SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

DATE: 10/01/18			DEPT. SS12
HONORABLE CAROLYN B. KUHL	JUDGE	L. M'GREENE	DEPUTY CLERK
HONORABLE	JUDGE PRO TEM		ELECTRONIC RECORDING MONITOR
NONE	Deputy Sheriff	NOT REPORTED	Reporter

BC649083

REXINA MIZE ET AL
VS
MENTOR WORLDWIDE LLC ET AL

Plaintiff Counsel: NO APPEARANCES

Defendant Counsel:

R/T BC711663

NATURE OF PROCEEDINGS:

RULING ON SUBMITTED MATTER

Defendant Mentor Worldwide LLC's Demurrer to the Third Amended Complaint previously taken under submission on 9/21/18, the Court rules as follows:

Court's Ruling: The Demurrer is sustained without leave to amend.

The issue is whether Plaintiff Mize's Third Amended Complaint addresses the defects that this court held required it to sustain Mentor's Demurrer to the Second Amended Complaint. On review of the Third Amended Complaint, and comparison to the allegations of the Second Amended Complaint, Plaintiff has failed to avoid the defects previously identified in the court's ruling of March 12, 2018. Therefore the demurrer is sustained without leave to amend. Because the Plaintiff has had multiple opportunities to amend and there appears to be no asserted basis on which a subsequent amended complaint could overcome the fatal shortcomings of the current Third Amended Complaint, the court sustains the demurrer without leave to amend.

Plaintiff's Claims Based on Manufacturing Defect

As noted in the court's ruling on Mentor's Demurrer

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to the Second Amended Complaint, Plaintiff had her surgery in September 2000. Therefore, no defect in manufacturing subsequent to that date could have affected the device that was placed in her body. Plaintiff's Third Amended Complaint alleges the specifics of deficient and faulty manufacturing practices that preceded the filing of an action brought by the United States against Mentor in 1998, resulting in a Consent Decree of Permanent Injunction against Mentor filed in May 1998. The court takes judicial notice of this Consent Decree (Exhibit 7 to Defendant's Request for Judicial Notice). The Consent Decree required validation and subsequent inspection and testing of Mentor's manufacturing processes for silicone gel-filled breast implants. The Federal District Court for the Northern District of Texas retained jurisdiction to modify or grant additional relief. The Consent Decree provides that "[i]f defendants maintain a state of continuous compliance with the terms of this Decree for a period of sixty months from the date defendants satisfy all the requirements of . . . this Decree, should defendants petition the Court to dissolve this Decree, the government will not oppose." This court also takes judicial notice of the fact that the Federal District Court dissolved the consent decree on motion by Mentor in August 2003 (Exhibit 9 to Defendant's Request for Judicial Notice).

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The specific allegations of manufacturing defects cited in the Third Amended Complaint at paragraphs 53-56 are allegations that supported the claims of the United States in obtaining the 1998 Consent Decree. While the pleadings of which this court takes judicial notice pertaining to the litigation in the Northern District of Texas are not evidence that Mentor did not defectively manufacture silicone breast implants after 1998, the pleadings are evidence of a promised change of practices under government supervision beginning in 1998. Plaintiff does not allege that her breast implant was manufactured in or prior to 1998 even though Plaintiff alleges that she has the lot number of the device that was implanted in her in 2000. Furthermore, insofar as the device was manufactured after the 1998 Consent Decree, the Plaintiff alleges no facts (on the basis of information or belief or otherwise) as to why the device was defectively manufactured, what FDA requirement was violated or how the Consent Decree was violated.

The Third Amended Complaint details the requirement that Mentor submit to the FDA detailed information to obtain an Informational Device Exemption (IDE), but the Third Amended Complaint does not allege in what respect Mentor failed to comply with the IDE prior to Plaintiff's surgery or how such failure affected the manufacture of the device implanted in her. Moreover, a claim premised on failure to comply

NATURE OF PROCEEDINGS:

with the IDE would be impliedly preempted under Buckman Co. v. Plaintiffs' Legal Comm. (2001) 531 U.S. 341, because such claim would hinge entirely on conduct that allegedly violated federal law. (See Coleman v. Medtronic, Inc. (2014) 223 Cal.App.4th 413, 427.)

Under California procedural law, the requirements for specificity in pleading facts supporting a claim (other than fraud) are very low. However, where facts of which a court must take judicial notice appear to constrain or contradict a pleading, a plaintiff must explain how the complaint may succeed in the face of such facts. Plaintiff's complaint here fails to do so. Plaintiff fails to assert that the device implanted in Plaintiff was subject to manufacturing defects that preceded 1998 as detailed in the allegations (on which Plaintiff relies) supporting the Northern District of California litigation, or to explain what defect occurring or persisting after the FDA intervention evidenced by the Consent Decree affected the device that was placed in her body.

Plaintiff's Claims Based on Failure to Warn

As explained in this court's ruling sustaining the Demurrer to the Second Amended Complaint, no warning based on events occurring subsequent to the surgery which placed Mentor's device in Plaintiff's body in

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Defendant Counsel:

R/T BC711663

NATURE OF PROCEEDINGS:

2000 could have caused her to refrain from deciding to have that surgery. Plaintiff now has alleged, however, that if Mentor had reported additional adverse incidents subsequent to 2000, and if the FDA had the made such incidents public, and if Plaintiff's doctors had been aware of such reports, Plaintiff's doctors might have provided an earlier diagnosis leading to earlier surgery to remove the implants and Plaintiff's damages from the implanted devices might have been lessened .

The problem with this causal chain, however, is that it is premised on Mentor's failure to report adverse incidents that were not detected because of how Mentor conducted the studies rather than on a failure to report adverse incidents that actually occurred. (See Third Amended Complaint paragraphs 78-95.) Because Plaintiff has failed to allege facts showing that Mentor failed to report actual adverse events that in fact occurred, the failure to warn (failure to report adverse events) claim is preempted because Plaintiff has failed to allege how Mentor's actions in conducting these studies violated federal law. In this regard, the court adopts the reasoning of Ebrahimi v. Mentor Worldwide LLC (C.C.Cal. Sept. 15, 2017, No. CV 16-7316-DMG) 2017 U.S.Dist.LEXIS 153840 (Gee, J.).

Claim for Loss of Consortium

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BC649083	Plaintiff Counsel	NO APPEARANCES
REXINA MIZE ET AL VS MENTOR WORLDWIDE LLC ET AL	Defendant Counsel	
R/T BC711663		

NATURE OF PROCEEDINGS:

Because Plaintiff Mize's claims have failed, the claims of her husband for loss of consortium also fails.

The Court sets a Further Status Conference on December 4, 2018 at 11:00 a.m. in Department 12.

The Clerk will provide notice via Case Anywhere.

CERTIFICATE OF ELECTRONIC SERVICE
CODE OF CIVIL PROCEDURE 1010.6

I, the below named Executive Officer/Clerk of the above entitled court, do hereby certify that I am not a party to the cause herein, and that on this date I served one copy of the 10/2/18 Minute Order entered herein, on 10/2/18, upon each party or counsel of record in the above entitled action, by electronically serving the document on Case Anywhere at www.caseanywhere.com on 10/2/18 from my place of business, Spring Street Courthouse, 312 North Spring Street, Los Angeles, California 90012 in accordance with standard court practices.

Dated: October 2, 2018

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Plaintiff Counsel: NO APPEARANCES

Defendant Counsel:

NATURE OF PROCEEDINGS:

Sherri R. Carter, Executive Officer/Clerk

By: _____, Deputy Clerk
L. M'Greene

MINUTES ENTERED
10/01/18
COUNTY CLERK