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Filed 7/2/20

CERTIFIED FOR PUBLICATION

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

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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

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

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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.*)

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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

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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

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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.

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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

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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.

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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.

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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.

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES, CENTRAL CIVIL WEST DISTRICT

REXINA MIZE, an individual; MINH NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE LLC; NEAL HANDEL, M.D.; and DOES 1-100, inclusive,

Defendants.

Case No.: BC649083

THIRD AMENDED COMPLAINT

(1) NEGLIGENCE/NEGLIGENCE PER SE
(2) STRICT PRODUCTS LIABILITY-FAILURE TO WARN
(3) STRICT PRODUCTS LIABILITY-MANUFACTURING DEFECT
(4) LOSS OF CONSORTIUM
(5) MEDICAL BATTERY
(6) FAILURE TO OBTAIN INFORMED CONSENT

DEMAND FOR JURY TRIAL

Judge: Honorable Carolyn B. Kuhl
Dept.: 309

Third Amended Complaint Filed: 4/2/2018
Second Amended Complaint Filed: 8/17/17
Complaint Filed: 2/2/2017
Trial Date: None

By Fax

APPENDIX B

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Plaintiff REXINA MIZE, an individual, and Plaintiff MINH NGUYEN, an individual by and through their attorneys, based on information and belief, and for causes of action against the Defendants, MENTOR WORLDWIDE LLC; NEAL HANDEL, M.D.; and DOES 1 through 100, inclusive, (hereinafter collectively referred to as "Defendants") and each of them, hereby allege as follows:

I. PARTIES

1. At all times relevant hereto, Plaintiff REXINA MIZE (hereinafter "Mize") is and was a citizen and resident of Los Angeles County, California.

2. At all times relevant hereto, Plaintiff MINH NGUYEN is married to, and the husband of, Plaintiff REXINA MIZE, and is and was a citizen and resident of Los Angeles County, California. (Hereinafter, Mize and Plaintiff Nguyen will be referred to, collectively, as "Plaintiffs").

3. Defendant NEAL HANDEL, M.D. (hereinafter "Handel") was and is licensed to practice medicine in the State of California, and does practice medicine in this State.

4. Upon information and belief, Handel practices medicine at 9201 W. Sunset Blvd., Suite 214, West Hollywood, California 90069.

5. Defendant MENTOR WORLDWIDE LLC ("Mentor") is a limited liability company incorporated under the laws of the State of Delaware, with its principal place of business located at 201 Mentor Drive, Santa Barbara, California, 93111, and with its headquarters located at 33 Technology Drive, Irvine, California, 92618.

6. Defendant Mentor was acquired by Johnson & Johnson ("J&J") in 2009 and currently operates as a subsidiary of J&J's wholly owned subsidiary Ethicon, Inc. ("Ethicon").

7. The true names and/or capacities, whether individual, corporate, associate or otherwise of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names.

8. Plaintiffs are informed and believe, and thereupon allege, that each of the Defendants fictitiously named herein as a DOE is legally responsible, negligently or in some other actionable

manner, for the events and happenings hereinafter referred to, and thereby proximately caused the injuries and damages to Plaintiffs as hereinafter alleged.

9. Plaintiffs will seek leave of court to amend this Complaint to insert the true names and/or capacities of such fictitiously named Defendants when the same have been ascertained.

10. Hereinafter, the aforementioned Defendants may collectively be referred to as "Defendants."

11. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

12. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

13. These concerted efforts resulted in significant harm to Plaintiffs. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiffs would not have been implanted with Mentor's MemoryGel Silicone Gel Breast Implants and would not have suffered severe injuries.

II. JURISDICTION AND VENUE

14. Jurisdiction is proper because the amount in controversy exceeds the jurisdictional minimum of this Court.

15. Venue and jurisdiction are also proper because the contracts that form the basis of this action were entered into and to be performed in the County of Los Angeles, State of California, and the acts alleged caused damage to Plaintiffs occurred in the County of Los Angeles.

III. FACTS RELEVANT TO ALL COUNTS

16. Plaintiffs' claims are based on injuries suffered as a result of Mize undergoing a bilateral breast augmentation procedure on September 27, 2000, during which Mize was implanted with

Mentor's MemoryGel® Silicone Breast Implants. (See, Exhibit A, Product Identification Labels).

A. FDA Regulation of Silicone Breast Implants

17. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic ("FDCA"). At the time that the MDA was enacted, certain medical devices[1], including breast implants[2], were already being sold in the United States.

18. Under the MDA, medical devices, such as the subject breast implants, are subject to three classifications and regulated accordingly. Class I devices require the least and most general oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are reviewed according to more stringent "special controls," such as performance standards. *Id.* § 360c(a)(1)(B). Finally, Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* §360c (a)(1)(C)(ii).

19. The FDA originally classified silicone gel-filled breast implants as Class II devices. However, because of reports of adverse events, the FDA re-classified silicone gel-filled breast implants as Class III devices.[3] Accordingly, the FDA required that manufacturers meet certain requirements to allow these medical devices to remain on the market.

20. Subsequently, on April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone gel-filled breast implants submit pre-market approval applications ("PMAs") with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991.

21. On August 22, 1991, the FDA determined that the PMAs submitted by the manufacturers of silicone gel-filled breast implants, including Mentor, did not contain sufficient data.

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[1] The term "medical device" includes any "implant [] which is [] intended to affect the structure or any function of the body of man, and which does not achieve its primary intended purposes through chemical action within or on the body of man [] and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321.

[2] A breast implant is a prosthesis product used to change the size, shape, and contour of a woman's breast.

[3] A more detailed explanation of the FDA's regulation of breast implants can be accessed at (Regulatory History of Breast Implants in the U.S.) (Last accessed March 30, 2018).

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22. In November of 1991, the FDA convened a panel to consider whether the PMA data regarding silicone gel-filled breast implants was sufficient to establish that they were safe and effective.

23. On January 6, 1992, the FDA called for a voluntary moratorium on the use of silicone gel-filled breast implants until new safety information could be thoroughly reviewed.

24. Additional information on silicone gel-filled implants was reviewed by the FDA panel on February 18, 1992, including case reports of autoimmune diseases, and evidence that some implants had leaked excessively.

25. On April 16, 1992 the FDA announced that there was not sufficient data to support approval of the sale of silicone gel-filled breast implants and that it would allow implantation of silicone gel-filled breast implants only under controlled clinical studies for reconstruction after mastectomy or correction of congenital deformities (reconstruction), or replacement of ruptured silicone gel-filled implants due to medical or surgical reasons (revision). The FDA expressly denied applications to use silicone gel-filled breast implants for breast augmentation.

26. The FDA further ordered that any silicone gel-filled implants used for reconstruction or revision would be considered to be "investigational devices," and that women who received these implants should be followed through clinical studies.

B. FDA Regulation of Investigational Devices

27. The FDA requirements concerning clinical investigations of investigational devices are governed by the Investigational Device Exemption ("IDE")[4] rules of the Food, Drug and Cosmetic Act.

28. Section 520(g) of the FDCA allows for the "Exemption for Devices for Investigational Use" and provides "It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and

[4] See, (Investigational Device Exemptions Manual) and (Guidance on IDE Policies and Procedures) for more detailed explanations of the IDE process.

development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose."

29. Under these rules, a manufacturer may submit a detailed IDE application asking that the FDA allow it to conduct an IDE clinical investigation.

30. The purpose of the IDE clinical investigation is to obtain sufficient evidence that the risks posed by the particular device are outweighed by anticipated benefits and that the device will be effective as used.

31. Submission of an IDE begins the regulatory process for conducting a study. The IDE is a dynamic document and the Sponsor-Investigator must ensure that the IDE be kept current as the study progresses and the Sponsor-Investigator agrees to keep the FDA as well as the study' Investigational Review Board apprised of any adverse events, any changes or amendments in the protocol; to file annual reports; and to notify the FDA at the completion of the study.[5]

32. "An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." 21 CFR 812.1.

33. The data gathered in an IDE clinical investigation is used to determine whether the medical device at issue will be approved for sale through either the pre-market approval ("PMA") or premarket notification ("510(k)") process.

34. Because silicone gel-filled breast implants present "a potential for serious risk to the health, safety, and welfare of a subject [or] otherwise poses a risk" they are classified as "significant risk" products. See, 21 CFR 812.3(m). Therefore, no studies could be started until the IDE is approved by FDA.

35. While there is no "form" for an IDE application, the does FDA require that any application include certain information including: "A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate,

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[5] See, *Understanding FDA Regulatory Requirements for an Investigational Device Exemption (IDE) for Sponsor-Investigators* (last accessed April 1. 2018) for a more detailed explanation of the IDE process.

installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device." See, 21 CFR 812.20(b) (3).

36. Once the IDE application is approved, the sponsor must also submit an IDE plan. That plan must include: "[a] written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound [;] [a] description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition[;] [a] description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation[;][t]he sponsor's written procedures for monitoring the investigation and the name and address of any monitor[;] [c]opies of all labeling for the device [;] [and] [c]opies of all forms and informational materials to be provided to subjects to obtain informed consent.[6]" See, 21 CFR 812.25 (b-g).

37. A sponsor of an IDE, such as Mentor, is also responsible for selecting qualified investigators, if it does not act as the investigator itself, and providing the investigators with the information that they need to conduct the investigation properly. The sponsor must also ensure proper monitoring of the IDE and that the Independent Review Board ("IRB")[7] and FDA promptly of any significant new information about the investigation. See, 21 CFR §812.40.

38. There are also specific requirements for the manner in which the IDE is to be conducted including the requirement that any "unanticipated adverse device effects"[8] occurring during an

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[6] The FDA further requires that the IDE application include: "Copies of all forms and informational materials to be provided to subjects to obtain informed consent." See, 21 CFR 812.20(b)(11).

[7] An IRB is an appropriately constituted group that has been formally designated by the FDA to review and monitor biomedical research involving human subjects.

[8] An "unanticipated adverse device effect" is "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects" (21 CFR 812.3(s)).

investigation be reported to the IRB and sponsor as soon as possible, but in no event later than 10 working days after the investigator first learns of the adverse effect. See, 21 CFR 812.150(a)(1).

39. After being notified of an unanticipated adverse device event, a sponsor is required to "immediately conduct an evaluation" (See, 21 CFR 812.46(b)) and to "report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect." See, 21 CFR 812.150(b)(1).

40. While the IDE regulations specifically provide that an IDE approved device is exempted from compliance with performance standards and good manufacturing practice requirements ("cGMP") (See 21 CFR § 812.1(a)), the IDE process does subject manufacturers to complex and comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective.

41. In order to obtain an IDE, a manufacturer must provide the FDA with extremely detailed information pursuant to FDA promulgated regulations about the device, its manufacture, and the experimental plan for its use.

42. Although the IDE process is overseen by the FDA, it is the manufacturers, such as Mentor, which are responsible for designing and conducting the studies, ensuring compliance with all governing rules, regulations and requirements and accurately and truthfully reporting all information gathered to the FDA

C. Mentor Seeks FDA Approval of its Silicone Gel-filled Implants

43. In order to eventually seek pre-market approval for its MemoryGel Silicone gel-filled breast implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of that medical device.

44. As part of this process, Mentor requested that it be allowed to use the medical device for clinical testing pursuant to an investigational device exemption ("IDE"). See, 21 U.S.C. § 360j (g). Mentor was prohibited from conducting research concerning the device on human subjects without prior approval by the FDA. See, 21 CFR § 812.20.

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45. Investigational devices are subject to complex and comprehensive regulations and detailed procedures intended to ensure that the devices are safe and effective.

46. In connection with Mentor's IDE, the FDA approved the following studies: "Adjunct Study" for reconstruction and revision patients only (July of 1992); "Core Study" (August of 1992[9]); and, "IDE" study (August 2, 2000).

47. The FDA also sent a letter to Mentor and other companies seeking approval for the sale of silicone gel-filled implants and discussing the type of information needed for core studies (IDE studies) of silicone gel-filled breast implants on January 11, 1996.

D. Mentor Manufacturing Problems prior to Mize's implantation

48. During the time period relevant to the present matter, all of Mentor's silicone gel-filled breast implants were manufactured at a facility in Irving, Texas operated by Mentor Texas, Inc. ("Mentor Texas") a wholly owned subsidiary of Mentor.

49. Based on whistle blower complaints and other information, an investigation was initiated by the United States into the manufacturing process for the silicone gel-filled breast implants made at the Mentor Texas plant.

50. As a result of the information gathered in that investigation, a complaint was filed on May 6, 1998, in the United State Court for the Northern District of Texas, *United States v. Mentor, et al.*, 3:98-cv-01105-G seeking an injunction to prohibit Mentor and Mentor Texas from manufacturing silicone gel-filled breast implants in violation of the requirements of Federal law.

51. On that same date, the parties to that case entered into a Consent Decree and Judgment of Permanent Injunction requiring that Mentor and Mentor Texas remedy the deficiencies identified and provide proof that their future manufacturing was being done in compliance with Federal law and regulations.

[9] "In April 1992, the [FDA] moratorium was lifted but only for reconstruction and revision patients. Every patient implanted had to be part of an adjunct study, and had to be offered participation in a registry of gel-filled breast implant patients. In order to be implanted with gel-filled implants for augmentation, women had to be enrolled in a core clinical study." See Exhibit B, Core Gel Study, pg. 3.

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52. Specifically, Mentor agreed to manufacture its breast implants in compliance with the FDA's Quality System Regulation, which is designed to ensure that medical devices are consistently high in quality and are safe and effective.

53. The evidence supporting the claims made by the United States included sworn testimony from individuals who had been senior officials at the Mentor Texas facility.

54. John C. Karjanis, who from 1996 until 1998 was manager of product evaluation at Mentor Texas, testified that basic quality standards for implant manufacturing were never met while he served in that capacity. He further testified that he was instructed by his supervisors to destroy reports detailing the high rupture rates and poor quality of implants manufactured at that facility because the products "are in the customers."

55. He also testified that implants were sometimes contaminated with fleas and that employees at the Mentor Texas facility would sometimes store defective implant parts above ceiling tiles so managers and inspectors would not realize how often the plant failed to make properly manufacture the implants.

56. Similarly, Cynthia Fain, the supervisor of the complaint unit testified that Mentor greatly underreported rupture rates for its implants to federal authorities and suppressed a report finding that some implant models had a high failure. Mentor also was cited for other manufacturing deficiencies prior to the date that Mize received her implants. These include, but are not limited, to a Form 483[10] issued to Mentor on October 16, 1997 indicating that prior to February of 1997 no finished device testing was performed on any of its gel or saline filled mammary devices and that certain post sterilization testing was not done for an unknown time and these materials were used for gel implants.

57. Upon information and belief, a Mentor chemist of 15 years reported to the FDA that Mentor's implants are more likely to break than the company reported. It has also been reported

[10] An FDA Form 483 is issued when an investigation establishes that a drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health or when an investigator has observed conditions that may constitute violations of the FDCA or related Acts. The purpose of the Form 483 is to notify the company of the objectionable conditions and to allow the company to propose a plan to correct these conditions.

that the silicone is more likely to leak, even when the implants are intact, and that the materials used in the implants are more dangerous than reported.

58. Mentor knew of these risks associated with its implants, but covered them up by terminating studies, sponsoring only self-serving research they could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

E. Mize receives her implants unaware that she is a participant in a study or that the implants have not been approved by the FDA

59. Mize consulted Handel for the purpose of having a bilateral breast augmentation. Mize had not previously received silicone gel-filled breast implants, so she was not a revision candidate, and she did not require breast reconstruction.

60. Despite the fact that Mize did not meet the criteria established by the FDA for receiving silicone gel-filled implants in any of the then existing IDE studies[11], Handel recommended that Mize be implanted with Mentor's MemoryGel Silicone breast implants. Failing to comply with procedures for including Mize in the IDE study violated 21 CFR § 812.18

61. Mize was not provided sufficient information to allow her to understand that she was receiving the Mentor silicone gel-filled implants as part of a clinical study, was not advised that the FDA had not approved these implants for sale in the United States and was not properly advised if the risks and potential adverse effects which she could suffer by having these implants placed in her body.

F. Mentor's actions after Mize's implantation surgery

62. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its silicone gel-filled breast implants.

[11] The Adjunct Study criteria as approved by the FDA limited participation to patients seeking breast implants for: Post-mastectomy or reconstruction due to cancer treatments other than mastectomy or complications from such reconstruction surgery; total or partial removal of the breast(s) through surgery (for any reason) or as a result of trauma; severe congenital deformities or deformity caused by medical or surgical complications; severe asymmetry; or, replacement or revision for patients with existing implants. The FDA specifically excluded patients who sought breast augmentation without meeting at least one of the inclusion criteria. See, (last accessed April 1, 2018).

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63. On November 17, 2006, the FDA approved Mentor's PMA for its silicone gel-filled breast implants, subject to certain conditions. One of the conditions was that Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of its silicone gel-filled breast implants and to answer long term questions that the clinical trials were not designed to answer.

64. Specifically, the FDA required Mentor to: (a) Continue and complete the "Core" post-approval study; (b) Conduct a large post-approval study to assess long-term outcomes and identify rare adverse events and follow patients for 10 years; (c) Conduct a device-failure study in concert with their large post-approval study to further identify the modes and causes of failure of explanted devices over the 10-year period; (d) Complete a focus-group study to evaluate how easily patients understand the information in the informed decision brochure about the risks associated with the use of silicone breast implants; (e) Complete an informed decision study to monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants; and (f) Complete the "adjunct" study and continue to follow existing participants through their 5-year post-implant evaluations.

65. Mentor failed to ensure that these mandated studies were preformed properly, in part by not ensuring that the participants were followed after implantation. Accordingly, the information which the FDA was seeking regarding adverse events and device failures was never gathered.

66. For example, the "Core" study involved 1008 patients and Mentor was required to continue to follow these patients for the ten years following implantation to assess the long-term clinical performance of the silicone gel-filled implants. This was required to include 11 follow-up visits, at 6 months post-operation, and annually 1 year to 10 years after surgery.

67. The FDA also stated that all non-MRI patients should have an MRI at years 6, 8, and 10, and that all patients who were explanted without replacement were to be evaluated through 10 years.

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68. Mentor was further required to update the patient and physician labeling or its product to reflect the results of the 5 and 10-year Core Study findings and to report to the FDA significant new information regardless of when the information became available.

69. Although the actual follow-up rates for the "Core" study at 9 years post-implant were only 59 percent, Mentor reported that the follow-up rate at 10 years post-implant was 62 percent. See Exhibit C, pg. 1.

70. Furthermore, the FDA requirements specifically mandated evaluation through 10 years, but the core post-approval study report schedule illustrates that reporting was only done for 6 years. See Exhibit C, pg. 2.

71. There were also other significant flaws and shortcomings in the information which Mentor provided to the FDA related to this study.

72. The lack of a sufficient statistical sample, due to the low follow-up rate, as well as the inconsistent data and the failure of Mentor to ensure that the study was completed violated the FDA requirements and significantly limited the information available regarding the long term effects of use of the product.

73. The manner in which Mentor conducted the large Post-Approval Study (the "Large" study) and reported the information which it did gather were equally flawed.

74. The purpose for the "Large" study was to address specific issues such as long term local complications experienced by patients, such as connective tissue disease ("CTD"), CTD signs and symptoms, neurological disease, neurological signs and symptoms; offspring, reproductive, and lactation issues; cancer rates, suicide, mammography issues, rupture results, and MRI compliance.

75. The study data was to be collected through annual patient questionnaires completed over the internet, by mail, or by telephone.

76. The study also required physician evaluations at years 1, 4-6, 9 and 10 to collect data on complications.

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77. Mentor was required to update their patient and physician labeling to reflect the 5 and 10-year study findings, as well as at any other time if necessary to report significantly new information from the study.

78. As with the other mandated studies, the follow up rate for the "Large" study was so low that the information obtained was not sufficient to allow for the identification of problems and adverse effects from long term use of the product.

79. By the seventh year of this study, the overall follow-up rate was 20.1% (approximately 8,331 participants out of 41,452), leaving 79.9% of the desired statistics unavailable for evaluation.

80. This was a study of significant importance required by the FDA for post market approval. The study was designed to address a critical spectrum of health issues for women with breast implants. Mentor did not comply with the required data collection. With nearly an 80% dropout rate, the study failed to collect data to demonstrate that use of the Mentor silicone gel implants was safe.

81. The inadequate results are even more disconcerting because the data collection was designed to examine reasons for reoperation-previously unevaluated-including MRI results, and rheumatologic or neurological symptoms.

82. The lack of participation and reliable results from this study show that Mentor has failed to comply with FDA requirements.

83. Mentor did not follow through with required data collection. The Year 1 follow-up rate of surgeon visit for study participants was 22.8%, leaving nearly 80% unaccounted for. Similarly, the Year 1, 2, and 3 follow-up rates were 21.4%, 24.3%, and 23.0%, respectively, leaving nearly 80% unaccounted for. At Year 7, the overall follow-up rate was 20.1%, leaving 79.9% of participants unaccounted for and did not have follow-ups for data collection. No follow-up rates were provided for the 10-year data collection.

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84. These follow-up rates were too low for Mentor to provide meaningful safety information to the FDA and insufficient to allow for the identification of adverse effects or other problems resulting from long term use of the product.

85. Mentor was also required to conduct a Device Failure Study to ascertain the reasons for, and frequency of, device failure. Specifically the FDA required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study."

86. The study design involved two components: 1) the collection of implant/surgery information and clinical data at the time of explantation, and 2) visual inspection and physical testing of the explanted devices. No study population was stated, and there was no patient follow-up.

87. Mentor's Device Failure post-approval study failed to contain an adequate sample size to provide meaningful data.

88. Further, Mentor's Device Failure post-approval study report of summary findings failed to meet the requirements established by the FDA as it did not list results of the data findings (no clinical data and no visual inspection data), did not list safety findings, did not list any recommendations or summary of safety and data or follow-up on the data, and did not list any changes to labeling, all in violation of the FDA's requirements.

89. Mentor was also required to conduct a Focus Group Study to gather information regarding the adequacy of the format and content of the approved product labeling.

90. Mentor used an inadequate number of individuals to properly evaluate how patients understood the safety and labeling brochures.

91. The FDA also required that Mentor conduct as Informed Decision Study to determine the success of the informed decision process provided to women who seek breast implant surgery. Both the physician and the patient were intended to sign designated sections in order to best assure that the patient had obtained the labeling in sufficient time prior to surgery to read it and understand the risks and other information associated with the Mentor device.

92. Mentor failed to provide sufficient information regarding the methodology used or the results obtained from this study.

93. The FDA further mandated that Mentor continue the Adjunct Study, which had been approved in 1992, including the requirement that Mentor continue to follow-up on all patients currently enrolled in that study for 5 years. The data from this follow-up was to be reported as part of the annual reports required by the FDA.

94. The Adjunct Study was designed to follow-up with patients post-operatively at years 1, 3, and 5 to assess satisfaction and occurrence of local complications. The study was to gather data regarding short-term and local (tissue) implant complications.

95. The overall patient follow-up rates declined as follows: Year - 44%; Year 3 - 24.7%' and, Year 5 - 13.8%. Mentor sought to attribute the poor follow up rates to a lack of patient compliance. Mentor also admitted that the lack of sufficient data significantly limited interpretation of the available safety results.

G. Mize suffers injuries from the implantation of Mentor's Silicone gel-filled breast implants

96. Plaintiff Rexina Mize underwent a bilateral breast augmentation procedure on September 27, 2000, wherein Mentor's MemoryGel Silicone breast implants were implanted by Defendant Neal Handel M.D.

97. Plaintiff was unaware that she was receiving the Mentor implants as a participant in Mentor's Adjunct Study.

98. Mize sought breast implants for primary augmentation purposes, not for reconstruction or revision, therefore, she was not a proper candidate for participation in the Adjunct Study.

99. Mize was not contacted for follow up information following this implantation, although such follow up was mandated by the FDA for all participants in the Adjunct Study. This is consistent with the fact that there was a very low follow up rate for all participants in this and the other studies required by the FDA.

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100. Prior to being implanted with Mentor's MemoryGel Silicone breast implants, Mize enjoyed an active and full life and regularly performed as a musician and singer in a band.

101. However, after her implant surgery with the product, Mize began experiencing extreme and chronic fatigue, muscle pain, muscle weakness, muscle cramps, bone pain, swelling in her joints, pain in her joints, stiffness in her joints, severe memory loss, mental confusion, irritability, shortness of breath, severe migraines, itching, nausea, dizziness, numbness in her extremities, vision dysfunction, skin rashes, signs of silicone toxicity, autoimmune issues, weight gain, hormonal problems, heart palpitations, and extreme sensitivity to coldness.

102. Mize's vision deteriorated to the point that had to get prescription glasses and her chronic fatigue was so pervasive and continuous that there were many days she could not even get out of bed in the morning.

103. Eventually, Mize had to give up her music and singing in the band as a result of the chronic fatigue and other symptoms which prevented her from performing.

104. Mize also missed several business opportunities due to her chronic fatigue and other symptoms.

105. Although Mize reported her worsening symptoms to her physicians, none of them made the connection between these physical ailments and her Mentor MemoryGel Silicone breast implants.

106. In or around the latter part of 2016, Mize reported to her physician that her left breast implant was causing her severe pain. Her physician ordered an MRI, which was conducted on or about December 6, 2016.

107. The results of this MRI revealed, for the first time, a problem with Mize's silicone gel-filled breast implants. Specifically, the imaging showed that Mize's right breast implant had ruptured.

108. On or about December 29, 2016, Mize had testing performed on her blood which showed that her erythrocyte sedimentation rate ("Sed rate") was elevated indicating the possibility that she was suffering from a disease linked to inflammation.

109. After learning that her silicone gel-filled breast implants had ruptured and that testing showed she was potentially suffering from an inflammatory disease, Mize agreed to undergo a bilateral explantation surgery, which occurred on January 3, 2017.

110. That procedure entailed a bilateral total capsulectomy (removal of the scar tissue or "capsule" that had formed around the implants) as well as removal of the implants.

111. The postoperative findings revealed there was a right extracapsular (escaped silicone gel in breast tissue outside of the capsule layer) and left intracapsular (escaped silicone gel confined by the surrounding fibrous capsule) ruptures of Mize's silicone gel-filled breast implants.

112. The operative report note: "both implant capsular complexes were examined. There was obvious silicone present on the outer capsule of the right side. Both capsules were incised. There was obvious free silicone gel on the right side and surprisingly some stranding of the silicone gel on the left side as well. Closer examination of the left implant showed smooth, round, 400 cc of silicone implant with a small hole. The right side showed smooth, round, 400 cc silicone gel implant with large tear."

113. On or about January 5, 2017, the surgical pathology report from Mize's explantation surgery reported the following diagnosis: Left breast, capsulectomy – hyalinized [thickened] fibrous tissue with calcifications, foamy macrophages, and focal chronic inflammation. Right breast, capsulectomy – hyalinized fibrous tissue with histiocytic reaction to foreign material, calcifications, and focal chronic inflammation.

114. After her explantation surgery, the majority of Mize's symptoms and injuries caused by the Mentor silicone gel-filled implants have improved. Mize no longer needs to use prescription eyeglasses, her chronic fatigue has been decreased and her mental clarity has improved. But she has still not fully recovered.

IV. DELAYED DISCOVERY

115. Mize adopts and incorporates the forgoing allegations as if fully set forth herein.

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116. Mize exercised reasonable diligence in investigating her injuries and the cause of her injuries, and could not have discovered that her injuries were caused by the product at an earlier time.

117. The discovery rule applies to toll the running of the statute of limitations until Mize knew, or through the exercise of reasonable care and diligence, should have known of the existence of her claims against all Defendants.

118. The nature of Mize's injuries and subsequent damages, and their causal relationship to the product were not, and could not, have been discovered through reasonable care and diligence.

119. Mize did not suspect, nor did she have reason to suspect, that her injuries were being caused by the product, or the tortious nature of the conduct causing those injuries, until less than the applicable limitations period prior to the filing of this action.

120. Mize did discover that her injuries were related to her silicone gel-filled breast implants until after December 6, 2016.

121. None of Mize's treating physicians had connected her injuries with her silicone gel-filled breast implants before, at the earliest, December 6, 2016.

122. Handel destroyed the records relating to Mize's implantation surgery and his care for her, including pre-surgery consultations and post-surgery follow ups.

123. The only information available to Mize consists of the product stickers showing the lot number, manufacturer and date she was implanted with Mentor's MemoryGel Silicone Gel-filled Implants.

124. Mize was never adequately advised that she was part of a study and was never told to follow up with Handel or Mentor for purposes of that study.

125. Handel never advised Mize that she was receiving the implants as part of a study, never told her that the implants he intended to use had not yet been approved for sale by the FDA and also failed to advise her of other relevant and material facts.

126. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Mize the true and significant risks associated with the product.

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127. Handel, through his affirmative misrepresentations and material omissions, actively concealed from Mize the true nature of the surgical procedure she underwent for implantation of her Mentor MemoryGel silicone gel-filled breast implants.

128. Under CCP § 340.5, the statute of limitations against a healthcare provider based upon negligence commences three years after the date of injury or one year after the plaintiff discovers, or through the use of reasonable diligence should have discovered, the injury. In no event shall the time for commencement of a legal action exceed three years unless tolled for any of the following: (1) upon proof of fraud, (2) intentional concealment, or (3) the presence of a foreign body.

129. Handel intentionally concealed material information from Mize and she did not discover that her injuries were potentially related to her silicone gel-filled breast implants until, at the earliest, December 6, 2016.

130. Mize did not learn that she was allegedly a participant in a study until Mentor's counsel informed Plaintiffs' counsel on June 30, 2017 that Ms. Mize was allegedly part of Mentor's Adjunct clinical study. This newly discovered information was relayed to Ms. Mize on June 30, 2017. As such, this action is timely filed.

131. Further, Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from, and misrepresented to, Plaintiff the connection between the injuries sustained and the Defendants' tortious conduct.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE AND NEGLIGENCE PER SE

(Plaintiff Rexina Mize as Against Defendant MENTOR WORLDWIDE LLC)

132. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

133. At all relevant times, Mentor had a duty to Mize to use reasonable care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising,

manufacturing, selling, distributing, marketing, and promoting its MemoryGel Silicone Gel Breast Implants.

134. Mentor formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted its MemoryGel Silicone Gel Breast Implants, including the product that was implanted into Plaintiff Rexina Mize.

A. Negligent Failure to Warn

135. Mentor had a duty under California law to exercise reasonable care to provide adequate warning about the risks and dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendants at the time of distribution.

136. Mentor was negligent by not using reasonable care to warn about the dangers of which it was aware related to its silicone gel-filled breast implants, including the MemoryGel implants placed in Mize or facts that this product was likely to become dangerous after being implanted into her body.

137. Mentor knew or reasonably should have known that the its silicone gel-filled breast implants, including the MemoryGel implants placed in Mize, were dangerous or were likely to be dangerous when used or misused in a reasonably foreseeable manner.

138. Defendants breached their duty under federal law, and the parallel state duty, in that they failed to warn the FDA, Mize and her physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Mentor's MemoryGel Silicone Gel Breast Implants prior to the time of Plaintiff's implantation, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiff.

139. Specifically, Mentor had a duty to report unanticipated adverse device effects (with evaluation) to the FDA, all IRBs, and investigators within 10 working days after notification by the investigator. 21 CFR 812.150(b). This duty is parallel to the state law duty to exercise reasonable care to provide adequate warning about the risks and dangers associated with their product.

140. Under both federal and state law, Mentor also had a continuing duty to monitor and report adverse events and risks associated with the use of its products.

141. Under both federal and state law, Mentor had a duty to exercise reasonable care in adequately warning Mize and Mize's treating physicians about the dangers of Mentor MemoryGel silicone breast implants that were known or knowable to Defendants at the time of distribution or which became known thereafter.

142. Under both federal and state law, and under the IDE and studies mandated by the FDA, Mentor had a duty to continue to monitor and report adverse events and risks associated with the product.

143. Despite having knowledge and possession of information that showed the use of Mentor MemoryGel silicone breast implants were dangerous and likely to place consumers' health at serious risk, Mentor failed to disclose and warn of the health hazards and risks associated with the product.

144. Instead, Mentor marketed, advertised, and promoted the product while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of California law and applicable FDA regulations and requirements.

145. Mentor also had a duty to continue to monitor and submit subsequent reports on the effect may be required by FDA. Mentor, as the device manufacturer, failed to comply with the FDA mandated requirement to continue to monitor the use of its product to determine the safety and effectiveness, and to report any findings of adverse health consequences that may be attributable to the product to the FDA.

146. This duty is parallel to the post-sale duty to warn under California law and applies as Mentor gained knowledge, which it was under a duty to communicate to the FDA and physicians which did not exist at the time Mize was implanted with Mentor's product.

147. Mentor failed to report adverse events from the studies it was required to conduct, which would have led to adverse event reports revealing the product's contribution to serious injury.

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148. Had Mentor complied with its obligation to report this newly acquired information, true information about: instances of silicone toxicity; instances of adverse events; instances of adverse events requiring removal; instances of constellations of adverse symptoms; instances of chronic/persistent autoimmune-like complaints and inflammatory issues; rupture rates; and other relevant information would have been provided to the FDA and would have been available to Mize's treating physicians, who would have communicated that information to Mize.

149. Mentor was, at all times, responsible for maintaining the labeling of the product, and had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by updating the labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired safety information without advance approval by the FDA.

150. During the IDE process, Mentor was under a duty to advise the FDA, IRB and study investigators of all significant new information, including the duty to monitor, evaluate and report all unanticipated adverse device effects and to terminate the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. See, 21 CFR 812.46.

151. Mentor was specifically required to report all unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. See, 21 CFR 812.150(b).

152. California imposes a parallel duty to warn and advise product users.

153. Once Mentor applied for pre-market approval for is MemoryGel Silicone Gel-Filled Implants, it had additional duties and responsibilities. This included the responsibility to file a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Mentor could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 CFR § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

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b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

154. Mentor breached their duties under federal law and state law, including California law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

155. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 CFR § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 CFR § 820.198(a).

156. Specifically, 21 CFR § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

157. The FDA publishes this information in a public, searchable Internet database called MAUDE (Manufacturer and User Facility Device Experience) and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

158. Despite the fact that evidence existed that Mentor MemoryGel Silicone Gel Breast Implants were dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

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159. Instead, Defendants manufactured, marketed, sold, advertised, and promoted Mentor MemoryGel Silicone Gel Breast Implants while failing to warn or otherwise ensure the safety of its users in violation of state law, including California law and applicable FDA regulations.

160. Mentor had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. Health & Saf. Code, §§ 111440 ("it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded"), 111445 ("it is unlawful for any person to misbrand any drug or device.").

161. Under parallel federal law, Defendants had the ability to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction...of any device that is ...misbranded, (b) the ...misbranding of any ...device...).

162. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Mize's treating physicians, regarding the dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendants at the time of distribution and afterwards.

163. If Plaintiff had been adequately warned of the serious risks and adverse events by Defendant Mentor, she would not have agreed to implantation of Mentor MemoryGel Silicone Gel Breast Implants.

164. Had Mentor complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Mize's treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Mize was experiencing were related to her Mentor MemoryGel Silicone Breast Implants. Had that

occurred, Mize would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

165. Mentor was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements the IDE approval process under 21 CFR § 800.100(a)(6)(7).

166. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

167. As a proximate and legal result of Mentor's failure to comply with its obligations under applicable Federal regulations, Mentor breached its duty of care and caused Mize to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

B. Negligent Manufacturing

168. Mentor had a duty under Federal law, and a parallel duty under California law, to exercise reasonable care in developing, manufacturing, testing, inspecting and selling their product to ensure that it was safe and further that it was made in conformity with the manufacturing and design specifications mandated by the FDA as part of Mentor's IDE.

169. Mentor was negligent under California law, in the development, manufacture, testing, inspection and sale of their MemoryGel Silicone Gel Breast Implants by: (a) manufacturing MemoryGel Silicone Gel Breast Implants that differed from the specifications agreed to by the FDA; manufacturing MemoryGel Silicone Gel Breast Implants using materials and components which differed from those approved by the FDA; failing to follow good manufacturing practices during the manufacture of their MemoryGel Silicone Gel Breast Implants; failing to properly meet the applicable standard of care by not complying with applicable federal regulations and failing to adhere to the manufacturing protocols approved by the FDA; carelessly and negligently

selling and distributing its MemoryGel Silicone Gel Breast Implants in violation of the terms of the IDE and applicable federal law; negligently incorporating components and/or materials into its MemoryGel Silicone Gel Breast Implants that could not stand up to normal usage and/or which differed from those which were commercially reasonable and/or failing to use the components and/or materials approved by the FDA; failing to exercise reasonable care in inspecting and testing of the product; and, failing to exercise reasonable care in its manufacturing, quality control and quality assurance processes.

170. Mentor had a duty under California law to exercise ordinary care in the manufacture of its MemoryGel Silicone Gel Breast Implants consistent with FDA specifications, the Mentor MemoryGel Silicone Gel Breast Implants IDE, and/or conditions of approval.

171. At all relevant times, Mentor was required to comply with the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30.

172. Mentor's MemoryGel Silicone Gel Breast Implants contained a manufacturing defect when it left Mentor's possession, in that Mentor's manufacturing process did not conform to FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30.

173. Upon information and belief, prior to the date that the subject implants were manufactured Mentor has received several Form 483 notifications and otherwise was aware that its manufacturing process was deficient and that the implants being produced did not comply with applicable Federal requirements.

174. Mentor failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of its MemoryGel Silicone Gel Breast Implants.

175. Mentor failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of its MemoryGel Silicone Gel Breast Implants.

176. Mentor failed to adequately inspect, test, and validate its MemoryGel Silicone Gel Breast Implants after completion of assembly.

177. Mentor failed to comply with the requirements imposed by the FDA and other applicable Federal requirements for the manufacture of its MemoryGel Silicone Gel Breast Implants.

178. Because Mentor failed to follow specifications, regulations, and required by the FDA, Mize's MemoryGel Silicone Gel Breast Implants were defective and were further vulnerable to degradation, deterioration, rupture and leakage.

179. Upon information and belief, when the MemoryGel Silicone Gel Breast Implants placed into Mize were manufactured, Mentor had the technological capability to manufacture its MemoryGel Silicone Gel Breast Implants in a reasonably safe manner.

180. Mentor was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements the IDE approval process under 21 CFR § 800.100(a)(6)(7).

181. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

182. Upon information and belief, Mize was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the FDA requirements, resulting in product failure and serious injury to her.

183. The injuries Mize suffered are expected to result from the manufacturing defects identified therein. Mize and her treating physicians were unaware that the product was defective at the time of implant and for years thereafter.

184. Mize is within the class of persons the statutes and regulations referred to herein were designed to protect, and Mize's injuries are of the type of harm these statutes and regulations are designed to prevent.

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185. Mentor's violations of these statutes and regulations proximately caused Mize's injuries alleged herein.

186. As a proximate and legal result of Mentor's failure to exercise reasonable care and the resulting defective condition of its MemoryGel Silicone Gel Breast Implants implanted into Mize, she suffered injuries and will continue to suffer injuries in the future including severe physical injuries, severe emotional distress, mental anguish, economic loss, future follow-up medical care, medical treatment, and procedures, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

187. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Plaintiff Rexina Mize as Against Defendant MENTOR WORLDWIDE LLC)

188. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

189. At all times relevant herein, Mentor was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

190. At all times relevant herein, Mentor intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Mize, and knew or should have known that the product would be surgically implanted into members of the general public, including Mize.

191. Mize failed to warn Plaintiff and her physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

192. Mentor also failed to revise the product labeling or otherwise communicate the true rate of occurrence of adverse events to the FDA, the IRB or to physicians based upon the adverse

event information available to it through, among other things, the studies which it was required to conduct and the reports of adverse events and effects which it received.

193. Mize's Mentor MemoryGel Silicone Gel Breast Implants were defective at the time of sale and distribution and at the time they left the possession of Mentor in that Mentor failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants.

194. The MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous when they left the possession of Mentor in that they contained warnings insufficient to alert physicians and consumers, including Mize, of the dangerous risks and complications associated with the MemoryGel Silicone Gel Breast Implants, including but not limited to, their propensity to cause injury, through leakage of the silicone gel into the tissues of the user's body, thereby introducing toxic metals and chemicals into those tissues, resulting in serious, dangerous and harmful side effects and complications all to the detriment of the health and well-being of the users of their product, including Mize.

195. Mentor knew, or should have known, the gel contained in the implants contained metals and toxic chemicals in such quantities that would be extremely harmful to users of their product if the gel were allowed to escape its shell and "bleed" into the user's body.

196. Mentor also knew, or should have known, that there was a significant risk of rupture or seepage of the gel through the shell and into the tissues of the user's body.

197. Mentor failed to adequately warn physicians and patients implanted with the product, including Mize, of these potential serious and harmful risks.

198. Mentor failed to provide follow-through post-approval studies required by the FDA's necessary in order to market and sell the product, and thus failed to report to, and warn, the FDA and the IRB of the risks described above.

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199. The accurate rate of occurrence for these and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Mize and Mize's treating physicians, as a result of Mentor's conduct.

200. Mentor MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Mentor knew or should have known that the products created a serious risk of degradation, deterioration, ruptures, and leakage, and other injuries that could, and did, harm consumers, including Mize, and Mentor failed to adequately warn consumers of said risks - including Mize and Mize's treating physicians - in accordance with Federal requirements and California law.

201. Mentor's MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous due to inadequate warnings and instructions because Mentor knew or should have known that Mentor MemoryGel Silicone Gel Breast Implants created, among other things, a higher than expected risk for adverse events, and Mentor failed to adequately warn of those risks, to monitor those risks, report them, test for them, and update its labeling and the information provided to the FDA and IRB regarding such risks when the information became available.

202. Mentor failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements the IDE approval process under 21 CFR § 800.100(a)(6)(7).

203. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

204. At all relevant times, Mize's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted into her as intended by Mentor and in a manner reasonably foreseeable to Mentor.

205. Mentor's MemoryGel Silicone Gel Breast were expected to, and did, reach Mize and Mize's implanting physician without substantial change in the condition in which they were sold.

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206. Despite the fact that Mentor knew, or should have known, that the use of Mentor MemoryGel Silicone Gel Breast Implants were unreasonably dangerous and likely to place users at serious risks to their health, Mentor failed to monitor and warn of the defects, health hazards, and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

207. Mize's Mentor MemoryGel Silicone Gel Breast Implants were also defective at the time of sale and distribution, and at the time the devices left the possession of Mentor, in that the devices differed from Mentor's intended result and design specifications as approved by the FDA.

208. Upon information and belief, Mize was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the specifications and requirements approved and mandated by the FDA, resulting in product failure and serious injury to Mize.

209. The injuries Mize suffered are expected to result from the manufacturing defects identified therein and by the FDA. Mize and her treating physicians were unaware that the product was defective at the time of implant and for years thereafter.

210. Mentor violated Federal regulations and California law, by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

211. Mentor was, at all times, responsible for maintaining the labeling of the product, and had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by updating the labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired safety information without advance approval by the FDA.

212. During the IDE process, Mentor was under a duty to advise the FDA, IRB and study investigators of all significant new information, including the duty to monitor, evaluate and report all unanticipated adverse device effects and to terminate the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. See, 21 CFR 812.46.

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213. Mentor was specifically required to report all unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. See, 21 CFR 812.150(b).

214. California imposes a parallel duty to warn and advise product users.

215. Once Mentor applied for pre-market approval for is MemoryGel Silicone Gel-Filled Implants, it had additional duties and responsibilities. This included the responsibility to file a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Mentor could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 CFR § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

216. Mentor breached their duties under federal law and state law, including California law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

217. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 CFR § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 CFR § 820.198(a).

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218. Specifically, 21 CFR § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

219. The FDA publishes this information in a public, searchable Internet database called MAUDE (Manufacturer and User Facility Device Experience) and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

220. Despite the fact that evidence existed that Mentor MemoryGel Silicone Gel Breast Implants were dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

221. Mentor MemoryGel Silicone Gel Breast Implants had a manufacturing defect when they left Mentor's possession in that Mentor's manufacturing process did not comply with the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30.

222. The defects inherent in Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's implanting physician.

223. Plaintiff could not, in the exercise of reasonable care, have discovered the defects herein mentioned and perceived their true danger.

224. Plaintiff and/or Plaintiff's implanting physician reasonably relied upon the skill, superior knowledge, and judgment of Mentor, including Defendant Mentor, when she consented to the implantation procedure using Mentor MemoryGel Silicone Gel Breast Implants.

225. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted as intended by Mentor and in a manner reasonably foreseeable to Mentor.

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226. Had Plaintiff and/or Plaintiff's physician received adequate warnings regarding the risks the risks of Mentor MemoryGel Silicone Gel Breast Implants, she would not have used them.

227. Had Mentor complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Mize's treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Mize was experiencing were related to her Mentor MemoryGel Silicone Breast Implants. Had that occurred, Mize would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

228. Mentor's MemoryGel Silicone Gel Breast Implants were expected to, and did, reach Mize and/or Mize's implanting physician without substantial change in the condition in which they were sold.

229. Mentor knew that its MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

230. At all times relevant to this action, the dangerous propensities of Mentor MemoryGel Silicone Gel Breast Implants were known to Mentor or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to implant Mentor MemoryGel Silicone Gel Breast Implants for their patients, including Mize.

231. Mentor was required to provide adequate warnings to consumers and the medical community under federal and California law, but failed to do so in a timely, truthful, accurate and responsible manner.

232. Had Mentor timely and adequately reported adverse events to the FDA and IRB, there would have been effective warnings to physicians, including Mize's treating physicians, of those

adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Mize and/or Mize's treating physicians, regarding the dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Mentor at the time of distribution.

233. Had Mentor complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Mize's treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Mize was experiencing were related to her Mentor MemoryGel Silicone Breast Implants. Had that occurred, Mize would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

234. Because Mentor failed to follow specifications, regulations, and required the FDA and applicable Federal regulations and requirements, the Mentor MemoryGel Silicone Gel Breast Implants implanted in Mize were vulnerable to degradation, deterioration, ruptures, and leakage.

235. Mentor's MemoryGel Silicone Gel Breast Implants were manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendants, and this was a substantial contributing factor in bringing about Mize's injuries, which would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

236. The defective warnings and failures to provide truthful, accurate and complete information as required under the IDE and other applicable Federal regulations and requirements were a substantial contributing factor in bringing about the injuries to Mize that would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

237. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Gel Breast Implants defective condition at the time they were sold, Mize suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future

medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

238. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth herein.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Plaintiff Rexina Mize as Against Defendant MENTOR WORLDWIDE LLC)

239. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

240. At all times relevant herein, Mentor was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

241. At all times relevant herein, Mentor intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Mize, and knew or should have known that the product would be surgically implanted into members of the general public, including Mize.

242. Mentor manufactured, tested, marketed, promoted, advertised, distributed, and sold the Mentor MemoryGel Silicone Gel Breast Implants that were implanted into Mize.

243. At all times relevant, Mentor placed Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce, and did so in a manner in which the Mentor MemoryGel Silicone Gel Breast Implants were defective in their manufacturing process did not comply with the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30.

244. Mentor violated Federal regulations and requirements and California law by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

245. Mentor failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish

and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements the IDE approval process under 21 CFR § 800.100(a)(6)(7).

246. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

247. Mentor's MemoryGel Silicone Gel Breast Implants implanted during Mize's surgery contained a manufacturing defect. The rupture, leakage, and bleeding of silicone of the Mentor MemoryGel Silicone Gel Breast Implants implanted into Mize, due to porous or weak containment in the Implant shell, is inconsistent with specifications and conditions of the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30, and therefore constitutes a manufacturing defect.

248. Mentor knew that the defects in its product were such that they would not be discovered through reasonable inspection by the users of the product, including Mize and Mize's implanting physician. Mentor knew that its MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

249. Mize and her implanting physician, foreseeable users and ultimate consumers of the Mentor's product, were unaware of these defects when Mize consented to have the product implanted in her body.

250. As a direct and legal result of the manufacturing defects contained in Mentor's MemoryGel Silicone Gel Breast Implants, Mize was injured in her health and well-being as described herein.

251. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Gel Breast Implants defective condition at the time they were sold, Mize suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future

medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

252. WHEREFORE, Plaintiffs prays for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(Spouse Plaintiff Minh Nguyen as Against All Defendants)

253. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

254. At all relevant times hereto, Plaintiff MINH NGUYEN was and is the lawful spouse of Plaintiff REXINA MIZE.

255. As a result of the injuries and damages suffered by Plaintiff REXINA MIZE by Defendants' wrongful conduct as alleged herein, Mize was unable to perform any activities as a spouse in the household.

256. Plaintiff REXINA MIZE was unable to take care of the house or provide companionship to Plaintiff MINH NGUYEN. Plaintiff MINH NGUYEN had to take full control over chores and acts around the house, including but not limited to, laundry, dishes, cooking, errands, cleaning taking Plaintiff REXINA MIZE to medical treatment, and taking care of Plaintiff REXINA MIZE's needs. Plaintiff MINH NGUYEN effectively lost the companionship and accompaniment of his wife, Plaintiff REXINA MIZE, as a result of Defendants' wrongful conduct.

257. As a direct and proximate result of the injuries sustained by Plaintiff REXINA MIZE and caused by Defendants, Spouse Plaintiff MINH NGUYEN suffered, and will continue to suffer the loss of his wife's consortium, companionship, society, affection, services and support.

258. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

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FIFTH CAUSE OF ACTION

MEDICAL BATTERY

(Plaintiff Rexina Mize as Against Defendant Handel)

259. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

260. Defendant Handel performed a breast augmentation procedure on Mize in Beverly Hills, California on or about September 27, 2000 using Mentor's gel-filled breast implants, Ref. No. 350-7400BC, Lot 209120.

261. Defendant Handel performed this procedure without obtaining Mize's informed consent, as Handel did not adequately inform Mize that she would be part of a clinical study or that the breast implants were not yet FDA-approved.

262. Handel performed an operation on Mize to which she did not consent.

263. Upon information and belief, Mize gave permission to Handel to perform one type of surgery – that is, implanting FDA approved silicone implants – but Handel performed another surgery – that is, implanting silicone implants which had not been approved by the FDA.

264. Upon information and belief, Mentor alleges that Mize was a participant in its Adjunct Study under the IDE.

265. Upon information and Handel was an investigator or leader of this study, but concealed this information from Mize.

266. Mize sought breast implant surgery from Handel for primary augmentation purposes. Mize did not meet any of the criteria for inclusion in the Adjunct Study and should have been excluded from this study. Failing to comply with procedures for including Mize in the IDE violated 21 CFR § 812.18

267. As a proximate result and/or substantial factor of Handel's conduct, Mize suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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268. By reason of the foregoing, Mize has been damaged by Handel's wrongful conduct.

269. WHEREFORE, Plaintiffs prays for judgment against Defendant Handel as set forth herein.

SIXTH CAUSE OF ACTION

FAILURE TO OBTAIN INFORMED CONSENT

(Plaintiff Rexina Mize as Against Defendant Handel)

270. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

271. Handel was negligent because he performed a breast implant surgery on Mize without first obtaining her informed consent.

272. Handel performed a breast augmentation procedure on Mize in Beverly Hills, California on or about September 27, 2000 using Mentor's gel-filled breast implants, Ref. No. 350-7400BC, Lot 209120. See Exhibit A.

273. Handel intentionally concealed material information from Mize, including but not limited to, that she would be part of a clinical study and that the breast implants she received were not yet FDA-approved. Thus, Ms. Mize did not give her informed consent to undergo such a procedure.

274. Handel failed to obtain Mize's informed consent for this surgery because he did not inform Mize that she would be included as a participant in a clinical study, and that the breast implants being used had not been approved by the FDA.

275. Had Handel told Mize the true and complete facts, including that he was an investigator or was otherwise a leader of a clinical study, that Mize would be a participant in that study and that the breast implants she was to receive were not FDA-approved medical devices, Mize would not have consented to, or undergone the surgery.

276. Mize sought breast implant surgery from Handel for primary augmentation purposes. Mize did not meet any of the criteria for inclusion in the Adjunct Study and should have been

excluded from this study. Failing to comply with procedures for including Mize in the IDE study violated 21 CFR § 812.18

277. As a proximate result and/or substantial factor of Handel's wrongful conduct, Mize suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

278. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

RELIEF REQUESTED

279. WHEREFORE Plaintiffs pray for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

(A) Economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

(B) For compensatory damages according to proof;

(C) For prejudgment interest and the costs of suit; and

(D) For such other and further relief as this Court may deem just and proper.

Dated: April 2, 2018

LENZE LAWYERS, PLC.

By: _____
JENNIFER A. LENZE
Attorney for Plaintiffs

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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand individual trials by jury as to all claims so triable in this action.

Dated: April 2, 2018

LENZE LAWYERS, PLC.

By: _____

JENNIFER A. LENZE

Attorney for Plaintiffs

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES, CENTRAL CIVIL WEST DISTRICT

REXINA MIZE, an individual; MINH NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE LLC; NEAL HANDEL, M.D.; and DOES 1-100, inclusive,

Defendants.

Case No.: BC649083

PLAINTIFFS' OPPOSITION TO DEFENDANT MENTOR WORLDWIDE, LLC'S DEMURRER TO PLAINTIFFS' THIRD AMENDED COMPLAINT

Hearing: July 11, 2018
Time: 11:00 a.m.
Judge: Honorable Carolyn B. Kuhl
Dept.: 12

Third Amended Complaint Filed 4/2/2018
Second Amended Complaint Filed: 8/17/17
Complaint Filed: 2/2/2017
Trial Date: None

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TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD HEREIN:

Plaintiffs Rexina Mize ("Ms. Mize" or "Plaintiff") and Minh Nguyen (collectively "Plaintiffs"), hereby oppose the Demurrer to Plaintiffs' Third Amended Complaint for damages of Defendant Mentor Worldwide, LLC ("Mentor"), being heard by the above-entitled court on July 11, 2018 at 11:00 a.m. in Department 309, located in the Central Civil West Courthouse, at 600 South Commonwealth Ave., Los Angeles, CA 90005.

This Opposition will be based upon the facts and law set forth in the Memorandum of Points and Authorities served and filed herewith, the pleadings, records and files in this action and on such oral and documentary evidence as may be presented at the hearing of this matter.

Respectfully submitted,

Dated: June 27, 2018

LENZE LAWYERS, PLC

By: _____
JENNIFER A. LENZE
Attorney for Plaintiffs

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MEMORANDUM OF POINTS AND AUTHORITIES

I - INTRODUCTION

Plaintiffs have made claims against Mentor for injuries Ms. Mize alleges were caused by Mentor's MemoryGel Silicone gel-filled breast implants. The claims made against Mentor in the operative Complaint are for: Negligence and Negligence Per Se; Strict Product Liability – Failure to Warn; Strict Product Liability – Manufacturing Defect; and a derivative claim for Loss of Consortium. *See* Third Amended Complaint ("TAC") filed [DATE]. Mentor has demurred to each of these claims arguing that they are expressly and impliedly preempted and further demurred to certain of the claims on the basis that they are barred by the learned intermediary doctrine. *See* Mentor Demurrer ("Demurrer") to TAC at p. 1-2. Mentor's arguments are unpersuasive and are not supported by the authority which it cites. Therefore, Mentor's Demurrer should be overruled.

II - FACTS

The relevant facts are not in dispute. Plaintiff was surgically implanted with Mentor's MemoryGel Implants in September 2000. (TAC ¶ 96) and she underwent explant surgery to remove them on January 3, 2017. (TAC ¶ 109). Ms. Mize filed the present lawsuit seeking to hold Mentor liable for injuries she alleges were caused by defects in the implants and other wrongful conduct of Mentor. Additional claims have also been made against Neal Handel, M.D. ("Handel").

On January 6, 1992, the United States Food and Drug Administration ("FDA") called for a voluntary moratorium on the use of silicone gel-filled breast implants until new safety information could be thoroughly reviewed. (TAC ¶ 23). Thereafter, the FDA allowed silicone gel-filled implants for use in reconstruction or revision surgery as investigational devices in clinical studies. (TAC ¶ 26).

Ms. Mize did not fall within the criteria established by the FDA for receiving silicone gel-filled implants as she was not seeking a revision or reconstruction. (TAC ¶ 59). Handel did not disclose that he was acting as an investigator or leader of a study sponsored by Mentor as part of its efforts to convince the FDA to approve the sale of its silicone gel filled implants in the United States, nor did he advise Ms. Mize that the implants he recommended had not been approved for sale and were investigational devices (TAC ¶¶ 26, 263-64; 274-75).

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III - LEGAL STANDARDS

A. Federal Preemption does not bar Parallel State Law Claims

The primary argument presented by Mentor in support of the pending demurrer is that the claims made in the TAC are expressly preempted[1] under the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetics Act ("FDCA"), specifically 21 U.S.C. § 360k(a), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) ("*Riegel*"). Mentor also argues that these claims are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ("*Buckman*"). Mentor's arguments are incorrect and governing authority clearly establishes that the claims made in the TAC should be allowed to proceed as they parallel, and do not add to, the federal requirements.

As discussed in *Riegel*, a two-step analysis is used to determine whether a claim is subject to express preemption under § 360k(a). The first step is to determine whether the FDA has established "requirements" for the medical device at issue. (*Riegel*, 552 U.S. at p. 321). If so, the next step is to determine whether the state law claims seek to impose requirements that relate to safety and effectiveness which are "different from, or in addition to" the FDA requirements. (*Riegel*, 552 U.S. at pp. 321–322). However, the fact that certain claims made against a medical device manufacturer may be subject to express or implied preemption does not mean that all such claims are preempted. As explained by the court in *Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413 ("*Coleman*"), "[s]tate law causes of action that provide 'a damages remedy for claims premised on a violation of FDA regulations' are not expressly preempted if they "'parallel,' rather than add to, federal requirements." 233 Cal. App. 4th at 425 (quoting *Riegel*, 552 U.S. at p. 330).

In *Buckman*, the Court held that MDA prohibits suits by private litigants which seek to enforce the provisions of the FDCA because all such actions "shall be by and in the name of the United States." 21

[1] "There is a presumption against federal preemption of state laws that operate in traditional state domains.' *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir.2013) (en banc) ("Stengel"). Claims against medical device manufacturersninvolve an area of traditional state law as "'the historic police powers of the State include the regulation of health and safety.' [Citation]. 'Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are "primarily, and historically, ... matter[s] of local concern," the "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."' [Citation]." *Stengel*, 704 F.3d at 1229.

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U.S.C. § 337(a). Therefore, a claim is impliedly preempted to the extent that it seeks to enforce an exclusively federal requirement not grounded in traditional state tort law. 531 U.S. 352–53.

The *Coleman* court succinctly summarized the scope of preemption as follows: "The rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Coleman*, 223 Cal. App. 4th at 427.

IV. ARGUMENT

A. Mize has Sufficiently Alleged Parallel State Law Claims which are not Preempted

The claims made in the TAC are not expressly or impliedly preempted because they are all based on state law claims that parallel, but do not add to, the federal requirements imposed by the FDA. Mentor agrees that "Section 360k(a) [], 'does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations' because the state duties in such a case "parallel," rather than add to, federal requirements.' *Riegel*, 552 U.S. at 330." Demurrer at p. 5. Because all of the claims which are presented against Mentor in the TAC are such "parallel" claims[2], they are not subject to either express or implied preemption. Plaintiffs allegations regarding violations of the FDCA are all based on parallel state law causes of action. Accordingly, these claims are not subject to implied preemption as they are not based solely on enforcement of a federal requirement.

Mentor attempts to avoid this reality by citing to federal cases in support of the incorrect assertion that "[c]ourts routinely find that claims involving breast implants are preempted" and are "subject to dismissal." A review of the cases cited by Mentor does not support this argument: See, *Rowe v. Mentor Worldwide*, 297 F.Supp.3d 1288 (M.D. Fla. 2018) (claim for negligent manufacture not preempted); *Laux v. Mentor Worldwide, LLC*, 2017 WL 5186329 (C.D. Cal. Nov. 8, 2017) (claims for manufacturing defect, negligence, and breach of warranty were not dismissed, but summary judgment was granted when plaintiff failed to identify any specific federal requirement which was violated after discovery and expert testimony); *Malonzo v. Mentor Worldwide, LLC*, 2014 WL 2212235 (N.D. Cal. May 28, 2014) (no parallel

[2] See, e.g., TAC at ¶ 138 ("Defendants breached their duty under federal law, and the parallel state duty []"); TAC at ¶ 139 ("[t]his duty is parallel to the state law duty []"); TAC at ¶ 146 ("[t]his duty is parallel to the post-sale duty to warn under California law []"); TAC at ¶ 152 ("California imposes a parallel duty to warn []"); TAC at ¶ 161 (duty "under parallel federal law []"); TAC at ¶ 168 ("Mentor had a duty under Federal law, and a parallel duty under California law []"); TAC at ¶ 214 ("California imposes a parallel duty []")

claims alleged and complaint "only referenced federal requirements and appears to seek to enforce those directly."); *Couvillier v. Allergan Inc.* 2011 WL 8879258 (W.D. La. Jan. 20, 2011) (Magistrate's report and recommendation which sets forth no discussion or analysis); *Ford v. Mentor Worldwide, LLC*, No. 2:13-cv-06317 (E.D. La. Dec. 17, 2013) ("Plaintiff does not oppose dismissal of her claims against Mentor"); *Harris v. Mentor Worldwide LLC*, No. 12-cv-916 (E.D. Cal. Aug. 21, 2012) ("Plaintiff did not file an opposition or statement of non-opposition to Defendants motion."); *Dorsey v. Allergan*, 2009 WL 703290, at *7 (M.D. Tenn. Mar. 11, 2009) (sole claim was for strict product liability under Tennessee law); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *1, *4 (D. Ariz. Oct. 14, 2009)(granting summary judgment because while "Plaintiffs are correct that claims paralleling the MDA are not preempted, such as where state tort claims are based on violations of federal law, [] Plaintiffs did not allege any such claims in their Complaint.")

In *Coleman*, which is binding precedent, the plaintiff made claims related to a medical device asserting theories of strict liability and negligence, including allegations of manufacturing defects and failure to warn. After reviewing the applicable law, the *Coleman* court reversed the trial court's sustaining the demurrer to the causes of action for "(1) strict liability failure to warn based on a failure to warn the FDA theory, (2) negligence, and (3) manufacturing defect." *Id.* at 319. That same result should be reached in the present case and Mentor's demurrer should be denied.

B. Plaintiffs' Failure to Warn Claim is Sufficiently Pled

Ms. Mize alleges that Mentor failed to report adverse event information to the FDA. This is sufficient at the demurrer stage to state a parallel claim for failure to warn under the analysis set forth in *Coleman*. The *Coleman* court concluded that to the extent Coleman's claims for failure to warn were based on the defendant's failure to file adverse event reports with the FDA, they were not subject to express or implied preemption and that same result should be reached in the present case. The very case Mentor cites in its Demurrer, *Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1024 (C.D. Cal. 2015) states: "[b]oth *Stengel* and *Coleman* demonstrate that a claim alleging a device manufacturer's failure to warn the FDA of something FDA regulations required it to warn about is not preempted—such a failure is both contrary to FDA regulations and California tort law." Unlike the plaintiff in *Funke*, in the present

case there are allegations regarding the duty under both federal law and California law which Mentor violated.

Mentor misstates the allegations set forth in the TAC by implicitly asserting that Ms. Mize seeks to recover "based on the theory that Mentor had a duty to provide warnings to her physicians that were different from those approved by the FDA." Demurrer at p. 7. Ms. Mize makes no such claim as she seeks to recover only under parallel claims.[3]

Mentor also seeks to place an evidentiary burden on Ms. Mize with regard to her claim of failure to report adverse events which does not exist under the law. Mentor improperly seeks to conflate the burden of proof applicable in federal court with the pleading burden at the demurrer stage in California courts. Mentor bases its entire argument on the claim that "[a]pplying *Coleman*, **federal courts** routinely dismiss claims where the plaintiff does not identify actual instances of unreported adverse events." (Demurrer at p. 9, bold added). The fact that a claim may not survive a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss under the heightened pleading requirements of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) does not govern whether that claim is sufficient under California pleading standards.

A demurrer tests the legal sufficiency of the complaint to determine whether the allegations state a legally cognizable cause of action and assumes the truth of the factual allegations pleaded. (*Siliga v. Mortgage Electronic Registration Systems, Inc.* (2013) 219 Cal.App.4th 75, 81.) The sole inquiry is "whether the complaint states a cause of action as a matter of law." (*McMahon v. Craig* (2009) 176 Cal.App.4th 1502, 1508–1509, 97 Cal.Rptr.3d 555.) The "complaint ordinarily is sufficient if it alleges ultimate rather than evidentiary facts" *Doe v. City of Los Angeles* (2007) 42 Cal.4th 531, 550, and allegation of "ultimate fact [] must be accepted as true for purposes of ruling on a demurrer." (*City of Industry v. City of Fillmore* (2011) 198 Cal.App.4th 191, 212.)

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[3] Mentor also asserts that it cannot be liable for violating a duty to revise its labeling through the Changes Being Effected ("CBE") procedure because "[t]hat procedure is permissive, not mandatory." (Demurrer at p. 8). Mentor cites no authority which supports this position and the California Supreme Court recently addressed this very question in discussing the duty of a brand-name drug manufacturer and ruled that the law allowed a manufacturer to unilaterally update a label, without waiting for FDA preapproval. *T.H. v. Novartis Pharmaceuticals Corp*,, (2017) 4 Cal.5th 145, 159, 407 P.3d 18226 Cal.Rptr.3d 336.

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In her TAC, Ms. Mize alleges that "Mentor failed to report adverse events from the studies it was required to conduct [and] had Mentor complied with its obligation to report this newly acquired information, [this] information [] would have been provided to the FDA and would have been available to Mize's treating physicians, who would have communicated that information to Mize. These allegations are sufficient at the demurrer stage.

Coleman's failure to warn claim based on Medtronic's failure to file adverse event reports with the FDA is not subject to express or implied preemption. Mentor inexplicably asserts that in *Coleman* the court mandated that "to prevail on failure-to-report claim, plaintiff must show that adverse events would have reached her doctor and prevented her injury." This assertion is incorrect and the actual holding in Coleman supports the claim made in the TAC that a claim based on the failure to file adverse event reports with the FDA is not subject to express or implied preemption. *Coleman* at 428.

While the *Coleman* court noted that the plaintiff would "ultimately" have to prove that a different warning would have reached the treating physician in time to prevent his injury, it found this was not the burden at the demurrer stage.[4] "However, at this stage of the proceedings, taking the allegations of the complaint as true, Coleman has alleged facts sufficient to state causes of action in strict liability and negligence based on Medtronic's failure to warn." *Coleman* at 429-30. The remainder of Mentor's arguments seeking to place burdens on Ms. Mize are equally flawed and she has alleged facts sufficient to present a claim for failure to warn.

C. Plaintiffs' Manufacturing Defect Claim is Sufficiently Pled

In its argument related to the claims for manufacturing defects, Mentor again ignores the binding decision in *Coleman* and instead seeks to rely on decisions from federal courts which are not controlling. Mentor does not appear to dispute that a claim of manufacturing defect would be a "parallel" claim which would not be subject to express or implied preemption. Instead it again focuses on the incorrect position that Ms. Mize has not alleged sufficient "facts" to support this claim. These arguments are unpersuasive, misstate the facts alleged and are contrary to the holding in *Coleman*.

[4] Mentor incorrectly asserts that "Plaintiff has acknowledged her pleading burden" by citing to a portion of the transcript from a prior hearing. Demurrer at p. 8. That discussion merely acknowledged the evidentiary burden which Ms. Mize will ultimately have to satisfy to prevail on this claim. That burden is inapplicable at the demurrer stage.

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As the court noted in *Coleman*, there is a significant "concern with the concept of dismissing a claim on preemption grounds without at least providing a plaintiff with some opportunity for discovery." *Coleman*, 223 Cal. App. 4th at 436 (citing *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation* (8th Cir. 2010) 623 F.3d 1200, 1205–06 and *Bausch v. Stryker Corp.* (7th Cir. 2010) 630 F.3d 546, 556–57. The *Coleman* court adopted the reasoning in *Bausch* "that claims of negligence and strict liability for a defective product can survive preemption based on general allegations that the company violated federal law." 223 Cal. App. 4th at 436.

The conclusion reached in *Coleman* clearly shows that Mentor's Demurrer is due to be denied. "In light of the reasoning in *Sprint Fidelis* and *Bausch* we conclude that it is premature to determine whether Coleman has alleged a state law requirement that is parallel to federal requirements so as to survive preemption. At the pleading stage, we can only conclude that the complaint alleges sufficient facts to state a cause of action for manufacturing defect, the issue of preemption will necessarily be addressed after Coleman has some opportunity to conduct discovery." 223 Cal. App. 4th at 436.

Mentor asserts that "manufacturers of investigational devices [] are exempt from compliance with virtually all current good manufacturing practice ("cGMP") requirements in the FDA's Quality System Regulation." Demurrer at p. 14. However, Mentor fails to advise the Court of the numerous requirements which did govern its conduct during the IDE process.[5]

To obtain IDE approval, a manufacturer must submit an application to FDA containing: (1) a complete report of prior device investigations; (2) a detailed description of the manufacturing procedures and quality controls used in device production; (3) copies of all device labeling; and (4) detailed information about the proposed clinical investigation including, an analysis of all risks involved" and "a full set of written procedures for monitoring the investigation, including record and report maintenance. 21 U.S.C. § 360j(g)(3); 21 C.F.R. §§ 812.20, 812.25, 812.27. Once the IDE application has been approved, the FDA prohibits any deviation from the investigational plan, design, manufacturing techniques, clinical protocol, warnings or consent form which could potentially affect clinical subjects

[5] Mentor cites to *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779 (1994), however that case is inapposite as it concerned intraocular lenses which are expressly exempted from federal misbranding requirements, registration requirements, performance standards, premarket approval requirements, record and reporting requirements and other federal requiremnents. (21 U.S.C. § 360j(g); 21 C.F.R. § 813.1).

unless the FDA first approves the change. See, *Robinson v. Endovascular Techs., Inc.*, 190 Cal. App. 4th 1490, 1494 (Cal. Ct. App. 2010) (citing 21 C.F.R. § 812.35).

As noted by the court in *Bausch,* courts "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law," and that as such, "formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." 630 F.3d 546, 558. This is particularly applicable to cases involving IDE products, as information regarding the manufacturing process which the applicant was required to follow is confidential and not publicly available.

The analysis set forth in *Killen v. Stryker Spine*, No. 11-1508, 2012 WL 4498865 (W.D. Penn. Sept. 28, 2012) ("Killen") is very instructive on this point. As that court reasoned, when ruling on a an argument similar to the one raised by Mentor in the present case, "it is disingenuous to identify the parallel claim exception to the Medical Device Act Amendments of 1976 ("MDA") exemption as articulated in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), but foreclose a plaintiff any opportunity to prove the exception." *Id.* at *3. The court quoted with approval from *Burgos v. Satiety*, No. 10–CV–2680, 2011 WL 1327684 (E.D.N.Y. Apr. 5, 2011)[6]: "[P]laintiffs alleging state-law parallel claims based on a violation of a manufacturer's agreement with the FDA often suffer from a unique disadvantage: **the agreements (including IDEs) that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA**. [A] plaintiff's pleading burden should be commensurate with the amount of information available to them. Other courts have similarly observed that it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury. See *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D.Ind.2009); see also *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir.2010)." (Bold added) Id. at *4. The *Killen* court concluded that because "Plaintiff advanced factual allegations that plausibly suggest the existence of parallel claims, **but does not have access to the confidential information to plead more specifically the alleged violation of FDA regulations**, the court concludes the pleading standards are satisfied." *Id.* at *3. (Bold added).

[6] Mentor acknowledges that the *Burgos* opinion is instructive and cites it at p. 5 of its Demurrer.

As the *Burgos* court noted, unlike PMA data which is a matter of public record, IDE documentation submitted to the FDA is confidential and not available to the public. *Id.* at *4. For that reason, the *Burgos* court found that the plaintiff had alleged facts as specifically as she could, without the benefit of the confidential IDE documentation, and allowed her claims to proceed. *Id.*

Mentor seeks to place an impossible burden on Ms. Mize by arguing that she must plead more specific facts to state a manufacturing claim, knowing that the information which it alleges Ms. Mize should have included is confidential and known only to Mentor and the FDA. Adopting the reasoning of Mentor would in insulate it from ever being subject to a claim related to the manufacturing process, as no plaintiff can allege facts based on information which is confidential.

Mentor is also incorrect in its assertion that references to cGMP are inappropriate in a case involving an IDE product. As noted by the court in *Killen*, a plaintiff may cite to cGMP's to "set forth a plausible claim of what [the IDE] requirements were [as] before discovery, she cannot determine what requirements the FDA actually imposed on defendant in the IDE approval process because that information is confidential." *Id.* at *1. As that court correctly reasoned: "claims, therefore, are not preempted to the extent that requirements imposed by the FDA [] during the IDE approval process were the same as the requirements imposed by the CGMPs." *Id.*

D. Plaintiffs' Negligence and Negligence Per Se Claims are Sufficiently Pled

In *Coleman*, the court held that the plaintiff had "alleged facts sufficient to state causes of action in [] negligence based on Medtronic's failure to warn." *Id.* at 431. In so ruling, the court cited with approval to the decision of the Ninth Circuit in *Stengel*.[7] The *Coleman* court reasoned that "California recognizes the applicability of negligence per se in a broad range of scenarios, including violation of federal law." *Id.* at 434. After analyzing California law on negligence per se, the *Coleman* court concluded that "Medtronic does not present a persuasive argument as to why a negligence claim resting on a theory of negligence per se would be subject to preemption. Because Coleman's negligence claim based on Medtronic's failure to file adverse event reports is cognizable under California law and is parallel to federal requirements, he may proceed on this theory." *Id.*

[7] The *Coleman* court acknowledged that *Stengel* was not binding on it, but found its reasoning to be very persuasive. *Id.* at 429-30.

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The court went further and held: "[w]e conclude that Coleman's negligence claim is not preempted. The claim is rooted in traditional state tort law and exists regardless of the FDCA and its regulations because the manufacturer of a medical device owes a duty of reasonable care to the consumer of such a device even in the absence of FDA regulations." *Id.* at 435.

E The Court Should Allow Amendment to Cure and Pleading Defect

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendant's Demurrer. However, if the Demurrer is sustained any of the causes of action, Plaintiffs request an opportunity to amend consistent with the facts stated here. If the Court believes that some elements of Plaintiffs' claim are inadequately pleaded, leave to amend should be granted so that any technical defect can be cured.

Respectfully submitted.

Dated: June 27, 2018

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By: _____
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