. AOB 40 ["[W]hile a layperson (or a judge) might expect device IFUs to contain all-inclusive risk disclosures, practicing surgeons do not, which is why they are not likely to be deceived by the omission of information they do not expect to see and do not need in the first place."] [quotations omitted]; ARB 22 ["This is not just the law, but also common sense. In the real world, a California surgeon was not likely to be deceived about the risks of Ethicon's devices simply because, for example, the word 'chronic' was not expressly mentioned on a convention flyer *unless* the surgeon expected that flyer to contain a comprehensive catalogue of risks."].)

undisputed facts." (*People v. Runyan* (2012) 54 Cal.4th 849, 859 fn.3.) Given the issue's importance, the Court should do so here.

II. THE COURT SHOULD RESOLVE A CONFLICT OVER THE PROPER METHOD TO IDENTIFY DISTINCT UCL AND FAL VIOLATIONS

The Court should also grant review to resolve a conflict over the proper standard for identifying distinct UCL and FAL violations eligible for civil penalties. The decisions below counted as violations all materials that Ethicon shipped into California, without regard to whether Ethicon actually distributed those materials to the target audience or, in the case of materials Ethicon distributed, whether members of the target audience saw or read them. This counting method conflicts with an unbroken line of authority, starting with this Court's decision in *Jayhill Corp.*, holding that UCL and FAL penalties should be based on the number of people to whom a misrepresentation was made, not a defendant's total circulation. The counting question raises an important and recurring issue in UCL/FAL civil penalty litigation, and this petition presents an ideal vehicle for clarifying the proper standard.

A. The Decision Below Creates A Conflict Over The Proper Standard For Identifying UCL And FAL Violations

This Court has addressed the standard for identifying "violations" only once, in its 1973 decision in *Jayhill Corp*. There, the Court rejected the argument that each misrepresentation made by a door-to-door salesperson represented a separate violation, such that a salesperson who made 25 misrepresentations

to each customer would trigger "a $62,500 penalty for each customer solicited." (*Jayhill Corp.*, *supra*, 9 Cal.3d at 288-289.) The Court found it "unreasonable to assume that the Legislature intended to impose a penalty of this magnitude for the solicitation of one potential customer." (*Ibid.*) "Rather," the Court explained, "the Legislature intended that the number of violations is to be determined by the number of persons to whom the misrepresentations were made, and not by the number of separately identifiable misrepresentations involved." (*Ibid.*)

In the half century since *Jayhill Corp.*, California law developed uniformly in the Courts of Appeal—until the decision below. Courts recognized that trial courts have discretion in selecting a method for "determining … the number of violations." (*Nationwide*, *supra*, 9 Cal.5th at p. 314),[7] but should exercise great caution in selecting a counting method, lest the method "result in excessive penalties of at least hundreds of millions of dollars," (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1087-88; see also, e.g., *People v. Superior Court (Olson)* (1979) 96 Cal.App.3d 181, 197-98). And, especially relevant here, Courts of Appeal uniformly held that when trial courts elected to employ a counting method based on the number of misleading communications, the count must be

[7] For example, based on number of victims (*People v. Dollar-Rent-a-Car Sys.* (1989) 211 Cal.App.3d 119, 132; *People v. Toomey* (1984) 157 Cal.App.3d 1, 22-23; *People v. Bestline Prods., Inc.* (1976) 61 Cal.App.3d 879, 903; *People v. Witzerman* (1972) 29 Cal.App.3d 169, 180), the amount of harm the defendant caused (*People ex rel. Kennedy v. Beaumont Inv., Ltd.* (2003) 111 Cal.App.4th 102, 130-31), or the number of days the misconduct occurred (*People v. Overstock.com, Inc.* (2017) 12 Cal.App.5th 1064, 1087-88).

based on the number of people who saw or heard those communications. Before the decision here, no California court had imposed penalties for all materials shipped into the State without regard to how many people actually received or read them.

The conflict is evident from the very decisions cited in the Court of Appeal's opinion. In *Olson*, *supra*, the People argued "that the number of violations resulting from a false advertisement in a newspaper" should be calculated based on the newspaper's total circulation. (96 Cal.App.3d at p. 197.) The Court of Appeal disagreed, holding that "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 advertisements or who responded to the advertisement by purchasing the advertised product or service or by making inquiries concerning such product or service." (*Id.* at p. 198.) "Violations so calculated"—i.e., based on the number of people who actually saw the advertisement—"would be reasonably related to the gain or the opportunity for gain achieved by the dissemination of the untruthful or deceptive advertisement." (*Ibid.*)

Olson is highly significant because the Legislature later amended the UCL and FAL penalty provisions "to codify [this] standard … for determining the number of violations and corresponding civil penalties resulting from the publication or broadcast of a media advertisement." (*Abbot Labs. v. Superior Court* (2020) 9 Cal.5th 642, 656 [citing Stats. 1992, ch. 430 § 4, pp. 1707-1708]; see also Sen. Com. on Judiciary, Analysis of Sen. Bill

No. 1586 (1991–1992 Reg. Sess.) as amended May 4, 1992, pp. 2-3 ["[I]t is not the sponsor's intent to change the present unfair competition laws which hold that a violation is determined on a 'per-victim' basis." [citing *Jayhill Corp.* and *Olson*]].)

In *People v. Morse* (1993) 21 Cal.App.4th 259, the Court of Appeal approved a total-circulation counting methodology, but only because total circulation was coextensive with the number of consumers who read the deceptive communications. The Court noted that "Morse selected recipients and designed his materials to ensure that his solicitations would be noticed and read." (*Id.* at p. 273-74.) "The address window on Morse's solicitations displayed not only the name and address of the homeowner-recipient, but also the name of the homeowner's lender." (*Id.* at p. 273.) Morse even included in the materials each individual's mortgage balance, which he obtained from public records. (*Ibid.*) On this record, the Court found it reasonable to conclude "that each person to whom Morse sent a solicitation constitutes a 'customer solicited by' Morse and a person 'to whom the misrepresentations were made.'" (*Id.* at p. 273 [quoting *Jayhill Corp.*, *supra*, 9 Cal.3d at p. 289].)

And in *People v. JTH Tax, Inc.* (2013) 212 Cal.App.4th 1219, a case involving both print and television advertisements, the Court of Appeal again took care to ensure that the trial court's counting method comported with *Jayhill Corp.* For its violation count of print advertisements, "the trial court did not rely on the kind of gross circulation figures disfavored in *Olson*" (*id.* at p. 1255.), but applied "a fraction of circulation as a proxy for [actual] readership." (*Ibid.*) For the TV ads, the trial court counted

violations based on Nielsen ratings, which themselves are a proxy (albeit not perfect) for "the number of adults who 'saw the ads at issue.'" (*Id*. at p. 1252.)[8] And consistent with *Jayhill Corp.*, the trial court counted only one violation for each adult, no matter how many times they may have seen the ads. (*Ibid.*) None of these decisions remotely supports the facially overbroad and arbitrary counting method endorsed in the Court of Appeal's decision here. On the contrary, as explained below, the Court's decision departs from all these precedents and creates dis-uniformity in the law that can only lead to excessive and unjustifiable punishment.

Print Marketing. Many of the marketing materials that the trial court counted as violations were never distributed to anyone, and therefore by definition were not likely to deceive anyone. Ethicon's PMQ on sales-related practices, for example, testified that she did not "hand out or distribute every brochure that [she] ordered," and that she maintained a large "back stock" of undistributed materials that "filled up two recycling bins." (26.RT.3458:14-3459:2; *supra* at 13.) This testimony was not controverted.

And unlike in *JTH Tax*, the People's counting expert made no effort to determine readership, even by approximation. He had no opinion on how many materials "were given to healthcare

[8] See also, e.g., Respondent's Opposition Brief, *JTH Tax, Inc. v. People*, (Cal. App. Dep't Super. Ct. Apr. 30, 2010) No. A125474, 2010 WL 2173464, at *26 [Nielsen data provided "credible basis for estimating viewership"]; *id*. at *28 ["Nielsen data provided substantial evidence of the number of individuals who saw each of the ads"].

professionals," "how many of those materials were then given by healthcare professionals to their patients," or "how many healthcare professionals [or patients] actually read any of th[e] print marketing material." (35.RT.5357:12-5361:3, 5388:1-7.) His task was to tally up the number of marketing materials that were shipped into the State.[9]

Device IFUs. The trial court also counted as violations every IFU included in the packaging of an Ethicon device. But it was undisputed that many device IFUs went unread. Experienced surgeons familiar with a medical device do not read, or need to read, the device's IFU before every procedure. (See, e.g., 28.RT.3932:13-18 [the People's expert could not "remember the last time [he] looked at the" IFU for the device he uses]; 50.RT.8416:12-14 ["I've been doing TVT-Os for many, many years. I am aware of the procedural steps that I learned back in 2003, and … I just don't feel a need to use [the IFU]."].)

Indeed, the evidence showed that device IFUs were typically discarded—often before surgeons would have had a chance to read them. Sometimes, staff removed the IFU before the surgeon arrived, "plac[ing] [it] into either the recycling bin, if they were

[9] In a footnote, the Court of Appeal discounted this shortcoming in the People's evidence because petitioners did not prove how many materials went undistributed and unread. (Opn. 74 fn.17.) But that was not petitioners' burden. As the parties prosecuting a case for civil penalties, the People bore the burden of proof, and if they wanted the trial court to employ a circulation-based violation count, it was *their* burden to identify and support with substantial evidence a counting methodology consistent with the case law, as they did in *JTH Tax* but did not even attempt to do here.

environmentally conscious, or into the waste bin if they weren't." (25.RT.3385:6-3386:2; 26.RT.3411:25-3412:10.) Other times, hospital staff would remove and discard the IFUs to facilitate efficient storage. (25.RT.3386:3-18; 26.RT.3412:11-17.) And still other times, the device packaging would be opened after the patient was on the operating table, so the IFU would either be left in the device packaging or thrown away. (26.RT.3411:14-24; 34.RT.5031:1-7; 50.RT.8416:1-10 ["[I]t honestly goes just in the trash."].) Yet the trial court imposed a civil penalty for every IFU included with every device Ethicon shipped into the State.

PR Kits. The trial court imposed more than $50 million in civil penalties based on circulation estimates for newsletters created by third-party entities that had received Ethicon PR kits. But the record contains no evidence of the newsletters' contents at all, much less evidence that they contained any Ethicon-created content likely to deceive their subscribers. (*Supra* at 13.) Again, counting violations on this basis flatly contradict the principle that circulation-based penalty calculation must reasonably estimate the number persons who actually saw or heard a deceptive statement. (See *supra* at 27-31.)

No California appellate decision before this one has endorsed the calculation of UCL and FAC penalties the way the trial court did here. The Court of Appeal's decision flatly contradicts the principles set out in *Jayhill Corp.* and later UCL/FAL penalty decisions, and creates a conflict in the Courts of Appeal. (See *Nationwide*, *supra*, 9 Cal.5th at p. 292 [granting review in similar

circumstances].) This Court should grant review to resolve this conflict and to restore uniformity to this critical area of the law.

B. The Test For Identifying Distinct UCL And FAL Violations Is Critically Important, And This Case Is An Ideal Vehicle To Resolve It

1. *This issue is important and recurring*

The proper method for identifying distinct violations of the UCL and FAL is exceptionally important. Indeed, the issue has the potential to arise in *every* UCL or FAL case brought by a public prosecutor. (See Bus. & Prof. Code §§ 17206, subd. (a), 17536, subd. (a).) So a decision by this Court will have import extending far beyond this case.

The issue takes on heightened importance because the Court of Appeal's decision, if allowed to stand, will make this State an inhospitable place to do business and lead to serious adverse consequences that the Legislature did not intend. Before the decision below, the question in cases like this one was simply whether the record afforded a basis to approximate the number of people who read, saw, or heard a misleading advertisement. That test is easy to apply. But the Court of Appeal here thought the relevant question was whether Ethicon's print marketing and device IFUs were more like the individualized solicitations in *Morse* than the newspaper advertisements in *Olson*. That test is far more difficult to apply and will inevitably open the door to unpredictable, excessive, and arbitrary statutory penalties.

The decision below well illustrates the problem. The Court of Appeal thought that this case was like *Morse* because Ethicon's IFUs and marketing materials "were substantively targeted to

well-defined groups of people." (Opn. 73.) But *Morse* says nothing about targeting well-defined groups of people. *Morse* approved a total-circulation methodology because the solicitations there were so "highly *individualized*" that it was reasonable to conclude that each one was read and thus that "each person to whom Morse sent a solicitation constitutes … a person 'to whom the misrepresentations were made.'" (*Morse*, *supra*, 21 Cal.App.4th at pp. 272-73 [emphasis added; quoting *Jayhill Corp.*, *supra*, 9 Cal.3d at p. 289].)[10] The same is not true here. Neither Ethicon's marketing nor its device IFUs were targeted to specific individuals, and not every piece was distributed, let alone read. The Court of Appeal erred precisely because it compared apples to oranges instead of making a record-based determination, as prior cases require.

The lack of predictability inherent in the Court of Appeal's test will have real practical consequences. Not only will it lead to penalties that are completely out of line with prior case law (as happened here) but it will make it difficult for litigants accurately to predict potential liability. That is important for a host of reasons, including settling cases: it is difficult to settle when both sides cannot agree on the defendant's likely exposure.

The Court of Appeal's reasoning will also greatly expand defendants' potential liability, making California an inhospitable place for business. As this Court found in *Jayhill Corp.*, penalties

[10] In *Morse*, *supra*, the court could conclude that each solicitation was distributed because the law presumes that the mail is delivered. (21 Cal.App.4th at p. 273 fn.23.)

tethered to reasonable estimates of the number of persons who read or heard communications likely to deceive them comport with the legislative purposes of the UCL and FAL. Penalties tethered indiscriminately to the volume of materials shipped into a State do not. On the contrary, such a rule would lead to absurd and arbitrary results. If a ship carrying advertising materials into California sank in State waters, penalties could be imposed for materials that never saw the light of day. The same would hold for materials shipped here but later discarded or destroyed, as happened in this case. There is no indication that the Legislature intended to enable such absurd results or to authorize courts to impose punishment for marketing materials that were never distributed or that no one saw. (See *supra* at 29-30.) But the Court of Appeal's decision does exactly that.

Finally, the Court of Appeal's decision will inevitably lead to massive and ever-increasing penalties, like the $300 million penalty here. Departing from the *Jayhill Corp.* standard, as the Court of Appeal did here, will invite and enable all manner of overreaching in calculating UCL and FAL. But California courts have consistently construed the UCL and FAL to avoid this result. (See *Hale v. Morgan* (1978) 22 Cal.3d 388, 401 ["Uniformly, we have looked with disfavor on ever-mounting penalties and have narrowly construed the statutes which either require or permit them."]; *Overstock.com*, *supra*, 12 Cal.App.5th at p. 1064; *Olson*, *supra*, 96 Cal.App.3d at p.197.)

2. *This case is an ideal vehicle to clarify the test for identifying distinct UCL and FAL violations*

There is no dispute that the record-breaking penalty in this case encompasses materials that the target audience never received or never saw. Whether the UCL and FAL permit courts to impose punishment for undistributed and unseen materials is both squarely presented in this case and outcome determinative. If this Court adheres to the well-settled rule that these statutes do not allow courts to punish statements that, by definition, were not likely to deceive, then the penalty below would have to be vacated and the case remanded so the trial court can calculate a penalty consistent with the record and the law.

III. THE COURT SHOULD GRANT REVIEW BECAUSE THE UNPRECEDENTED PENALTY VIOLATES DUE PROCESS

California's statute books are "filled with more and more civil laws bearing more and more extravagant punishments." (*Sessions v. Dimaya* (2018) 138 S.Ct. 1204, 1229 [Gorsuch, J, concurring].) And these "laws regularly impose penalties far more severe than those found in many criminal statutes." (*Ibid.*) Historically, at least, California courts have exercised caution when construing these statutes, lest they "result in excessive penalties of at least hundreds of millions of dollars." (*Overstock.com*, *supra*, 12 Cal.App.5th at p. 1064; see *Hale*, *supra*, 22 Cal.3d at p. 401.) Yet the Court of Appeal here did the opposite.

This Court should grant review to ensure that individuals and companies subject to potentially-crushing civil penalties have fair notice that their conduct violates the law. Ethicon did not.

The trial court punished Ethicon for failing "to include all risks reasonably associated with [its] devices in the IFUs," as well as descriptors of those risks (e.g., chronic, severe), "whether already known to doctors or not." (26.AA.5640.) But before this litigation, no California court had ever read the UCL or FAL to impose such a requirement. In fact, the only remotely on-point case found *for the defendant*. (*Patricia A. Murray Dental Corp. v. Dentsply Int'l, Inc.* (2018) 19 Cal.App.5th 258.) A reasonable company consulting California law would have concluded that including "all risks" was *not* required. (*Ibid.*; see also *Nolte v. Cedars-Sinai Med. Ctr.* (2015) 236, Cal.App.4th 1401, 1409 ["no requirement" of "best possible notice"].)

This is especially true when one considers the regulatory overlay. Device IFUs are fundamentally regulatory documents, required by FDA. Not only did Ethicon comply with its regulatory obligations, which expressly allow manufacturers to omit complications from IFUs (21 C.F.R. § 801.109(c)), but some of the statements the trial court punished were *written* by FDA, as the Court of Appeal acknowledged (Opn. 61). The Court also affirmed penalties for marketing materials that referred to or excerpted from the IFUs, but that too is FDA-required. (53.RT.8811:23-8812:11.) And probably the best illustration of the fair-notice problem is that the Court of Appeal concluded that Ethicon's IFUs became *more* deceptive under California law (Opn. 41) when Ethicon changed them at the request of Canada's health authority (Opn. 8 fn.2).

The UCL's and FAL's penalty scheme makes the problem even more acute. "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." (Opn. 69.) Before, there at least were intelligible limits on how courts would exercise their discretion. (*Supra* Part II.) But now, "[c]hoice … is required" and "[w]ill, not judgment, dictates the result." (*Sessions*, *supra*, 138 S.Ct. at p. 1232 [Gorsuch, J., concurring].) Regulated companies hoping to comply with California law stand little chance of doing so and avoiding exorbitant penalties under the Court of Appeal's decision. Due process requires more.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for review and reverse.

O'MELVENY & MYERS LLP

By: *Charles C. Lifland*
Charles C. Lifland

CERTIFICATE OF WORD COUNT

In accordance with California Rules of Court Rule 8.504(d)(1), I certify that, exclusive of this certification and the other exclusions referenced in Rule of Court 8.504(d)(3), this PETITION FOR REVIEW contains 8173 words, including footnotes, as determined by the word count of the computer used to prepare this brief.

Dated: May 20, 2022

/s/ *Charles C. Lifland*
Charles C. Lifland

Court of Appeals Opinion, as Modified

Filed 4/27/22 (unmodified opn. attached)

CERTIFIED FOR PUBLICATION

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) ORDER MODIFYING OPINION AND DENYING REHEARING NO CHANGE IN JUDGMENT

THE COURT:

It is ordered that the opinion filed herein on April 11, 2022, be modified as follows:

On page 30, after the second sentence ending "Ethicon has waived its claim of error," add as footnote 10 the following footnote, which will require renumbering of all subsequent footnotes:

> [10] Ethicon filed a petition for rehearing challenging our determination that it waived its claim of error concerning the trial court's alleged failure to apply the correct legal standard for omissions-based claims. We reject Ethicon's argument. Ethicon's merits briefs purport to discuss the

> *circumstances* under which an omissions-based claim may be raised, but they do not set forth the proper *legal standard* a court must employ when assessing such a claim. Thus, Ethicon's argument is waived. Even if Ethicon had preserved its argument, our disposition of the case would remain the same because, as we will soon discuss, the argument fails on the merits.

There is no change in the judgment.

Appellant's petition for rehearing is denied.

McCONNELL, P. J.

Copies to: All parties

Filed 4/11/22 (unmodified opinion)

CERTIFIED FOR PUBLICATION

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.

PROOF OF SERVICE

I, Deresa Gade, declare:

I am an employee of the law firm of O'Melveny & Myers LLP, a resident of California, a citizen of the United States, over the age of eighteen, and not a party to the within action. My business address is 400 South Hope Street, 18th Floor, Los Angeles, California 90071-2899.

On May 20, 2022, I served the following documents:

PETITION FOR REVIEW

☒	**U.S. MAIL**: By placing the documents listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California, addressed as set forth below. I am readily familiar with the firm's practice of collecting and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on the same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

☒	**WEBSITE UPLOAD**: By causing to be uploaded to the Attorney General's official website for service of papers under Cal. Bus. & Prof. Code§§ 17209 and 17536.5, htt2s://oag.ca.gov/services-info/17209-brief/add.
☒	**ELECTRONIC**: By serving an electronic version of the documents listed above via TrueFiling EFS on the recipients designated below, who are registered TrueFiling EFS users.

The People of the State of California JON WORM (State Bar No. 248260) MONICA ZI (State Bar No. 245434) ADELINA ACUÑA (State Bar No. 284576) DANIEL OSBORN (State Bar No. 311037) GABRIEL SCHAEFFER (State Bar No. 308899) California Department of Justice 600 West Broadway, Suite 1800 P.O. Box 85266 San Diego, California 92101 Telephone: (619) 645-2001 Facsimile: (619) 645-2271	**1 Copy via Electronic**

San Diego District Attorney Summer Stephan Hall of Justice 330 W. Broadway San Diego, CA 92101 Telephone: (619) 531-4040 Facsimile: (619) 237-1351	**1 Copy via U.S. Mail**
California Attorney General Consumer Protection Section 1300 "I" Street Sacramento, CA 95814-2919 Phone: (916) 445-9555	**1 Copy via Website Upload**
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4th District California Court of Appeal, Division 1 750 B Street, Suite 300 San Diego, CA 92101	**1 Copy via Electronic**

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on May 20, 2022, at Los Angeles, CA.

Deresa Gade

Deresa Gade

STATE OF CALIFORNIA
Supreme Court of California

PROOF OF SERVICE

STATE OF CALIFORNIA
Supreme Court of California

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Case Number: **TEMP-79V06HBP**
Lower Court Case Number:

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Lifland, Charles (108950)

Last Name, First Name (PNum)

O'Melveny & Myers LLP

Law Firm

EXHIBIT 5

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

S274680

IN THE SUPREME COURT OF CALIFORNIA

En Banc

THE PEOPLE, Plaintiff and Respondent,

v.

JOHNSON & JOHNSON et al., Defendants and Appellants.

The petition for review is denied.

CANTIL-SAKAUYE

Chief Justice

EXHIBIT 6

S280018

S_____

IN THE SUPREME COURT OF CALIFORNIA

TAYLOR CAPITO,

Plaintiff, Appellant, and Petitioner

vs.

SAN JOSE HEALTHCARE SYSTEM LP, a Delaware limited partnership, DBA REGIONAL MEDICAL CENTER OF SAN JOSE,

Defendant and Respondent.

After a Decision by the Court of Appeal, Sixth Appellate District
Case Nos. H049022 and H049646

PETITION FOR REVIEW

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Service on the Attorney General of the State of California and the District Attorney for the County of Santa Clara Required by Cal. Bus. & Prof. Code, § 17209 and Cal. Rules of Court, Rule 8.29

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IN THE SUPREME COURT OF CALIFORNIA

TAYLOR CAPITO,

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vs.

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Defendant and Respondent.

After a Decision by the Court of Appeal, Sixth Appellate District
Case Nos. H049022 and H049646

PETITION FOR REVIEW

ISSUE PRESENTED

Under the strong consumer protections of the Unfair Competition Law (Bus. & Prof. Code, § 17200, *et seq*.) ("UCL") and the Consumers Legal Remedies Act (Civ. Code, § 1750, *et seq*.) ("CLRA"), does a hospital have a "duty to disclose" to emergency room consumers its intention (exclusively known by hospital) to charge a substantial Visitation Fee to each and every emergency room patient simply for being seen in the emergency room?

INTRODUCTION: WHY REVIEW SHOULD BE GRANTED

This Court should grant review to resolve a split in the Courts of Appeal as to whether a hospital has a "duty to disclose" its intention to charge a substantial, separate Emergency Room Visitation Fee ("ER Visitation Fee") to its emergency room patients simply for seeking treatment in the emergency room, when such Fee is in addition to, and on top of, the charges for services actually provided to the patient, such as lab tests, CT scans, x-rays, etc. The current split of authority arises as a result of the conflict between the Fifth District Court of Appeal, which published *Torres v. Adventist Health System/West* (2022) 77 Cal.App.5th 500, *review denied* (July 27, 2022) ("*Torres*") and *Naranjo v. Doctors Medical Center of Modesto, Inc.* (Cal. Ct. App., Apr. 28, 2023, No. F083197) 2023 WL 3144144, as modified on May 16, 2023 (certified for publication) ("*Naranjo*"), and the First District Court of Appeal, which published *Gray v. Dignity Health* (2021) 70 Cal.App.5th 225, *review denied* (Jan. 26, 2022) ("*Gray*") and *Saini v. Sutter Health* (2022) 80 Cal.App.5th 1054, *review denied* (Sept. 14, 2022) ("*Saini*"). The Opinion in this case relied almost entirely on the decisions in *Gray* and *Saini*. The Fifth District Court of Appeal has held that there is a "duty to disclose" the same ER Visitation Fees as are at issue in this case, based on a hospital's "exclusive knowledge" that it intends to charge such a Fee. The First District Court of Appeal and the Sixth District Court of Appeal in the instant case, on the other hand, have held that, because federal and state law have other specific disclosure requirements for hospitals, hospitals have no duty to disclose their intent to charge ER Visitation Fees. The Fifth

District and the First and Sixth Districts of the Court of Appeal have therefore reached the exact opposite conclusions as to whether there is a "duty to disclose" under the same factual and legal circumstances. Therefore, review is appropriate "to secure uniformity of decision or to settle an important question of law." Cal. Rules of Court, 8.500(b)(1).[1]

It is also important to note that this case presents a particularly appropriate vehicle for this Court's review, and the issue presented will have a strong impact across the State. The

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[1] Further, there are currently other cases pending in California courts raising the exact same "duty to disclose" issue raised herein, such that review will avoid further conflicting rulings at the appellate level as well. At least the following cases, in which Plaintiff/Appellant/Petitioner Taylor Capito's ("Capito") counsel are also counsel for the plaintiffs, currently involve the same "duty to disclose" question:

1. *Moran v. Prime Healthcare Management, Inc., et al.*, Orange County Superior Court Case No. 30-2013-00689394-CU-BC-CXC. The trial court granted the defendant's motion to strike allegations concerning the defendant's duty to disclose its intention to charge ER Visitation Fees, and the plaintiff appealed. That appeal is currently pending in the Fourth District, Division Three Court of Appeal (Case No. G060920) and has been fully briefed. Oral argument is scheduled on June 22, 2023.

2. *Salami v. Los Robles Regional Medical Center*, Ventura County Superior Court Case No. 56-2021-00560715-CU-BC-VTA. The trial court sustained the defendant's demurrer to the third amended complaint without leave to amend, and the plaintiff appealed. That appeal is currently pending in the Second District Court of Appeal (Case No. B327348). Appellant's Opening Brief is currently due on June 21, 2023.

3. *Fleschert v. Cedars-Sinai Medical Center*, Los Angeles County Superior Court Case No. 19STCV05681. The defendant's demurrer to the second amended complaint was overruled, and the case is currently proceeding in the trial court.

"duty to disclose" question presented directly impacts an industry-wide practice of virtually every hospital in California and therefore directly impacts millions of hospital emergency room visits and billions of dollars annually. If this Court grants review, and if Capito is successful, the beneficial result will be greater hospital pricing transparency, more informed consumer patients (who can therefore take more control of their own medical decisions), and fewer patients using hospital emergency rooms for "non-emergency" conditions.

For these reasons, as set forth more fully below, this Court should grant review.

FACTUAL AND PROCEDURAL BACKGROUND

I. Factual Background

In her second amended complaint, Capito challenged Defendant/Respondent San Jose Healthcare System LP, DBA Regional Medical Center of San Jose's ("Hospital") unfair, deceptive, and unlawful practice of charging its emergency room patients a substantial, undisclosed ER Visitation Fee, which is billed on top of and in addition to the charges for the individual items of treatment and services provided to the patient. (I AA 316-326.) Capito alleged that these ER Visitation Fees, set at one of five "levels," ranging in 2019 from $672.00 to $5,635.00, are undisclosed separate charges that are assessed simply for seeking treatment in the emergency room. (I AA 320.) Despite the ease by which Hospital could disclose its intention to charge such Fees (such as in its Conditions of Admission and Consent for Outpatient Care contract ("Contract"), through posted signage in the emergency room, on its website,

and/or during the patient registration process, among other possible methods) (I AA 317), Hospital fails to disclose such intention to prospective patients, thereby denying them the right to reasonably evaluate their situation and make informed decisions about their own health care. The choice should be up to the patient, rather than relying on Hospital's paternalistic (and self-serving) excuse that such costs are intentionally concealed in order to protect patients from making bad choices.

Capito's basic legal claim at issue was made in her second amended complaint, dismissed on demurrer without leave to amend. (II AA 928-938). The complaint alleged that a patient seeking medical treatment at Hospital's emergency room has the right to be informed that Hospital intends to add a substantial ER Visitation Fee to the total charges for the visit. (I AA 316-347.) The ER Visitation Fee was systematically imposed on the accounts of patients seen in the emergency room, and was billed on top of the charges for all individual items of treatment, services, and diagnostic testing actually provided to the patient during the patient's visit. (I AA 317-318.)

Regardless of the justification for such Fees, Hospital's intention to bill a substantial ER Visitation Fee is unfairly and intentionally concealed from unsuspecting emergency room patients who are entitled to know about the Fees and participate in their own medical decisions and treatment. Because Hospital fails to disclose these ER Visitation Fees to prospective emergency room patients by any available means, unsuspecting emergency room patients, including Capito, had no idea they would incur such Fees

for their visits. (I AA 317, 324-325.)

Pricing transparency and informed consent are critical issues in today's healthcare marketplace, and patients presenting at emergency rooms have an absolute right to know they will be charged a hefty ER Visitation Fee for their visit, so they can make an informed decision as to whether to remain despite the expense or leave and seek less costly treatment elsewhere (such as a much less expensive urgent care center).

Capito alleges that she fell victim to the wrongdoing alleged in the complaint. After presenting at Hospital's emergency room on two occasions in June 2019, Capito's total billed charges (before discounts) were $7,758.00 for her June 18, 2019 emergency room visit and $33,258.00 for her June 20, 2019 emergency room visit, both of which included a surprise ER Visitation Fee of $3,780.00, with such Fee being added to the charges for the individual items of service and treatment actually provided to her. (I AA 325.) At the time of Capito's emergency room visit, Capito was totally unaware of Hospital's intention to bill an ER Visitation Fee because it was not disclosed in any manner. (I AA 324-325.) There was no reasonable way for Capito to find out about Hospital's ER Visitation Fee, and she did not know about it at the time. Had Capito been informed about the ER Visitation Fee prior to incurring treatment that would result in such a Fee, Capito would have left and sought less expensive treatment elsewhere. (I AA 325.)

Based on Hospital's concealment of its intention to charge substantial ER Visitation Fees to emergency room patients, in her second amended complaint, Capito asserted causes of action for

declaratory relief, violation of the UCL, and violation of the CLRA; she sought damages and injunctive relief. (I AA 328-334.)

II. Procedural Background

The relevant procedural background of this petition is as follows: On September 17, 2021, the trial court sustained Hospital's demurrer to the second amended complaint without leave to amend. (II AA 928-938.) The court entered judgment (II AA 1017-1035), and Capito appealed (II AA 1036-1038.)

On April 6, 2023, the Court of Appeal affirmed the trial court's ruling in its unpublished Opinion (attached hereto), based on its agreement with the First District Court of Appeal's earlier decisions in *Gray*, 70 Cal.App.5th 225 and *Saini*, 80 Cal.App.5th 1054, which had themselves relied heavily on the Second District Court of Appeal's decision in *Nolte v. Cedars-Sinai Medical Center* (2015) 236 Cal.App.4th 1401 ("*Nolte*"). (Opinion, pp. 9-23.) In doing so, the Court of Appeal in this case reached the opposite conclusion as had the court in *Torres*, 77 Cal.App.5th 500 (Opinion, pp. 16-17, 20) and as has the court now in *Naranjo*, 2023 WL 3144144, as well.

On April 10, 2023 and April 18, 2023, respectively, Hospital and a non-party (California Hospital Association) requested publication of the Opinion, which the Court of Appeal denied on April 20, 2023.

On April 21, 2023, Capito filed a petition for rehearing, which the Court of Appeal denied on May 1, 2023.

Capito now petitions this Court to review the Opinion.

LEGAL DISCUSSION

I. This Court Should Grant Review to Settle the Conflict in the Courts of Appeal on the Important Legal Question of Whether a Hospital Has a "Duty to Disclose" to Prospective Emergency Room Patients That They Will be Charged a Substantial ER Visitation Fee Simply for Seeking Treatment and Being Seen in the Hospital's Emergency Room

This Court should grant review to settle the conflict in the Courts of Appeal on the important legal question of whether, under the strong consumer protections of the UCL and CLRA, Hospital has (or may have) a "duty to disclose" to prospective emergency room patients that they will be charged a separate ER Visitation Fee (billed on top of the charges for the individual items of service and treatment actually provided to the patient (such as CT scans, lab tests, drugs, etc.)) simply for seeking treatment in the emergency room.

As noted above, the conflict arises between the Fifth District Court of Appeal, on the one hand, and the First District Court of Appeal (and the Sixth District's Opinion in this case), on the other hand. Specifically, in *Torres,* 77 Cal.App.5th at pp. 510-513, the Fifth District recognized that a hospital has a "duty to disclose" an ER Visitation Fee under the CLRA based on the hospital's "exclusive knowledge" that it intends to charge such a Fee.[2] In *Naranjo*, 2023 WL 3144144, at **8-15, the Fifth District very recently expanded this holding to claims under both the CLRA and the UCL (as well as a claim for declaratory judgment). In doing so,

[2] The *Torres* and *Saini* cases only involved claims under the CLRA; *Naranjo*, *Gray*, and this case involved claims under both the CLRA and the UCL.

the court in *Naranjo* discussed the relevant case law (*Gutierrez v. Carmax Auto Superstores California* (2018) 19 Cal.App.5th 1234, *Torres*, *Gray*, *Saini*, and *Nolte*) (*id.* at **8-14) at length, affirmed the reasoning of *Gutierrez* and *Torres* (*id.* at **11-13), and expressly disagreed with the conclusion in *Gray* (*id.* at **6, 14) (and *Saini*, which relied almost entirely on *Gray*). More specifically, in reversing the trial court's dismissal of the case on the pleadings, the court in *Naranjo* held that "the trial court impliedly created a 'safe harbor' in violation of *Cel-Tech* [*Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163]'s ["*Cel-Tech*"] pronouncements when it determined no action would lie for claims alleging a breach of the duty to disclose material facts because federal and state law have other specific disclosure requirements." *Id.* at *13. The court in *Naranjo* recognized that this was the same incorrect ruling made by the court in *Gray*. *Id.* at *14. It was also the same ruling made by the courts in *Saini* and in the instant case.

Indeed, in approving the hospital defendants' concealment of their intent to charge ER Visitation Fees to patients simply for seeking treatment in the emergency room, the courts in *Gray* and *Saini*, and in the instant case, all relied on what they referred to as the "spirit of the law." *See Gray*, 70 Cal.App.5th at p. 240 ("[R]equiring individualized disclosure that the hospital will include an ER Charge in its emergency room billing, prior to providing any emergency medical services, is at odds with the spirit, if not the letter, of the hospital's statutory and regulatory obligations with respect to providing emergency medical care."); *Saini*, 80 Cal.App.5th at pp. 1060, 1065 (citing *Gray*); Opinion, p. 11 (same).

In doing so, these courts ignored this Court's holding in *Cel-Tech* (recognized by the court in *Naranjo*, 2023 WL 3144144, at *13) that a "safe harbor" does not arise by implication, but only when there is another statute that "actually 'bar[s]' the action or clearly permit[s] the conduct." *Cel-Tech*, 20 Cal.4th at 183. Therefore, *Gray* and *Saini* (and the Opinion in this case) directly conflict with this Court's holding in *Cel-Tech*.[3]

The Fifth District and the First and Sixth Districts of the Courts of Appeal have therefore reached the exact opposite conclusions as to whether there is a "duty to disclose" under the same factual and legal circumstances. Review is appropriate to resolve this conflict.[4]

II. The Statewide Impact of the Issue Presented is Enormous

Review is also particularly appropriate in light of the enormous beneficial impact that will likely result from this Court's review. Indeed, the significance of the specific question presented in this petition is of overwhelming importance, since, contrary to the *Torres* and *Naranjo* courts, the Court of Appeal here has essentially stated (as had the courts in *Gray* and *Saini*) that California

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[3] Further, even if the "spirit" of the law was a valid defense to liability in a UCL/CLRA case (which, under *Cel-Tech*, it is not), the courts in *Gray*, *Saini*, and the instant case incorrectly found that the "spirit" of the California Payors' Bill of Rights (along with the Emergency Medical Treatment and Active Labor Act ("EMTALA")) is to conceal a hospital's intent to impose an ER Visitation Fee for an emergency room visit.

[4] As also noted above, there are other cases pending in California trial courts and Courts of Appeal that would benefit from this Court's review.

hospitals are authorized to conceal a huge, hidden charge from millions of unsuspecting patients, now and in the future, a self-serving practice adopted by virtually all hospitals throughout California (of which there are more than 300). The monumental impact results from the industry-wide practice of California hospitals to systematically assess a substantial, up-front visitation charge for emergency room visits, and to conceal from unsuspecting patients their intention to do so. The ER Visitation Fees at issue are not mentioned in hospital form admission agreements; they are not described on emergency room signage; they are not explained during the patient registration process; and they are not even mentioned on hospital websites, or disclosed in any other manner at all. Thus, if Capito is successful, the disclosures requested would impact virtually every California hospital and would directly impact millions of hospital emergency room visits and billions of dollars annually. The disclosures would provide potential emergency room consumers with information that would allow them to make informed decisions about their own medical care, which is every patient's right.

It is also important to note that, if review is granted, and if Capito is successful, another significant (and related) benefit will result. Despite the Court of Appeal's stated concern that patients cannot "'accurately diagnose whether their ailment is 'relatively minor' and whether they can safely transport themselves or be transported to a lower acuity facility'" (Opinion, p. 14, citing *Gray*, 70 Cal.App.5th at pp. 241-242), it is well-known that a very large number of patients who present to the emergency room, including

Capito, have "non-emergency" conditions that could be appropriately treated in much less expensive urgent care centers or private doctors' offices (or even without receiving treatment at all).[5] *See, e.g.*, https://www.usnews.com/news/health-news/articles/2019-07-22/avoidable-er-visits-fuel-us-health-care-costs (citing to United Health Group data showing that "of 27 million emergency department visits annually by patients with private insurance, two-thirds are 'avoidable' and 'not an actual emergency.'")[6] For many of these patients, an emergency room visit is a matter of convenience, or the result of a prospective patient not being aware of the substantial expense of an emergency room visit. These consumers

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[5] Indeed, Hospital is obviously aware that many patients go to the emergency room for "non-emergency" matters, since it includes its emergency room wait times on its website. *See* https://regionalmedicalsanjose.com/about/er-wait-times.dot

[6] The UnitedHealth Group research also concluded:

> The average cost of treating common primary care treatable conditions at a hospital ED is $2,032, according to UnitedHealth Group. That number is 12 times higher than visiting a physician office ($167) and 10 times higher than traveling to an urgent care center ($193) to treat those same conditions. In other words, visiting either a physician's office or an urgent care facility instead of a hospital would save an average of more than $1,800 per visit – creating a $32 billion annual savings opportunity systemwide.
>
> What is driving the higher costs at hospital EDs? Higher costs are driven in part by hospital facility fees, which increase the cost of an average hospital ED visit by $1,069 ...

https://www.unitedhealthgroup.com/newsroom/posts/2019-07-22-high-cost-emergency-department-visits.html

have the absolute right to leave and seek less expensive treatment elsewhere (or not). Indeed, an emergency room patient always has the legal right to leave the premises, even "against medical advice."

Armed with the information that just walking through the emergency room door will result in a hefty charge, often in the thousands of dollars, billed on top of the charges for treatment and services actually provided to the patient, patients will be able to make their own informed medical and financial decisions, including leaving the premises if that is their informed choice. Accordingly, if review is granted, and if Capito is successful, the disclosures she seeks will result in many "non-emergency" patients leaving the emergency room, thereby "lessening the load on our emergency rooms," which even the court in *Gray* acknowledged, "might be a laudable goal." *Gray*, 70 Cal.App.5th at p. 242. For this additional reason, review is appropriate and should be granted.

CONCLUSION

As set forth herein, review should be granted to settle a direct conflict in the Courts of Appeal on an important and timely issue of consumer protection law relating to hospitals' "duty to disclose" material facts to consumers. For the reasons discussed above, this case, arising in the context of substantial hidden hospital emergency room fees, presents a particularly good vehicle for review.

DATED: May 16, 2023

Respectfully Submitted,

CARPENTER LAW

By: /s/ Gretchen Carpenter
Gretchen Carpenter
Attorneys for Plaintiff, Appellant, and Petitioner Taylor Capito

CERTIFICATE OF WORD COUNT

Pursuant to California Rule of Court 8.504(d)(1), I hereby certify that the attached petition contains 3,302 words, as counted by the Word Perfect X7 processing program used for the preparation of this petition.

I hereby declare and certify under the laws of the state of California that the foregoing statement is true and correct.

DATED: May 16, 2023

Respectfully Submitted,

CARPENTER LAW

By: /s/ Gretchen Carpenter
Gretchen Carpenter
Attorneys for Plaintiff, Appellant, and Petitioner Taylor Capito

ATTACHMENT

FILED 4/6/2023

NOT TO BE PUBLISHED IN OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SIXTH APPELLATE DISTRICT

TAYLOR CAPITO, Plaintiff and Appellant, v. SAN JOSE HEALTHCARE SYSTEM LP, Defendant and Respondent.	H049022, H049646 (Santa Clara County Super. Ct. No. 20CV366981)

On two occasions appellant Taylor Capito received treatment in the emergency room of respondent San Jose Healthcare System LP dba Regional Medical Center San Jose (Regional). The bill she received for her treatment included an "Evaluation and Management Services" fee (EMS fee) for each of the visits. Capito sued Regional for billing these fees, initially alleging one cause of action for violation of the Consumers Legal Remedies Act (CLRA) (Civ. Code, § 1750 et seq.) based on her contention that Regional charged its emergency patients an EMS fee without any advance notice to the patient. The trial court sustained Regional's demurrer to the first amended complaint and granted its motion to strike the class allegations with leave to amend. Capito thereafter filed a second amended complaint, to which she added causes of action for declaratory and injunctive relief, and violation of the Unfair Competition Law (UCL) (Bus. & Prof. Code, § 17200 et seq.). The trial court sustained Regional's demurrer to the second amended complaint without leave to amend. After denying Capito's motion for

reconsideration, the trial court entered a judgment of dismissal with prejudice in favor of Regional.

On appeal, Capito contends the trial court erred in striking the class allegations from the first amended complaint, and sustaining the demurrer to the second amended complaint. Based on the facts alleged in her complaint, and the recent decision in *Torres v. Adventist Health System/West* (2022) 77 Cal.App.5th 500 (*Torres*), Capito alleges that Regional had a duty to disclose its intention to charge an EMS fee, and its failure to do so constitutes a violation of the UCL and CLRA. She further alleges that the contract she signed with Regional for services neither authorized it to charge an EMS fee, nor included an agreement to pay such a fee, allegations which support her claims for declaratory judgment in addition to the UCL and CLRA causes of action. At minimum, Capito asserts that she should be allowed leave to amend her complaint to assert a cause of action for breach of contract. Discerning no error in the trial court's orders, we will affirm.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background

Regional is a major hospital in San Jose with an emergency room (ER). In June 2019, Capito sought emergency medical treatment at Regional on two occasions. At each visit, Capito signed Regional's "Conditions of Admission and Consent for Outpatient Care" (COA) form. In doing so, Capito promised to "pay the Patient's account at the rates stated in the hospital's price list (known as the 'Charge Master') effective on the date the charge is processed for the service provided, which rates are hereby expressly incorporated by reference as the price term of this agreement to pay the Patient's account."[1] (Emphasis omitted.) When she signed the COA, Capito acknowledged that

[1] " 'Charge description master' [chargemaster] means a uniform schedule of charges represented by the hospital as its gross billed charge for a given service or item, regardless of payer type." (Health & Saf. Code, § 1339.1, subd. (b)(1).)

she was given the opportunity to read and ask questions about the information in the COA, including the financial obligations provisions.

Regional initially billed Capito $41,016 for her two visits, including two " 'Level 4' Evaluation and Management Services Fee" charges of $3,780. Regional thereafter reduced Capito's total bill to $8,855.38, after deducting adjustments and discounts. Apart from the COA, which did not specifically reference the EMS fee, Capito did not receive advance notice that Regional would charge the EMS fee in addition to each item of service and treatment provided by the hospital. Capito alleges that had she been informed that she would be charged the EMS fee before incurring treatment, she would have left Regional and sought less expensive treatment elsewhere.

Regional's EMS fee is set at one of five levels, determined after the patient is discharged, based on a method known only to Regional. The five levels vary depending on the severity of treatment, ranging from minor to complex and life-threatening, and are disclosed in Regional's chargemaster, which is filed with the California Department of Health Care Access and Information (HCAI), formerly known as the Office of Statewide Health Planning and Development (OSHPD).[2] Capito alleges that the fee is designed to cover emergency room overhead expenses, separate from individual billable items of treatment or service. In 2019, the EMS fee amounts for Regional were as follows: Level 1: $672; Level 2: $1,660; Level 3: $2,836; Level 4: $3,780; and Level 5: $5,635. Regional charged Capito the Level 4 EMS fee for each of her visits, classified in the chargemaster as "high severity without significant threat."

[2] The court grants Regional's request for judicial notice and takes judicial notice of the exhibits attached thereto (text of first and second amended complaint, excerpts from Regional's chargemaster, the list of Regional's 25 most common procedures, legislative history documents authenticated by the Legislative Intent Service, and excerpts from the Federal Register and Code of Federal Regulations), as did the trial court.

B. Procedural History

Capito filed a complaint against Regional on behalf of herself and all others similarly situated for violation of the CLRA in June 2020, which she amended shortly thereafter, challenging Regional's "unfair, deceptive, and unlawful practice of charging [an EMS fee] without any notification of its intention to charge a prospective emergency room patient such a Fee for the patient's emergency room visit." Capito claimed that Regional charged the EMS fee simply for seeking care in the emergency room—describing it as designed to cover " 'overhead' type expenses of operating an emergency room"—without correlating the fee to the individual items of treatment and service that a patient received, and that the EMS fee "invariably comes as a complete surprise to unsuspecting emergency room patients." She further alleged that knowledge of the fee would be a substantial factor in a prospective patient's decision to remain at Regional and proceed with treatment, but claimed that ER patients could not reasonably be expected to be aware of the EMS fee, because Regional did not post signage notifying patients of the fee, and did not orally disclose the fee at the time of registration.

Capito acknowledged that Regional filed its chargemaster with OSHPD. She alleged that the chargemaster was not available on Regional's website or otherwise reasonably available to emergency room patients at the time of treatment, claiming that on June 20, 2020, a year after she received treatment at Regional, clicking on the " 'view our detailed price list' " link on Regional's website led to a "dead link." Because the chargemaster lists over 25,000 individual line items of treatment and services, Capito alleged that the inclusion of the EMS fee on the price list does not inform a prospective patient that the EMS fee will be added to their bill for seeking treatment in the emergency room. Capito asked the trial court to issue an order requiring Regional to notify patients of the EMS fee by posting "a simple, prominent sign placed in [Regional's] emergency room," setting forth the five levels of EMS fee with the explanation, "These fees are in addition to our charges for your actual treatment and services, and are intended to cover

the costs of your initial evaluation and management and the costs of operating and maintaining our 24-hour Emergency Department."

Capito brought the action on behalf of herself and "all individuals who, on or after June 10, 2017, received or will receive treatment at [Regional's] emergency room, and who were or will in the future be charged an [EMS fee]. . . ." Capito included one cause of action for violation of the CLRA, alleging that Regional "engage[d] in deceptive practices, unlawful methods of competition, and/or unfair acts to the detriment of [Capito] and the Class," in violation of Civil Code section 1770, subdivisions (a)(5) and (a)(14), by charging the EMS fee without advance notification to emergency room patients.[3]

Regional responded by filing a demurrer to the first amended complaint (FAC), as well as a motion to strike the class allegations, alleging that the proposed class did not meet California's standards for class certification as set forth in Code of Civil Procedure section 382.[4] The trial court overruled Regional's demurrer to the FAC, finding that Regional failed to establish as a matter of law that it had no duty to disclose the EMS fee under the CLRA. The court stated it would be "willing to entertain Regional's argument on a fuller record at the summary adjudication/judgment stage." It granted the motion to strike class allegations, with leave to amend, finding that while the class was "clearly

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[3] Civil Code section 1770 provides in relevant part: "(a) The unfair methods of competition and unfair or deceptive acts or practices listed in this subdivision undertaken by any person in a transaction intended to result or that results in the sale or lease of goods or services to any consumer are unlawful: [¶] . . . [¶] (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have. [¶] . . . [¶] (14) Representing that a transaction confers or involves rights, remedies, or obligations that it does not have or involve, or that are prohibited by law."

[4] "[W]hen the question is one of a common or general interest, of many persons, or when the parties are numerous, and it is impracticable to bring them all before the court, one or more may sue or defend for the benefit of all." (Code Civ. Proc., § 382.)

ascertainable," "the face of the FAC reveals that individual issues of reliance and materiality will predominate in this case as currently framed." Capito timely filed a notice of appeal from the order granting the motion to strike plaintiff's class allegations.[5]

Capito filed a second amended complaint in March 2021 (SAC). She reiterated the allegations and CLRA cause of action that survived Regional's demurrer to the FAC. In addition, Capito alleged two causes of action, for declaratory judgment and injunctive relief under Code of Civil Procedure section 1060, and for violation of the UCL. Capito stated in the SAC, "The Complaint is not that [Regional] fails to list an EMS Fee as a line item in the Hospital's published Chargemaster, [fn. omitted] or that [Regional] fails to list the price of such EMS Fees in the Hospital's Chargemaster, but rather the fact that [Regional] gives no notification or warning that it charges a separate EMS Fee for an emergency room visit," as the EMS fee is not explicitly disclosed in the COA, or specifically set forth in any emergency room signage or on Regional's website. Capito contended that the fact Regional would charge an EMS fee was not known or reasonably accessible to herself or other class members at the time of their emergency room visits, and the existence of such a fee would have been an important factor in determining whether to remain and obtain treatment at Regional.

In seeking declaratory judgment, Capito contended that she and members of the class were entitled to a declaration that Regional's "practice of charging a substantial undisclosed EMS Fee, in addition to the charges for the specific services and treatments

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[5] Although the court afforded Capito the opportunity to amend her complaint as to the class action claims, she filed the notice of appeal to protect her appellate rights under the so-called "death knell doctrine," which renders appealable an order that effectively terminates the entire action as to a class, such as the trial court's order striking the class allegations in the instant matter, even if it allows leave to amend. (See *Williams v. Impax Laboratories, Inc.* (2019) 41 Cal.App.5th 1060, 1070-1071.) We assigned this appeal number H049022 and ordered it considered together with Capito's appeal from the later-filed judgment of dismissal (appeal number H049646, discussed *post*) for purposes of briefing, oral argument, and disposition.

provided, is not authorized by [Regional's] Contract." She further sought a declaration that she and members of the class "have a right to know about [Regional's] separate EMS Fees, and that [Regional] owed Plaintiff and Class members a duty to disclose, in advance of providing treatment that would trigger an EMS Fee, its intention to charge such an EMS Fee."

She alleged that Regional violated the UCL, "insofar as the UCL prohibits 'any unlawful, unfair or fraudulent business act or practice.' " Capito claimed that Regional's conduct in billing the EMS fee was "unfair" because it violated the CLRA, such that the claim was "tethered to a legislatively declared policy" and because Regional's practices "offend established public policies, and are immoral, unethical, oppressive, and unscrupulous." Capito further contended that Regional's conduct was "unlawful" under the UCL because it violated the CLRA. Capito alleged that Regional violated the CLRA "by engaging in and continuing to engage in deceptive practices, unlawful methods of competition, and/or unfair acts to the detriment of [Capito] and the Class," contending that Regional's "acts and practices constitute omissions/concealment that the services and/or supplies in question had characteristics, uses and/or benefits which they did not have," in violation of Civil Code section 1770, subdivision (a)(5), and that Regional "omit[ted]/conceal[ed] that a transaction involves obligations which it does have," in violation of Civil Code section 1770, subdivision (a)(14).

Regional demurred to the SAC and moved to strike the class allegations. In doing so, it briefed the legislative history behind the Payers' Bill of Rights (Health & Saf. Code, § 1339.50 et seq.) and other federal and state regulations governing its pricing disclosures. Capito opposed the demurrer, arguing that the trial court had already rejected most of the arguments Regional raised. The court issued a tentative ruling prior to the initial hearing overruling the demurrer and denying the motion to strike. Regional contested the tentative ruling, after which the trial court held a hearing and took the matter under submission.

The trial court thereafter issued an order sua sponte reconsidering its previous legal analysis concerning Regional's demurrer arguments, and asked for supplemental briefing from the parties regarding: the relevance of the legislative history of Assembly Bill No. 1627 (2002-2003 Reg. Sess.) on Capito's UCL claim; and the effect, if any, on Capito's other claims if the court were to determine that Regional's failure to provide additional notice about the EMS fee was not "unfair" under the UCL. After receiving additional briefs from both parties, the court issued a supplemental order sustaining the demurrer to the SAC without leave to amend, finding that Regional did not have a duty to disclose the EMS fee beyond what was already required by the Payers' Bill of Rights. Based on its ruling, it deemed Regional's motion to strike the class allegations moot.

Capito filed a motion for reconsideration of the trial court's order under Code of Civil Procedure section 1008, subdivision (a), alleging that new law decided after the court entered the order sustaining the demurrer without leave to amend required the court to revisit its ruling as to the declaratory judgment cause of action. In addition, Capito asserted that the trial court should have held a hearing before reconsidering its tentative ruling overruling the demurrer to the SAC, arguing that the court's order sustaining the demurrer without leave to amend included "rulings beyond the two supplemental questions asked by the Court" when it requested supplemental briefing after it heard argument on the demurrer.

After considering briefing from both parties and oral argument, the trial court denied Capito's motion for reconsideration, ruling that case law supported its order sustaining the demurrer. In doing so, the trial court noted, "[Capito] argues that the Court should have held a hearing on the motion for reconsideration. But [Capito] did not request oral argument when the Court stated in its July 2021 notice that it would likely not hold a hearing, but would ask for (and did receive and consider) supplemental briefing. The Court therefore provided the parties 'a reasonable opportunity to litigate the question.' (*Le Francois v. Goel* (2005) 35 Cal.4th 1094, 1097 [*Le Francois*].)"

In December 2021, the trial court issued an "amended judgment of dismissal with prejudice," dismissing Capito's action with prejudice and entering judgment in favor of Regional.[6] Capito timely appealed from the judgment (appeal No. H049646).

II. DISCUSSION

We review the judgment of dismissal after a demurrer is sustained de novo, assuming the truth of all facts properly plead by the plaintiff, and exercising our independent judgment to determine whether the plaintiff stated a cause of action under any legal theory. We do not assume the truth of contentions, deductions, or conclusions of law. (See *Gray v. Dignity Health* (2021) 70 Cal.App.5th 225, 236, fn. 10 (*Gray*).)

A. Capito's UCL Claim

Capito contends that Regional's notice to patients of the EMS fee violates the UCL as an unfair business practice because there was no sign in the emergency room listing the five levels of EMS fee, no fee expressly set forth in the COA or on Regional's website, and no verbal notification of the EMS fee. She additionally asserts that Regional's notification practice is "unlawful" under the CLRA. Because Regional's practices violate the CLRA, Capito contends that the UCL is further violated as "tethered to a legislatively declared policy." As we discuss below, these arguments were rejected persuasively by Division One of the First District Court of Appeal in *Gray*, *supra*.

We first address Capito's claim that Regional's failure to disclose the EMS fee was an unfair business practice under the UCL.

The purpose of the UCL is "to safeguard the public against the creation or perpetuation of monopolies and to foster and encourage competition, by prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." (Bus. & Prof. Code, § 17001.) " 'The UCL does not proscribe specific acts, but broadly prohibits "any

[6] Although entitled an "amended" judgment, the record indicates this was the only judgment entered by the trial court after it sustained the demurrer to the SAC.

unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. . . ." (Bus. & Prof. Code, § 17200.) "The scope of the UCL is quite broad. [Citations.] Because the statute is framed in the disjunctive, a business practice need only meet one of the three criteria to be considered unfair competition." [Citation.] " ' "Therefore, an act or practice is "unfair competition" under the UCL if it is forbidden by law or, even if not specifically prohibited by law, is deemed an unfair act or practice." ' " [Citation.]'[7] [Citation.]" (*Gray*, *supra*, 70 Cal.App.5th at pp. 236-237.)

An "unlawful" act or practice is "anything that can properly be called a business practice and that at the same time is forbidden by law." (*Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 180 (*Cel-Tech*).) The UCL does not define the term "unfair" as it pertains to actions by consumers. Some courts will find a business practice to be unfair "if it violates established public policy or if it is immoral, unethical, oppressive or unscrupulous and causes injury to consumers which outweighs its benefits. [Citations.]" (*Gray*, *supra*, 70 Cal.App.5th at p. 238.) Others require that the alleged " 'unfairness' be 'tethered to some legislatively declared policy.' [Citations.]" (*Ibid.*) We agree with the court in *Gray* that, regardless of which standard is applied, Regional's failure to disclose the EMS fee is not an "unfair" practice that either violates established public policy or is immoral, unethical, oppressive or unscrupulous. (*Id.* at p. 242.)

The plaintiff in *Gray* alleged, as Capito does here, that the failure of a hospital to separately disclose in advance of medical treatment that its bill for emergency services would include an EMS fee—either by posting signage or verbally advising the patient during the registration process—was an unfair business practice under the UCL. (*Gray*, *supra*, 70 Cal.App.5th at p. 238.) Discussing at length the regulatory scheme governing

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[7] " 'Although the likelihood of deception is often too fact intensive to decide on the pleadings, courts can and do sustain demurrers on UCL claims when the facts alleged fail as a matter of law to show such a likelihood.' [Citations.]"

emergency room providers, the court rejected the contention that the hospital's practice provided the basis for a UCL claim. "[R]equiring individualized disclosure that the hospital will include an ER Charge in its emergency room billing, prior to providing any emergency medical services, is at odds with the spirit, if not the letter, of the hospital's statutory and regulatory obligations with respect to providing emergency medical care." (*Id.* at p. 240.) These obligations reflect "a strong legislative policy to ensure that emergency medical care is provided immediately to those who need it, and that billing disclosure requirements are not to stand in the way of this paramount objective." (*Id*. at p. 241.)

The court in *Gray* described the complex regulatory scheme applicable to medical providers under state and federal law that addresses billing transparency along with the imperative of providing emergency medical services. The Payers' Bill of Rights sets forth "numerous obligations California hospitals owe to consumers with respect to the pricing of medical services." (*Gray*, *supra*, 70 Cal.App.5th at p. 229.) The Legislature enacted and later amended the Payers' Bill of Rights in an effort to "increase transparency in hospital pricing to enable consumers to comparison shop for medical services." (*Id*. at pp. 229-230, citing Cal. Health & Human Services Agency, Enrolled Bill Rep. on Assem. Bill No. 1045 (2005-2006 Reg. Sess.).)

Under state and federal law, hospitals are required to provide emergency care to any person presenting to the emergency department for such care. The patient must first be stabilized before discussing the patient's ability to pay. (*Gray*, *supra*, 70 Cal.App.5th at pp. 240-241.) The hospital must make a copy of its chargemaster available online or at the hospital and post notice at various locations, including in the emergency department, that the chargemaster is available. (Health & Saf. Code, § 1339.51, subds. (a), (c).) Each hospital must file the chargemaster with OSHPD, as well as submit a list of 25 common outpatient procedures, compiled annually, to OSHPD, which OSHPD then publishes on its website. (Health & Saf. Code, § 1339.55, subds. (a), (c).) Although hospitals are

generally required to provide uninsured patients a written estimate of services upon request, that obligation does not apply when a patient is treated in the emergency department. (Health & Saf. Code, § 1339.585.)[8] "Together, this multi-faceted statutory and regulatory scheme reflects a strong legislative policy to ensure that emergency medical care is provided immediately to those who need it, and that billing disclosure requirements are not to stand in the way of this paramount objective." (*Gray*, at p. 241.)

Under federal regulations from the Centers for Medicaid and Medicare Services (CMS), hospitals bill emergency visits using a five-level system of current procedural terminology codes (CPT codes), which "are used to report [evaluation and management] services provided in the emergency department. . . ." (72 Fed.Reg. 66581, 66789, 66790; see *Gray*, *supra*, 70 Cal.App.5th at p. 235; *Torres*, *supra*, 77 Cal.App.5th at p. 505.) The codes "were defined to reflect the activities of physicians and do not necessarily fully describe the range and mix of services provided by hospitals during visits of clinic and emergency department patients and critical care encounters." (72 Fed.Reg. 66790.) CMS requires hospital guidelines for setting charges for EMS fee levels to meet certain standards. The guidelines must be designed to reasonably relate the intensity of hospital

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[8] "As originally introduced, this legislation required hospitals to provide an estimate of charges upon the request of any patient—including those receiving care in the emergency department. (Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as introduced Feb. 22, 2005.) As the bill moved through the legislative process, it was amended first to apply only to non-emergency patients (Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as amended May 27, 2005) and then amended again to apply only to uninsured persons. (Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as amended Sept. 6, 2005.)" (*Gray*, *supra*, 70 Cal.App.5th at p. 231.) Capito correctly observes that Civil Code section 1339.585 as first introduced applied "[u]pon admission of a patient," without reference to patients seen in the emergency department (Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as introduced Feb. 22, 2005), suggesting the *Gray* court misinterpreted the legislative history. However, the *Gray* court correctly described the evolution of the statute which ultimately included a specific exclusion of its application to emergency services' patients. (Compare Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as introduced Feb. 22, 2005, with Assem. Bill No. 1045 (2005-2006 Reg. Sess.) as amended April 20, 2005, May 27, 2005, June 22, 2005, July 6, 2005, and Sept. 6, 2005.)

resources to the different levels of effort represented by the code, and be based on hospital resources and not physician resources. (72 Fed.Reg. 66805.)

"Federal regulatory law, pursuant to the Patient Protection and Affordable Care Act (Pub.L. No. 111-148 (Mar. 23, 2010) 124 Stat. 119), imposes additional pricing disclosure requirements on Medicare participating hospitals—namely that they must file, in addition to their chargemaster, a 'list' of 'standard charges' in accordance with guidelines promulgated by the Secretary of Health and Human Services. (42 U.S.C. § 300gg-18(e).)" (*Gray*, *supra*, 70 Cal.App.5th at p. 232, fn. omitted.) In expanding the disclosure requirements, federal regulators made efforts to ensure that such obligations did not interfere with obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA).[9] (*Id.* at p. 241.)

The court in *Gray* observed that while pricing disclosure requirements are focused on medical services that can be planned in advance (i.e., non-emergency services), the need for emergency treatment generally arises "for serious, and often grave, unplanned accidents or medical calamities." (*Gray*, *supra*, 70 Cal.App.5th at p. 241.) Though the CMS "applauded" hospitals who made efforts to provide information to patients in addition to meeting the posting requirements, the CMS confirmed that "the price transparency provisions . . . do not require that hospitals post any signage or make any

[9] Under the EMTALA, an emergency department must provide appropriate screening to any person who presents to the department requesting examination or treatment. If the hospital determines that the person has an emergency medical condition, the hospital must provide treatment to stabilize the condition. " 'Under EMTALA, hospitals with emergency departments have two obligations. First, if any individual comes to the emergency department requesting examination or treatment, a hospital must provide for "an appropriate medical screening examination within the capability of the hospital's emergency department." (42 U.S.C. § 1395dd(a).) Second, if the hospital "determines that the individual has an emergency medical condition," it must provide "within the staff and facilities available at the hospital" for "such treatment as may be required to stabilize the medical condition" and may not transfer such a patient until the condition is stabilized or other statutory criteria are fulfilled. (*Id*., § 1395dd(b) & (c).)' [Citation.]" (*Gray*, *supra*, 70 Cal.App.5th at p. 234, fn. 8.)

statement at the emergency department regarding the cost of emergency care or any hospital policies regarding prepayment of fees or payment of co-pays and deductibles." (84 Fed.Reg. 65536, 65577.)

In *Gray*, having considered the comprehensive scheme governing medical billing practices and those relevant to emergency room services, the appellate court determined that the signage and verbal pretreatment disclosure obligation that the plaintiff was claiming the hospital owed was the same obligation "the [CMS] has reassured hospitals does not exist." (*Gray*, *supra*, 70 Cal.App.5th at p. 241.)[10] Moreover, the court rejected the plaintiff's contention that a pretreatment duty to disclose the emergency room fee would make emergency departments less crowded because it would encourage patients with "relatively minor ailments" to seek treatment elsewhere. "[Plaintiff's] sweeping assumption that those seeking care at an emergency department can accurately diagnose whether their ailment is 'relatively minor' and whether they can safely transport themselves or be transported to a lower acuity facility, is unsupportable. And while [plaintiff] complains this is a 'paternalistic' attitude and asserts every person has a right to decide for him or herself whether to seek medical treatment at an emergency department, and to do so based on readily accessible cost information, this disregards the long standing regulatory environment within which emergency departments operate, which emphasizes that no one in need of emergency care should be deterred from receiving it because of its cost." (*Id.* at pp. 241-242.)

Noting that the plaintiff did not allege that the hospital violated "any of the statutory and regulatory duties" governing the provision of emergency room services, the appellate court determined that the hospital's failure to disclose the emergency room charge did not meet the substantive definition of an "unfair," actionable practice, as the alleged conduct did not " ' "violate[] established public policy," ' " nor was it

[10] Although the Gray court referenced the "CMC" in its discussion, it is clear from context that it is referring to the CMS. (See *Gray*, *supra*, 70 Cal.App.5th at p. 233.)

" ' "immoral, unethical, oppressive or unscrupulous." ' " (*Gray, supra,* 70 Cal.App.5th at p. 242, citing *Nolte v. Cedars-Sinai Medical Center* (2015) 236 Cal.App.4th 1401, 1407-1408 (*Nolte*).)

The *Gray* court's thoughtful deference to the complex legislative and regulatory system relevant to emergency medical services is well placed. While we are not bound by the opinion of another appellate district, "we generally follow the decisions of other appellate courts unless there is good reason to disagree." (*County of Kern v. State Dept. of Health Care Services* (2009) 180 Cal.App.4th 1504, 1510.) Here we conclude that defining the circumstances under which hospitals should be required to disclose fees for services rendered to emergency room patients "is a task for which legislative and administrative bodies are particularly well suited," and "would involve matters that are peculiarly susceptible to legislative and administrative investigation and determination, based upon empirical data and consideration of the viewpoints of all interested parties." (*Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539, 552-553.) Capito's claim under the UCL would require this court to establish a notice requirement beyond that mandated by statute and regulation. Consistent with *Gray*, we conclude that Regional's failure to separately disclose the possible imposition of an EMS fee before providing emergency treatment does not meet the substantive definition of an "unfair" practice actionable under the UCL.

B. Capito's CLRA Claim

We next turn to Capito's CRLA claim. Capito asserts that Regional had exclusive knowledge of and concealed the material fact that an EMS fee could be charged to her, thus violating the CRLA. She then argues that the claim provides a "tether" to the UCL, and therefore separately forms the basis for a UCL violation.

" ' " 'The [CLRA], enacted in 1970, "established a nonexclusive statutory remedy for 'unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of

goods or services to any consumer. . . .' [Citation.]" ' [Citation.] 'The self-declared purposes of the act are "to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection." ' " ' " (*Gray*, *supra*, 70 Cal.App.5th at pp. 242-243.) The appellate court in *Gray* held that the assertion that a hospital's failure to disclose an emergency room charge similar to the EMS fee at issue here does not state a CLRA claim under Civil Code section 1770, subdivision (a)(5) or (a)(14). (*Gray,* at p. 245.)

Since the opinion in *Gray* in 2021, two additional courts have addressed whether a failure to disclose a fee similar to the EMS fee at issue here can form the basis for a claim under the CLRA. In *Torres*, the Fifth District Court of Appeal determined that the plaintiff, in making a CLRA claim under Civil Code section 1770, subdivisions (a)(5) and (a)(14), had adequately alleged that the hospital failed to disclose facts that were known exclusively to the hospital and were not reasonably accessible to the plaintiff, which was one of four situations recognized by the court "where a failure to disclose a material fact constituted a deceptive practice actionable under the CLRA. . . ." (*Torres*, *supra*, 77 Cal.App.5th at pp. 509, 510-513.) As Capito did in the instant matter, the plaintiff in *Torres* alleged that the hospital charged an EMS fee set at one of five levels determined after discharge based on a formula known exclusively to the hospital. (*Id*. at p. 510.) The appellate court found that the plaintiff adequately alleged that she "did not know an EMS Fee existed, did not know the events that triggered its imposition, did not know there were five levels of EMS Fees, did not know the formula used to determine which level of fee to impose on an emergency room patient, did not know the amount charged for each fee level, and did not know she would be billed an EMS Fee." (*Id*. at p. 511.)

The appellate court also concluded, based on a "reasonable person standard," that the plaintiff sufficiently plead a lack of reasonable access to 1) the facts that would trigger the imposition of the EMS fee and 2) the formula used to determine which level of

fee would apply to a particular patient, despite the plaintiff's access to the chargemaster and list of 25 common outpatient procedures. (*Torres*, *supra*, 77 Cal.App.5th at pp. 512-513.) Unlike Capito, the plaintiff in *Torres* alleged that the "chargemaster was 'unusable and effectively worthless for the purpose of providing pricing information to consumers'; the chargemaster failed to include the standardized CPT codes recognized in the industry; and the chargemaster used coding and highly abbreviated descriptions that are meaningless to consumers. "[T]hese allegations [which the court accepted as true for purposes of a motion for judgment on the pleadings] are sufficient to allege the material facts were not reasonably accessible and the factual question of reasonable access cannot be resolved at the pleading stage." (*Torres*, *supra*, 77 Cal.App.5th at p. 512.)[11] The *Torres* court expressly relied on these allegations in reaching its decision. (*Id*. at pp. 512-513.)

However, the appellate court ultimately determined that the plaintiff in *Torres* failed to properly plead a CLRA claim because she did not sufficiently allege reliance as was necessary to claim that the misrepresentation or omission of fact was material. (*Torres*, *supra*, 77 Cal.App.5th at p. 513.) The plaintiff's allegation that she " 'relied on not being billed' " coupled with her failure to allege that she would have behaved differently if the information had been disclosed was "not sufficient to properly plead reliance for purposes of alleging a claim under the CLRA based on a failure to disclose a material fact." (*Id*. at p. 514.)

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[11] The *Torres* court acknowledged the seemingly inapposite holdings in *Gray* and *Nolte*, stating, "We note that this interpretation of the SAC does not contradict the conclusions reached in *Gray*[, *supra*, 70 Cal.App.5th 225] or *Nolte*[], *supra*, 236 Cal.App.4th 1401 because neither of those decisions addressed whether the hospital had a duty to disclose based on its exclusive knowledge of material facts. [Citation.] As a result, neither decision explicitly addressed the patient's lack of reasonable access of a material fact. Therefore, they did not establish that a disclosure of the price charged for a service also discloses the circumstances in which the charge is imposed." (*Torres*, *supra*, 77 Cal.App.5th at p. 513.)

Shortly after the Fifth District issued its opinion in *Torres*, Division Four of the First District Court of Appeal decided *Saini v. Sutter Health* (2022) 80 Cal.App.5th 1054 (*Saini*). As in the instant matter and *Torres*, the plaintiff in *Saini* alleged a violation of the CLRA based on a hospital's failure to separately disclose an EMS fee apart from the COA and chargemaster prior to providing emergency medical treatment.[12] (*Id*. at pp. 1056-1057.) Recognizing that a different division of the First District held otherwise in *Gray*, the plaintiff argued that *Gray* was wrongly decided; the appellate court was not persuaded and held that the trial court properly sustained the hospital's demurrer to the CLRA cause of action. (*Saini*, at pp. 1057, 1066.)

Like Capito, the plaintiff in *Saini* alleged that the EMS fee "is charged to emergency room patients simply for seeking treatment in the emergency room and is designed to cover 'overhead' and general operating and staffing expenses for operating an emergency room on a 24 hour basis. . . . Further, the fact that [the hospital] intends to charge an EMS Fee to patients simply for being seen in the emergency room is not visibly posted on signage in or around defendant's emergency rooms or at its registration windows/desks, where a patient would at least have the opportunity of knowing of its existence . . . .' " (*Saini*, *supra*, 80 Cal.App.5th at pp. 1057-1058.) The complaint alleged that the hospital complied with the requirements of the Payers' Bill of Rights by listing and publishing the EMS fee in its chargemaster, stating, as Capito did in her SAC, that plaintiff's claim was " 'not that defendant fails to list an EMS Fee as a line item in its published chargemasters, or that defendant fails to list the price of such fees in its chargemasters.' " (*Id*. at p. 1058.) The plaintiff contended that the requirement for hospitals to post their chargemasters was not intended to and did not inform emergency room patients of the EMS fee. (*Id*. at p. 1059.) The trial court sustained a demurrer to

[12] Capito's attorneys represented the appellants in *Gray*, *Torres*, and *Saini*.

the complaint without leave to amend, determining that the hospital did not have a duty to post notice of the EMS fee in the emergency room.

On appeal, plaintiff argued that the hospital "had a duty to disclose under the CLRA based on its 'exclusive knowledge' and 'intentional concealment' as alleged in his complaint." (*Saini*, *supra*, 80 Cal.App.5th at p. 1061.) Citing the "well-reasoned opinion" in *Gray*, the appellate court affirmed the trial court. (*Saini,* at p. 1059.) While the *Saini* court acknowledged that the hospital had a general duty to disclose medical fees based on exclusive knowledge of material facts, it agreed with the *Gray* court that the hospital did not have a duty to "call attention to the EMS Fee by additional signage in the emergency room visible to a person seeking emergency care" in addition to disclosing the fee in its chargemaster "to which signage in the emergency room directs those interested," noting that there was "no withholding of information that is provided on the hospital's chargemaster." (*Id*. at p. 1062.)

The court approved the *Gray* court's consideration of "the competing interests served by ensuring that patients are fully apprised in advance of the costs of emergency services and ensuring that patients have timely access to emergency services," and addressed the additional legislative history offered by the plaintiff, suggesting that the CMS has considered whether to require hospitals to provide more information about the cost of care in emergency departments. (*Saini, supra*, 80 Cal.App.5th at pp. 1062-1063.) "As *Gray* makes clear, the state and federal legislative bodies are in a superior position to balance these competing interests and have done so in crafting the applicable 'multifaceted statutory and regulatory scheme.' (*Gray*, *supra*, 70 Cal.App.5th at p. 241.) Our conclusion is consistent with the balance struck by the existing regulatory scheme and does not, as plaintiff suggests, disregard the 'important policy in favor of providing pricing transparency to medical patients.' " (*Saini*, at p. 1063.) The court further noted that claims concerning compliance with the laws governing a hospital's provision of a chargemaster could be raised with the HCAI. (*Ibid*., citing Health & Saf. Code,

§§ 1339.54, 1339.55, subd. (a).) Thus, it declined to "imply that [the hospital's] chargemaster provides insufficient notice of the existence of the EMS Fee." (*Ibid*.)

Capito contends that the SAC sufficiently pleads her lack of reasonable access to material facts known exclusively to Regional. Thus, she asks this court to apply the holding in *Torres*. We decline to do so. As we have discussed, we agree with the *Gray* court's deferential approach to the legislative and regulatory determinations of what constitutes requisite notice of the costs of emergency medical services.

Further, the allegations in Capito's SAC are distinguishable from the plaintiff's in *Torres*. There the plaintiff alleged in the complaint that the chargemaster was "unusable and effectively worthless," that it failed to include the standard CPT codes, and that the coding and descriptions in the chargemaster were "meaningless to consumers" (*Torres*, *supra*, 77 Cal.App.5th at p. 512). In contrast, Capito, like the appellant in *Saini*, "expressly disavow[ed] any claim that 'defendant fails to list an EMS Fee as a line item in its published chargemasters, or that defendant fails to list the price of such fees in its chargemasters.' " (*Saini*, *supra*, 80 Cal.App.5th at p. 1062, fn. 8.)

Similarly, Capito, in the SAC, does not allege that Regional's chargemaster was " 'unusable and effectively worthless for the purpose of providing pricing information to consumers[,]' " nor is there any allegation that the chargemaster failed to include standardized codes recognized in the industry or that the chargemaster used " 'highly abbreviated descriptions that are meaningless to consumers.' " In effect, Capito concedes in the SAC that the chargemaster complies with the applicable " 'multifaceted statutory and regulatory scheme,' " and as in *Saini*, our conclusion that the SAC does not state a cause of action for violation of the CLRA is "consistent with the balance struck by the existing regulatory scheme." (*Saini*, *supra*, 80 Cal.App.5th at p. 1063; *Gray*, *supra*, 70 Cal.App.5th at p. 241.) Further, unlike the contract in *Torres*, in which plaintiff agreed to "promptly pay all hospital bills in accordance with the regular rates and terms of the medical center. . . ," Regional's COA expressly referenced the chargemaster and invited

Capito to request an estimate of costs before receiving treatment. (*Torres*, *supra*, 77 Cal.App.5th at p. 504.)

But Capito argues that Regional concealed exclusive knowledge that an EMS fee would be charged in violation of the CLRA because the hospital did not disclose the EMS fee in specific ways. She alleges in the SAC that the EMS fees are "effectively hidden by [Regional's] intentional failure to provide notice of them in its Contract, in any emergency room signage, on its website, during the patient registration process, or by any means reasonably designed to apprise prospective patients of such EMS Fees." Capito seeks to distinguish the SAC from the complaint considered in *Saini* by arguing that the SAC sought disclosure of the EMS Fee not only through signage posted in the ER, but also in the COA and on Regional's website. But this claim again presupposes that notice of the EMS fee should be provided in a manner exceeding that required by the scheme governing charging practices for emergency medical services.

Similarly, Capito contends in the SAC that "at least during part of the Class Period, [Regional] did not make its chargemaster available on its own website or reasonably available to emergency room patients at the time of their emergency room visits," alleging that clicking on " 'view our detailed price list' on [Regional's] website led to a dead link" as of July 20, 2020. We observe that while Capito clearly alleged that the EMS Fee was not specifically disclosed on signage in or around the ER, she did not allege in the complaint that Regional failed to comply with the requirements of Health and Safety Code section 1339.51, subdivision (c), requiring the hospital to "post a clear and conspicuous notice in its emergency department, if any, in its admissions office, and in its billing office that informs patients that the hospital's charge description master is available." Capito did not allege that the chargemaster was not available either online *or* at the hospital at the time she received treatment in June 2019. As we have determined that hospitals have no duty to disclose potential charges beyond the means established in the applicable regulatory scheme, and because the Payers' Bill of Rights requires

hospitals to make a written or electronic copy of the chargemaster available online *or* at the hospital, this allegation does not ameliorate the deficiency in Capito's pleading. (Health & Saf. Code, § 1339.51, subd. (a).) Absent an allegation that Regional did not have its chargemaster available to Capito either online *or* at the hospital at the time Capito received treatment, or that it failed to give proper notice of the availability of the chargemaster at that time, Capito cannot demonstrate causation under Civil Code section 1780, subdivision (a). (See *Gray*, *supra*, 70 Cal.App.5th at p. 243.)

Capito further contends that the reliance on *Gray* by the *Saini* court and the trial court in this matter was contrary to the California Supreme Court's decision in *Cel-Tech*, arguing that these decisions rely not on the language of a specific statute barring her action or clearly permitting Regional's conduct, but instead created an impermissible " 'implied' safe harbor." The *Saini* court rejected a similar argument. "In *Cel-Tech*[, *supra*,] 20 Cal.4th 163, 182 [83 Cal. Rptr. 2d 548, 973 P.2d 527], the court held that where specific legislation provides a 'safe harbor,' plaintiffs 'may not use the general unfair competition law to assault that harbor.' The court held further, however, that there is no implied 'safe harbor' under California law for claims asserted under the UCL. . . . *Cel-Tech* did not address claims asserted under the CLRA. In any event, the *Gray* court's conclusion that the proposed duty would interfere with the statutory and regulatory requirements that hospitals provide emergency care without first addressing the costs for care or the patient's ability to pay does not imply a 'safe harbor' for the alleged omission. (*Gray*, *supra*, 70 Cal.App.5th at p. 241.)" (*Saini*, *supra*, 80 Cal.App.5th at pp. 1064-1065.)

Consistent with the holdings in *Gray* and *Saini*, we conclude that Capito has not stated a cause of action under the CLRA for concealment of a material fact not accessible to Capito. The material fact—the existence of an EMS fee—was disclosed and available to the public, including Capito, in accordance with the procedure mandated by the Legislature, and Capito did not allege that Regional failed to comply with the statutory

procedure. (See *Nolte*, *supra*, 236 Cal.App.4th at p. 1408.) The SAC does not sufficiently plead a cause of action, either under the CLRA or the UCL.

C. Declaratory Relief/ Contract-Based Claims

In the SAC, Capito raised two bases for seeking declaratory judgment under Code of Civil Procedure section 1060: first, that she is not required to pay the EMS fee under the COA, because the "practice of charging a substantial undisclosed EMS Fee, in addition to the charges for the specific services and treatments provided, is not authorized by [the COA]"; second, that Regional had a duty to disclose its intention to charge a separate EMS fee to ER patients before they receive treatment triggering such a charge.

Based on our determination that Regional did not have a duty to separately disclose the EMS fee, Capito's declaratory relief claim fails in this regard, as it does not materially differ from the UCL and CLRA claims as discussed above. "The object of [Code of Civil Procedure section 1060] is to afford a new form of relief where needed and not to furnish a litigant with a second cause of action for the determination of identical issues." (*General of America Ins. Co. v. Lilly* (1968) 258 Cal.App.2d 465, 470; accord *Hood v. Superior Court* (1995) 33 Cal.App.4th 319, 324.) Capito does not explain how her declaratory relief cause of action based on a duty to disclose differs from similar UCL and CLRA claims.

As to the request for declaratory relief based on the terms of the contract-based claim, Capito alleged in the SAC that the COA does not allow Regional to charge an EMS fee, and that the COA did not effect an agreement that she would pay a separate EMS fee. In the COA, Capito agreed to pay her account "at the rates stated in the hospital's [chargemaster]," "in consideration of the services to be rendered to [her]." Capito admits in the SAC that she signed the COA, which includes an acknowledgement that she had the opportunity to read and ask questions about the information contained in the COA, including the financial obligations set forth therein. While Capito contends in the SAC that the EMS fee is billed not for services rendered to a patient, but rather as an

overhead cost unrelated to services, we are not required to assume the truth of such contention. (*Gray*, *supra*, 70 Cal.App.5th at p. 236, fn. 10.) Rather, we determine that the COA did authorize the EMS fee, as it was included in the chargemaster.

Despite Capito's contention to the contrary, the relevant authority reveals that the EMS fee charged by a hospital is dependent on the severity of a specific patient's condition and the resources required to render care for that condition. As discussed in section II(A), *ante*, the CMS requires hospitals to meet various standards in setting EMS fee levels, including the requirement that the fee "should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the code [citation]." (72 Fed.Reg. 66805.) The CMS further describes the CPT codes used for EMS fees as being "used to report [evaluation and management] *services* provided in the emergency department," (italics added) and confirms they were defined to reflect the activities of physicians without "necessarily fully describ[ing] the range and mix of services provided by hospitals during visits of clinic and emergency department patients and critical care encounters." (72 Fed.Reg. 66581, 66790.)

Thus, under the terms of the COA and the authority discussed above, the EMS fee is a fee for services rendered to a patient. Capito agreed to pay the rates set forth in the chargemaster in consideration for services rendered to her.[13] The EMS fee is set forth in the chargemaster. Capito has failed to state a cause of action for declaratory judgment based on contentions that the COA does not allow Regional to charge an EMS fee, and

[13] Capito argues that the reference to the chargemaster in the COA does not constitute an agreement to pay whatever items Regional chooses to bill her for, so long as they are included in the "thousands of items" listed in the chargemaster. We agree. If the billed item at issue was for a service that Regional did not provide to Capito, such as a CT scan that she did not receive, she would not be obligated to pay as she did not receive the consideration required by the COA. Here, Capito received evaluation and management services in the ER, and those services are reflected in the EMS fee charged to her.

does not constitute an agreement that she would pay a separate EMS fee. The trial court properly sustained Regional's demurrer on this basis.

Capito contends that her contract-based claims support not only her cause of action for declaratory judgment, but also her claims under the UCL and CLRA. For the reasons discussed, Capito has failed to state a contract-based claim for violation of the UCL or CLRA, as the facts as alleged in her complaint do not support her contention that the COA does not authorize the EMS fee and does not constitute an agreement that she would pay the EMS fee.[14]

D. Leave to Amend

Capito argues that the trial court erred in sustaining the demurrer without leave to amend, as she contends the allegations concerning the COA support a claim for breach of contract, citing *Gray*. In *Gray*, the appellate court suggested that while the plaintiff failed to state a cause of action under Civil Code section 1770, subdivision (a)(14) of the CLRA, the allegation that he was not required to pay the undisclosed EMS fee under the hospital's contract would "at most" suffice to allege a breach of contract. (*Gray*, *supra*, 70 Cal.App.5th at p. 245.) Based on this acknowledgment that the plaintiff "might have alleged a breach of contract," Capito seeks leave to amend her complaint to allege breach of contract as well.

"When any court makes an order sustaining a demurrer without leave to amend the question as to whether or not such court abused its discretion in making such an order is open on appeal even though no request to amend such pleading was made." (Code Civ. Proc., § 472c, subd. (a).)[15] "A plaintiff against whom a demurrer is sustained is entitled

[14] As we hold that the trial court properly sustained the demurrer to Capito's SAC, we need not consider whether the trial court erred in striking the class allegations from the FAC.

[15] Capito contends she did ask the trial court for leave to amend her complaint as part of her motion for reconsideration. Specifically, in her reply brief in support of the reconsideration motion, Capito noted the *Gray* court's comment regarding a potential breach of contract cause of action, and stated, "At the very least, then, even under the

to leave to amend the defective complaint if she can 'prov[e] a reasonable possibility that the defect can be cured by amendment.' [Citation.] The onus is on the plaintiff to articulate the 'specifi[c] ways' to cure the identified defect, and absent such an articulation, a trial or appellate court may grant leave to amend 'only if a potentially effective amendment [is] both apparent and consistent with the plaintiff's theory of the case.' [Citation.]" (*Shaeffer v. Califia Farms, LLC* (2020) 44 Cal.App.5th 1125, 1145.) To seek amendment for the first time on appeal, Capito must show how she can amend her complaint and how the amendment will change the legal effect of the complaint. (*Rakestraw v. California Physicians' Service* (2000) 81 Cal.App.4th 39, 43-44.) It is not sufficient to assert an "abstract right to amend"; "[Capito] must clearly and specifically set forth the 'applicable substantive law' [citation] and the legal basis for amendment, i.e., the elements of the cause of action and authority for it. Further, the plaintiff must set forth factual allegations that sufficiently state all required elements of that cause of action. [Citations.] Allegations must be factual and specific, not vague or conclusionary. [Citation.]" (*Id*. at p. 43.)

Capito has not met her burden to demonstrate that leave to amend the complaint should be granted. While she asserts that the opinion in *Gray* somehow authorizes a breach of contract claim, she does not set forth the elements of or authority for the cause of action, and does not set forth the factual allegations that sufficiently state all required elements of the breach of contract cause of action. Thus, Capito's request for leave to amend the complaint is denied.

Gray case, Plaintiff should be granted leave to allege a claim for breach of contract here." She did not include an affirmative request for leave to amend in the conclusion of her brief. Nor did she submit supplemental briefing to the trial court based on the dicta in *Gray*.

E. Hearing Prior to Reconsideration

Citing *Le Francois*, *supra*, 35 Cal.4th at page 1108 and *Paramount Petroleum Corp. v. Superior Court* (2014) 227 Cal.App.4th 226, 238 (*Paramount*), Capito argues that the trial court erred in reconsidering its tentative ruling overruling the demurrer to the SAC without first holding a hearing. We disagree.

The trial court has inherent power to reconsider its prior orders "as long as it gives the parties notice that it may do so and a reasonable opportunity to litigate the question." (*Le Francois*, *supra*, 35 Cal.4th at p. 1097.) "To be fair to the parties, if the court is seriously concerned that one of its prior interim rulings might have been erroneous, and thus that it might want to reconsider that ruling on its own motion-something we think will happen rather rarely-it should inform the parties of this concern, solicit briefing, and hold a hearing." (*Id*. at p. 1108.) In *Le Francois*, the Supreme Court held that a trial court erred in granting a renewed motion for summary judgment that did not meet the statutory requirements. However, it determined that the trial court was not precluded, on remand, from reconsidering its previous ruling on the initial motion for summary judgment on its own motion, as long as it gives the parties notice and opportunity to litigate the question. (*Id*. at pp. 1097, 1109.) In *Paramount*, the appellate court determined that the trial court erred in reconsidering a prior order denying a motion for summary judgment without giving the parties an opportunity to provide further oral or written argument before issuing a new ruling. (*Paramount*, *supra*, 227 Cal.App.4th at pp. 237-238.)

Here, the trial court did not "reconsider" a previously issued order. It issued a tentative ruling on the demurrer to the second amended complaint, and then, after argument, issued a new order allowing the parties to provide supplemental briefing on specified issues without ruling on the demurrer. The trial court issued its order on the demurrer only after receiving the supplemental briefing. Capito does not cite legal authority precluding a trial court from changing its mind about a tentative ruling without

holding a new hearing. Even if the principles of *Le Francois* do apply to tentative rulings, the trial court did give the parties notice of its intention to reconsider the previous demurrer arguments and an opportunity to litigate the issue further through supplemental briefs. Moreover, in giving such notice, it stated it would issue its order based on the supplemental briefs, indicating "no further oral argument is likely." Capito did not request further oral argument in her supplemental brief. As required by *Le Francois*, the trial court gave appropriate notice and opportunity for the parties to litigate the proposed reconsideration of the tentative ruling overruling the demurrer to the SAC.

III. DISPOSITION

The February 24, 2021 order striking the class allegations in the first amended complaint (appeal No. H049022) and the December 14, 2021 judgment of dismissal with prejudice (appeal No. H049646) are affirmed.

Greenwood, P. J.

WE CONCUR:

Grover, J.

Lie, J.

H049022
Capito v. San Jose HealthCare System LP

Greenwood, P. J.

WE CONCUR:

Grover, J.

Lie, J.

H049646
Capito v. San Jose HealthCare System LP

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is:

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On May 16, 2023, I served the foregoing documents, described:

PETITION FOR REVIEW

[X] via U.S. Mail; and
[X] via electronic transmission to the recipients addressed as follows:

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Clerk of Court Santa Clara County Superior Court 191 North First Street San Jose, CA 95113	[Via U.S. Mail]
Appellate Coordinator Office of the Attorney General Consumer Law Section 300 South Spring Street Los Angeles, CA 90013-1230	[Via Electronic Service]
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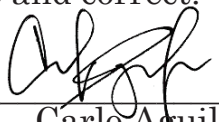
Executed on May 16, 2023, at Corona, California.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.



Carlo Aguilar

STATE OF CALIFORNIA
Supreme Court of California

PROOF OF SERVICE

STATE OF CALIFORNIA
Supreme Court of California

Case Name: **Capito v. San Jose HealthCare System, L.P.**
Case Number: **TEMP-SVPK2HH3**
Lower Court Case Number:

1. At the time of service I was at least 18 years of age and not a party to this legal action.

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5/16/2023
Date

/s/Carlo Aguilar

Signature

Carpenter, Gretchen (180525)

Last Name, First Name (PNum)

Carpenter Law

Law Firm