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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION SIX

REXINA MIZE et al., Plaintiffs and Appellants, v. MENTOR WORLDWIDE LLC, Defendant and Respondent.	2d Civil No. B295829 (Super. Ct. No. BC649083) (Los Angeles County)

This case is about preemption and causation: whether the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA) preempt the state-law products liability claims at issue here, and whether Rexina Mize and her husband, Minh Nguyen, sufficiently pled causation to survive Mentor Worldwide LLC's demurrer to those claims. We conclude that the tort claims in this case survive preemption because they are "'"'premised on conduct that both (1) violates the [MDA] and (2) would give rise to a recovery under state law even in the absence of the [MDA].'"' [Citation.]" (*Glennen v. Allergan, Inc.* (2016) 247 Cal.App.4th 1, 11-12 (*Glennen*).) We further conclude that Mize and Nguyen pled the requisite "'causal connection'" between their injuries and Mentor's tortious acts to

survive a demurrer. (*Rannard v. Lockheed Aircraft Corp.* (1945) 26 Cal.2d 149, 156 (*Rannard*).) Because the trial court reached contrary conclusions, we reverse.

FACTUAL AND PROCEDURAL HISTORY[1]

The Medical Device Amendments of 1976

Since 1976, the MDA has required the Food and Drug Administration (FDA) to provide "detailed federal oversight" of medical devices. (*Rigel v. Medtronic, Inc.* (2008) 552 U.S. 312, 316 (*Rigel*).) "The devices receiving the most federal oversight are those in Class III." (*Id.* at p. 317.) Such devices include those that pose potentially unreasonable risks of illness or injury. (*Ibid.*) Breast implants are assigned to Class III.

A Class III device must undergo premarket approval to "provide reasonable assurance of its safety and effectiveness." (21 U.S.C.[2] § 360c(a)(1)(C).) "Premarket approval is a 'rigorous' process." (*Rigel*, *supra*, 552 U.S. at p. 317.) It includes submission of an application that includes studies of the device's safety and effectiveness, a statement of its components and principles of operation, a description of its manufacturing methods, samples of the device, and proposed labels. (*Id.* at pp. 317-318.) The FDA will grant premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" (*Ibid.*) Once it does, "the MDA forbids the

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[1] The facts are taken from Mize and Nguyen's third amended complaint, which we accept as true in our review of the trial court's order sustaining Mentor's demurrer. (*Blank v. Kirwan* (1985) 39 Cal.3d 311, 318 (*Blank*).)

[2] Further unlabeled statutory references are to title 21 of the United States Code.

manufacturer to make . . . changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness." (*Id*. at p. 319.)

Before obtaining premarket approval, a Class III device manufacturer may apply to use the device in clinical tests pursuant to an investigational device exemption (IDE). (§ 360j(g).) To qualify for an IDE, the manufacturer must submit an application and investigational plan for the device. (See 21 C.F.R. §§ 812.20(b), 812.25.) The FDA must then determine that the benefits to test participants and the knowledge to be gained from the tests outweigh the device's risks. (21 C.F.R. § 812.30.) If the FDA approves an IDE application, few changes to the investigational plan are permitted. (21 C.F.R. § 812.35(a)(1).)

Mentor's MemoryGel breast implants

In the early 1990's, Mentor applied for an IDE to permit clinical testing of its MemoryGel silicone breast implants. The FDA granted Mentor's application and approved three studies: an adjunct study for patients undergoing either breast reconstruction after a mastectomy or breast implant revision,[3] approved in July 1992; a core study, approved in August 1992; and an IDE study, approved in August 2000.

In 1998, the FDA sued Mentor, alleging that the company failed to meet manufacturing quality standards, destroyed evidence of its implants' high rupture rates, sold contaminated implants, and failed to comply with FDA-mandated design and materials specifications. The FDA and Mentor entered into a consent decree to address the alleged violations, which required the company to remedy the deficiencies, comply

[3] Breast implant revision involves the removal or replacement of existing breast implants.

with federal law, and adhere to good manufacturing practices. If Mentor complied with the terms of the decree for five years, the FDA would not oppose a petition to dissolve it.[4]

Mize's breast implants

Two years after the FDA and Mentor finalized the consent decree, Mize underwent a bilateral breast augmentation, receiving MemoryGel breast implants as part of Mentor's adjunct

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[4] The trial court took judicial notice of the consent decree and its subsequent dissolution. We grant Mentor's unopposed request to judicially notice these documents and all others properly noticed by the court below. (*Rea v. Blue Shield of California* (2014) 226 Cal.App.4th 1209, 1223; see Evid. Code, § 459, subd. (a).)

Mentor also requests that we consider several additional documents that were not presented to the court below: (1) five documents, other than those cited above, attached to the request for judicial notice, (2) pages 53 to 558 of the Respondent's Appendix, and (3) two documents attached to a declaration in support of Mentor's brief on appeal. We deny these requests. As to the first set of documents, Mentor "puts forth no reason for its failure to request [that] the trial court . . . take judicial notice of" them. (*Brosterhous v. State Bar* (1995) 12 Cal.4th 315, 325-326.) As to the second, though Mentor lodged these documents with the trial court, it did not request that the court take judicial notice of them. They are thus not a proper part of the record for review of Mentor's demurrer. (*Cloud v. Northrop Grumman Corp.* (1998) 67 Cal.App.4th 995, 999 [demurrer "attacks only defects disclosed on the face of the pleadings or by matters that can be judicially noticed".]) As to the third, "documents not before the trial court cannot be included as part of the record on appeal." (*Pulver v. Avco Financial Services* (1986) 182 Cal.App.3d 622, 632.) We disregard all of these documents and the portions of Mentor's brief that cite to and rely on them. (*Ibid.*)

study. Mize did not meet the study's criteria because she did not need breast reconstruction or implant revision. She was unaware she was participating in the study, and did not know that her implants had not been approved for sale by the FDA.

After her breast augmentation, Mize began to experience a variety of health problems, including chronic fatigue, muscle and bone pain, joint swelling and stiffness, memory loss, and numbness. Her vision deteriorated, and she had to get prescription eyeglasses. She lost several business opportunities and abandoned her music career. None of Mize's doctors connected her health problems to her implants.

Premarket approval

In August 2003, a federal court dissolved Mentor's consent decree with the FDA. Four months later, Mentor sought premarket approval for its MemoryGel implants. The FDA approved Mentor's application in November 2006. As a condition of approval, the FDA required Mentor to conduct six studies that would document the safety and effectiveness of its implants and answer questions the earlier clinical trials did not answer. As part of these studies, Mentor had to submit adverse event reports, either as individual medical device reports that would be stored in the FDA's publicly accessible Manufacturer and User Facility Device Experience (MAUDE) database (for deaths and unusual adverse events), or as postmarket spreadsheet reports that would not be included in the database (for well-known or expected adverse events, including implant rupture).

Mentor failed to properly perform the six studies. It did not follow up with enough study participants and did not fully report the myriad adverse events—such as silicone toxicity, implant removal, autoimmune complaints, ruptures, and

inflammation—documented in the studies. According to Mize, the FDA would have included the adverse events in the MAUDE database had Mentor properly reported them.

The removal of Mize's implants and ensuing lawsuit

In December 2016, an MRI revealed that Mize's breast implants had ruptured. She had them removed the following month. After their removal, Mize's mental clarity improved. She no longer suffered from chronic fatigue, and no longer needed her prescription eyeglasses.

Mize and Nguyen sued Mentor. In the third amended complaint, Mize alleged causes of action for negligence and negligence per se based on Mentor's negligent failure to warn and negligent manufacturing, strict products liability for failure to warn, and strict products liability for manufacturing defects. Nguyen alleged a derivative cause of action for loss of consortium.

In support of her manufacturing defect claims, Mize alleged that Mentor: (1) manufactured its MemoryGel implants in a manner that "differed from the specifications agreed to by the FDA"; (2) "us[ed] materials and components [that] differed from those approved by the FDA"; (3) "fail[ed] to follow good manufacturing practices"; (4) "fail[ed] to properly meet the applicable standard of care by not complying with applicable federal regulations and . . . manufacturing protocols approved by the FDA"; (5) distributed its implants "in violation of the terms of the IDE and applicable federal law"; (6) "negligently incorporat[ed] components and/or materials into its . . . [i]mplants that could not stand up to normal usage and/or [that] differed from those [that] were commercially reasonable and/or fail[ed] to use the components and/or materials approved by the FDA"; (7) "fail[ed] to exercise reasonable care in inspecting and

testing of the product"; (8) "fail[ed] to exercise reasonable care in its manufacturing, quality control, and quality assurance processes"; and (9) "was negligent in its recordkeeping and did not disclose manufacturing flaws."

In support of her failure-to-warn claims, Mize alleged that Mentor breached its duty to report to the FDA, as part of the IDE clinical tests and the six postapproval studies, "adverse events similar to the injuries [she] suffered" despite having "knowledge and possession of information" that its MemoryGel implants were dangerous. Mentor also did not ensure that the FDA-mandated studies were properly performed and did not ensure follow-up with enough study participants. "Accordingly, the information . . . the FDA [sought] regarding adverse events and device failures was never gathered." Had it been gathered and reported, doctors would have seen and relayed it to Mize, who would have then had her implants removed.

The demurrer

Mentor demurred to the complaint. It asserted that Mize's claims were preempted by federal law and insufficiently pled, and that Nguyen's claim failed because it was derivative of his wife's.

The trial court agreed with Mentor. As to the manufacturing defect claims, the court found that they were impliedly preempted because they "hinge[d] entirely on conduct that allegedly violated federal law." Even if they were not, the allegations that underlay the claims all preceded the 1998 consent decree between Mentor and the FDA. But Mize did not allege that her implants were manufactured prior to the decree. And if they were manufactured after, the decree showed that Mentor promised to change any faulty manufacturing practices.

To the extent Mize based her claims on Mentor's alleged noncompliance with IDE requirements, the complaint did not specify how that noncompliance occurred, that it occurred prior to her implant surgery, or how it "affected the manufacture of the device implanted."

As to the failure-to-warn claims, the trial court found them expressly preempted because Mize did not allege that Mentor's failure to report adverse events violated any FDA requirement. Even if she did, to succeed on her claims Mize had to allege that "if Mentor had reported additional adverse incidents [after she received her implants in] 2000, and if the FDA had made such incidents public, and if [Mize's] doctors had been aware of such reports, [the] doctors might have provided an earlier diagnosis leading to earlier surgery to remove the implants," reducing Mize's damages. The trial court found she did not do so.

The trial court impliedly rejected Mize's negligence per se claim since it was based on the same allegations as her other claims. The court rejected Nguyen's loss-of-consortium claim as derivative of his wife's. It sustained Mentor's demurrer without leave to amend.

DISCUSSION

Standard of review

"In reviewing the sufficiency of a complaint against a general demurrer, we are guided by long-settled rules." (*Blank*, *supra*, 39 Cal.3d at p. 318.) "'We treat the demurrer as admitting all material facts properly [pled], but not contentions, deductions, or conclusions of fact or law.'" (*Ibid*.) "'We also consider matters [that] may be judicially noticed.'" (*Ibid*.) "[W]e give the complaint a reasonable interpretation, reading it as a whole and

its parts in their context." (*Ibid.*) Our fundamental task is to "determine whether the complaint states facts sufficient to constitute a cause of action." (*Ibid.*)

Preemption

Federal law is the "supreme [l]aw of the [l]and." (U.S. Const., art. VI, cl. 2.) State laws that conflict with federal laws are preempted. (*Murphy v. National Collegiate Athletic Assn.* (2018) __ U.S. __, __ [138 S.Ct. 1461, 1476].) Preemption can be express or implied. (*English v. General Electric Co.* (1990) 496 U.S. 72, 78-79.) It is express if Congress defines "the extent to which its enactments preempt state law." (*Id.* at p. 78.) It is implied if state law "regulates conduct in a field that Congress intended the [f]ederal [g]overnment to occupy exclusively" or if it "actually conflicts with federal law." (*Id.* at p. 79.)

The MDA expressly preempts any state requirement that: (1) "is different from, or in addition to, any requirement applicable under [the FDCA]," and (2) "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." (§ 360k(a).) The MDA "does not prevent a [s]tate from providing a remedy for claims premised on a violation of FDA regulations," however, because "the state [requirements] in such a case 'parallel,' rather than add to, federal requirements." (*Riegel*, *supra*, 552 U.S. at p. 330.) A state requirement parallels a federal requirement if the two are """"generally equivalent."""" (*Glennen*, *supra*, 247 Cal.App.4th at p. 10.) But "[i]f state law liability could be found notwithstanding compliance with the federal requirements, those state law duties are not parallel to the federal requirements." (*Ibid.*) Claims seeking to enforce those duties are expressly preempted. (*Ibid.*)

Alternatively, a plaintiff's claim will be impliedly preempted if it conflicts with the MDA's enforcement scheme. (*Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 352 (*Buckman*).) Section 337(a) provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the MDA] shall be by and in the name of the United States." This provision prohibits claims that "seek[] to enforce an *exclusively* federal requirement that is not grounded in traditional state tort law." (*Glennen*, *supra*, 247 Cal.App.4th at p. 11, italics added.) Thus, if an FDA requirement is "a critical element" of a plaintiff's tort claim, the claim conflicts with the MDA's enforcement scheme and is impliedly preempted. (*Buckman*, at pp. 352-353.)

Together, express preemption under section 360k(a) and implied preemption under section 337(a) and *Buckman* create a """narrow gap' through which a state-law claim must fit to [survive] preemption."" (*Glennen*, *supra*, 247 Cal.App.4th at p. 11.) The claim must be based on ""conduct that *violates* the [MDA],"" but the plaintiff cannot be ""suing *because* the conduct violates the [MDA]."" (*Id*. at pp. 11-12, original italics.) Thus, ""to survive preemption, [a] claim[] 'must be premised on conduct that both (1) violates the [MDA] and (2) would give rise to a recovery under state law even in the absence of the [MDA].'" [Citation.]" (*Id*. at p. 12.)

Manufacturing defect

Mize first contends the trial court erred when it concluded that: (1) the MDA impliedly preempts her manufacturing defect claims, and (2) the complaint fails to link the alleged defects in her implants to her injuries. We agree.

1. Preemption

Mize's manufacturing defect claims are premised, at least in part, on Mentor's alleged failure to comply with manufacturing requirements imposed by the FDA. But it does not follow that the claims "hinge entirely on conduct that allegedly violated federal law," as the trial court concluded. Mize does not seek to enforce any exclusively federal requirement; her claims are predicated on violations of state tort law. (Cf. *Jiminez v. Sears, Roebuck, & Co.* (1971) 4 Cal.3d 379, 384-387 [California recognizes negligence and strict liability claims of manufacturing defects].) That these tort theories "impose[] obligations identical to those imposed by the [FDA] . . . does not substantively transform [Mize's] action into one seeking to enforce federal law." (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1095.) Her lawsuit would exist regardless of whether the FDA or some other federal or state agency imposed the obligations. (*Id.* at pp. 1095-1096.) There is thus no conflict with section 337(a), and no implied preemption under *Buckman*. (*Ibid.*; see, e.g., *Mink v. Smith & Nephew, Inc.* (11th Cir. 2017) 860 F.3d 1319, 1330 [manufacturing defect claims not impliedly preempted]; *Bass v. Stryker Corp.* (5th Cir. 2012) 669 F.3d 501, 513-514 (*Bass*) [same]; *Bausch v. Stryker Corp.* (7th Cir. 2010) 630 F.3d 546, 556-558 (*Bausch*) [same].)

Glennen, *supra*, 247 Cal.App.4th 1, on which Mentor relies, is not to the contrary. In *Glennen*, the plaintiff's claim was based on the defendant's alleged failure to train physicians how to use its product, as the FDA required. (*Id.* at p. 20.) But "there is no state law duty that requires a medical device manufacturer to offer a physician training program." (*Ibid.*) The claim thus "'exist[ed] solely by virtue of [FDA] requirements'" and was

impliedly preempted. (*Ibid.*) Here, in contrast, Mentor had a tort duty, under California law, to manufacture its breast implants in compliance with FDA requirements. (*Armstrong v. Optical Radiation Corp.* (1996) 50 Cal.App.4th 580, 595 (*Armstrong*).)

Evraets v. Intermedics Intraocular, Inc. (1994) 29 Cal.App.4th 779 (*Evraets*) does not suggest there is no such duty, as Mentor asserts. That case involved claims based on inadequate testing, defective design, and failure to warn, not manufacturing defects. (*Id.* at p. 787.) "It is axiomatic that cases are not authority for propositions . . . not considered." (*California Building Industry Association v. State Water Resources Control Board* (2018) 4 Cal.5th 1032, 1043.) More significantly, *Evraets* predated the U.S. Supreme Court's decision in *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 497-502 (*Lohr*), which held that the MDA does *not* preempt state-law claims based on manufacturing defects. Thus, to the extent *Evraets* suggested otherwise, it is no longer good law. (*Armstrong*, *supra*, 50 Cal.App.4th at p. 596, fn. 13.) Mize's claims are not impliedly preempted.

2. Causation

"[U]nder either a negligence or strict liability theory of products liability, to recover from a manufacturer a plaintiff must prove that a defect caused [their] injury." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479.) This requires showing "some substantial link or nexus" between the alleged defect and the injury. (*Saelzler v. Advanced Group 400* (2001) 25 Cal.4th 763, 778.) At the pleading stage, the plaintiff need only allege "'a causal connection'" between the two. (*Rannard*, *supra*, 26 Cal.2d at p. 156.) "'Ordinarily that is accomplished by implication from the juxtaposition of the allegations of wrongful conduct and harm.'" (*Christensen v. Superior Court* (1991) 54 Cal.3d 868, 900

(*Christensen*).) It is only "'where the pleaded facts of negligence and injury do not naturally give rise to an inference of causation [that] the plaintiff must plead specific facts affording an inference the one caused the others.' [Citation.]" (*Id.* at pp. 900-901.)

Mize sufficiently pled her manufacturing defect claims. She alleged that in the years leading up to her implant surgery Mentor failed to meet FDA-imposed manufacturing quality standards, destroyed evidence of its implants' high rupture rates, sold contaminated implants, and failed to comply with FDA-mandated design and materials specifications. She alleged that she later suffered a number of ailments that subsided once her implants were removed. That juxtaposition naturally gives rise to an inference that Mentor's alleged manufacturing defects caused her injuries. (*Christensen*, *supra*, 54 Cal.3d at pp. 900-901.)

The trial court improperly refused to make this inference. As part of the 1998 consent decree between Mentor and the FDA, Mentor promised to remedy its alleged violations, comply with federal law, and implement good manufacturing practices. To the court below, this promise broke any causal connection between Mentor's manufacturing conduct and Mize's defective implants. But a company's promise to do something does not establish that it did so. The FDA's 2003 nonopposition to the consent decree's dissolution similarly does not defeat an inference of causation; it merely shows that the FDA believed that Mentor remedied the problems, not that it did.

The trial court also faulted Mize for insufficiently pleading how Mentor failed to comply with IDE requirements or how that failure affected the manufacture of her implants. The court required too much of Mize at the pleading stage. Under

California law, a plaintiff may allege facts "in a conclusory fashion if their knowledge of the precise cause of injury is limited." (*Bockrath v. Aldrich Chemical Co., Inc.* (1999) 21 Cal.4th 71, 80 (*Bockrath*).) That is particularly true where, as here, the "'defendant has superior knowledge of the facts.'" (*Doe v. City of Los Angeles* (2007) 42 Cal.4th 531, 549-550.)

"[I]n the context of Class III medical devices," such as Mentor's MemoryGel breast implants, "much of the critical information is kept confidential as a matter of federal law." (*Bausch*, *supra*, 630 F.3d at p. 560.) "An injured patient," like Mize, thus "cannot gain access to that information without discovery" (*ibid.*), and cannot "fairly be expected to provide a detailed statement of the specific bases for her claim" (*id.* at p. 558). She should not be required to meet a pleading standard that identifies specific IDE requirements breached by Mentor based on information available only to Mentor and the FDA. (*Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413, 436 (*Coleman*); see *Bockrath*, *supra*, 21 Cal.4th at p. 82 [plaintiff could pursue claim despite lack of knowledge of specific cause of injury]; *Bass*, *supra*, 669 F.3d at p. 511 [requiring allegations about confidential manufacturing processes "make[s] pleading a parallel [state] claim regarding defective manufacturing nearly impossible"].) The trial court erred when it sustained the demurrer to Mize's manufacturing defect claims because she could not meet that standard.

Failure to warn

Mize next contends the trial court erred when it concluded that: (1) her failure-to-warn claims were expressly preempted, and (2) she did not sufficiently plead that Mentor's

failure to report adverse events to the FDA caused her injuries. We again agree.

1. Preemption

Mize's failure-to-warn claims are based on Mentor's breach of its duty to report information about adverse events to the FDA. During clinical testing pursuant to an IDE, if a manufacturer evaluates unanticipated adverse events, it must "report the results of [that] evaluation to the FDA." (21 C.F.R. § 812.150(b)(1).) If the manufacturer later wins premarket approval of its device, it must report to the FDA whenever the device "[m]ay have caused or contributed to a death or serious injury" or when it "[h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury[] if the malfunction were to recur." (21 C.F.R. § 803.50(a).) "A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty." (*Jacob v. Mentor Worldwide, LLC* (C.D.Cal. 2019) 393 F.Supp.3d 912, 925; see also *Stengel v. Medtronic, Inc.* (9th Cir. 2013) 704 F.3d 1224, 1233 (*Stengel*).) California law recognizes a manufacturer's duty to warn the FDA of adverse events. (*Coleman*, *supra*, 223 Cal.App.4th at pp. 428-429.) Mize's failure-to-warn claims are thus not expressly preempted. (*Id*. at p. 428.)

Mentor counters that Mize's claims do not survive preemption because the authority on which *Coleman* relied is no longer good law. In reaching its conclusion that the MDA does not preempt a failure-to-warn claim, the *Coleman* court relied largely on the Ninth Circuit's decision in *Stengel*, *supra*, 704 F.3d 1224. (*Coleman*, *supra*, 223 Cal.App.4th at pp. 428-429.) That case concluded that: (1) a state-law tort claim based on a manufacturer's failure to warn the FDA of problems with its

product is not preempted if state law recognizes a parallel duty, and (2) Arizona law recognizes such a duty. (*Stengel*, at pp. 1232-1233.) The Arizona Supreme Court subsequently rejected *Stengel*'s latter conclusion: "[E]stablished law does not recognize a claim merely for failing to provide something like adverse event reports . . . to a government agency." (*Conklin v. Medtronic, Inc.* (Ariz. 2018) 431 P.3d 571, 579.)

But that does not mean that *Coleman* is no longer good law in California. *Conklin* did not reject the *Stengel* court's framework that a claim based on a manufacturer's failure to warn of adverse events is not preempted if state law recognizes a parallel duty; it simply rejected the conclusion that Arizona law recognizes such a duty. Unlike Arizona, California does recognize a duty to report adverse events to the FDA. *Coleman* thus remains good law.

The trial court employed a different rationale than Mentor, concluding that Mize's failure-to-warn claims were expressly preempted because she did not show that Mentor's failure to report adverse events violated any FDA requirement. In reaching this conclusion, the court adopted the reasoning of the federal district court in *Ebrahimi v. Mentor Worldwide LLC* (C.D.Cal., May 25, 2018, No. CV 16-7316-DMG (KSX)) 2018 WL 2448095. But *Coleman* was binding on the court below. (*Auto Equity Sales, Inc. v. Superior Court* (1962) 57 Cal.2d 450, 455.) *Ebrahimi* was not. (*Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 69.) Moreover, in her complaint Mize alleged that Mentor failed to report adverse events to the FDA, as it was required to do in both the IDE clinical tests and the postapproval studies. Because these allegations are based on a duty that is not "different from, or in addition to, any [FDA]

requirement," Mize's failure-to-warn claims are not expressly preempted.

2. Causation

To prevail on her failure-to-warn claims, Mize "'will ultimately have to prove that if [Mentor] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [her] doctors in time to prevent [her] injuries.' [Citation.]" (*Coleman*, *supra*, 223 Cal.App.4th at pp. 429-430.) But at this stage, Mize need only allege "'a causal connection'" between Mentor's failure to report and her injuries. (*Rannard*, supra, 26 Cal.2d at p. 156.) Here, Mize alleged that if Mentor complied with the reporting duties required in the IDE and postapproval studies, a fuller picture of the adverse events associated with its MemoryGel implants would have been available to the FDA, which would have in turn made that information available to Mize's doctors via the MAUDE database. Mize's doctors would then have communicated that information to Mize, who would have had her implants removed earlier. Assuming these allegations are true, they allege a sufficient causal connection between Mentor's failure to report and Mize's injuries.

Mentor counters that Mize has not shown that information about adverse events would have reached her doctors in time to prevent her injuries. We conclude that her allegations are sufficient.

First, while Mentor was required to report adverse events to the FDA, the evidence attached to its demurrer showed that for adverse events associated with implant ruptures it could submit spreadsheet reports that would not be included in the MAUDE database. But this ignores that Mentor was required to

provide individual medical device reports—which could be included in the database—whenever one of its implants contributed to a person's death.

Second, Mentor claims that even if it had submitted individual medical device reports, the FDA had discretion to not include those reports in the database. (21 C.F.R. § 803.9(a); see also *Pinsonneault v. St. Jude Medical, Inc.* (D. Minn. 2013) 953 F.Supp.2d 1006, 1016 [adverse events not "automatically" made public].) But because the FDA regularly publishes such information in the database, it is reasonable to infer that it would have done so here. (See, e.g., *Hughes v. Boston Scientific Corp.* (5th Cir. 2011) 631 F.3d 762, 770, fn. 5; *Rosen v. St. Jude Medical, Inc.* (N.D.N.Y. 2014) 41 F.Supp.3d 170, 187.)

Finally, Mentor claims that even if it submitted individual medical device reports about implant ruptures, and even if the FDA would have exercised its discretion to include that information in the MAUDE database, there is no evidence that Mize's doctors consulted the database when making decisions about her implants and their removal. But Mize alleges otherwise, and further claims that her doctors would have told her of the information in the database. It is reasonable to infer that they did review the database and would have provided that information to Mize. (See, e.g., *Gravitt v. Mentor Worldwide, LLC* (N.D.Ill. 2018) 289 F.Supp.3d 877, 891.)

"'One of the dangers of winning on demurrer is that you are stuck, on appeal, with your opponent's version of the facts.'" (*Silguero v. Creteguard, Inc.* (2010) 187 Cal.App.4th 60, 64.) Here, Mize's version of the facts is sufficiently pled to demonstrate a causal connection between Mentor's reporting failures and her delayed decision to remove her implants.

Whether Mize can ultimately prove those facts is of no concern to us here. (*Ibid*.) A demurrer "'may not be turned into a contested evidentiary hearing'" into the "'truthfulness or proper interpretation'" of the evidence. (*Ibid*.) Because the trial court's decision reflects such a consideration of the evidence, it erroneously sustained Mentor's demurrer to Mize's failure-to-warn claims.

Negligence per se

Mize contends the trial court erred when it dismissed her negligence per se claim since it is based on the same allegations as her manufacturing defect and failure-to-warm claims. She is correct.

Under the doctrine of negligence per se, negligence will be presumed if: (1) a person violated a statute or regulation, (2) that violation injured another person or their property, (3) the injury was of a type the statute or regulation was designed to prevent, and (4) the person or property injured was of the class the statute or regulation was designed to protect. (Evid. Code, § 669, subd. (a).) Federal statutes, such as the FDCA or MDA, and federal regulations, such as those imposed by the FDA, may provide the applicable state standard of care, satisfying the first of these requirements. (*DiRosa v. Showa Denko K.K.* (1996) 44 Cal.App.4th 799, 807; see *Coleman*, *supra*, 223 Cal.App.4th at p. 433; *Evraets*, *supra*, 29 Cal.App.4th at pp. 791-792.) State-law tort claims that attempt to enforce these standards are not expressly preempted since the state requirements are identical to federal requirements. (*Evraets*, at p. 792; see § 360k(a) [only state requirements that are "different from, or in addition to" FDCA requirements are preempted].) Nor are such claims impliedly preempted when the plaintiff attempts to enforce state

requirements that parallel federal law.[5] (*Coleman*, *supra*, 223 Cal.App.4th at pp. 432-433.)

Here, Mize alleged that Mentor violated the MDA and FDA-imposed requirements. She also alleged that Mentor's manufacturing defects and its failure to properly report adverse events to the FDA caused her injuries. These injuries are clearly those the MDA and FDA regulations sought to prevent, and Mize is in the class the FDA sought to protect. She may therefore pursue her negligence per se claim. (*Coleman*, *supra*, 223 Cal.App.4th at p. 433.)

Loss of consortium

Finally, Nguyen contends the trial court erroneously sustained Mentor's demurrer to his loss-of-consortium claim because it was derivate of his wife's claims. He is correct. Because Mize sufficiently pled valid, non-preempted causes of action, Nguyen's loss-of-consortium cause of action remains viable. (*Armstrong*, *supra*, 50 Cal.App.4th at p. 597; see *Hahn v. Mirda* (2007) 147 Cal.App.4th 740, 746 [loss of consortium claims "stands or falls" based on whether spouse suffered actionable injury].)

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[5] We disagree with the pre-*Lohr* and other non-California cases cited by Mentor that hold otherwise.

DISPOSITION

The judgment is reversed, and the matter is remanded to the trial court with directions to enter an order overruling the demurrer to the third amended complaint. Mize and Nguyen shall recover their costs on appeal.

CERTIFIED FOR PUBLICATION.

TANGEMAN, J.

We concur:

GILBERT, P. J.

YEGAN, J.

Michelle Williams Court & Carolyn B. Kuhl, Judges

Superior Court County of Los Angeles

Law Office of Martin N. Buchanan, Martin N. Buchanan; Lenze Lawyers and Jennifer A. Lenze, for Plaintiffs and Appellants.

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