Grant & Eisenhofer P.A.
Attn: Graham, M. Elizabeth
123 Justison St.
Wilmington, DE 19801____

Sidley &Austin LLP
Attn: Degen, Alycia A
555 West Fifth Street
Suite 4000
Los Angeles, CA 90013-1010

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

ESSURE PRODUCT CASES	No. JCCP004887
	Order
	Demurrer and Motion to Strike Complaint
(Abbreviated Title)	

The Demurrer and Motion to Strike Complaint filed for Bayer HealthCare Pharmaceuticals Inc. and Bayer Essure Inc. and Bayer HealthCare LLC and Bayer Corporation was set for hearing on 03/28/2018 at 09:00 AM in Department 21 before the Honorable Winifred Y. Smith. The Tentative Ruling was published and was contested.

The matter was argued and submitted, and good cause appearing therefore,

IT IS HEREBY ORDERED THAT:

The Demurrer of defendants Bayer Corp., et al. ("Defendants") To The Second Amended Complaint of plaintiffs Yolanda Birruete and Bernardino Birruete-Rubio ("Plaintiffs"), and the Motion of Defendants To Strike Portions of the Second Amended Complaint, are ruled on as follows:

BACKGROUND:

In the wake of rulings regarding the sufficiency of earlier versions of complaints filed by these and other plaintiffs, specifically, the August 2, 2016 order entered prior to coordination in eleven cases, identified by the parties as "Lance v. Bayer Corp, RG16809860, slip op. (Cal. Super. Ct. Aug. 2, 2016)" (hereafter, "Order On Preemption Demurrer"), and the April 2, 2017 Order On Demurrer and Motion To Strike directed to the Second Amended Complaint of plaintiff Sarah Journey (hereafter, "Journey Order"), Plaintiffs filed their Second Amended Complaint on October 31, 2017 (SAC). The SAC includes 8 causes of action, 1) Negligence, 2) Strict Product Liability, 3) Breach of Express Warranty, 4) Breach of Implied Warranty, 5) Fraud/Intentional Misrepresentation, 6) Negligent Misrepresentation, 7) Concealment, and 8) Loss of Consortium.

DEMURRER:

Defendants now demur to the 1st and 2nd causes of action in the SAC "to the extent [they] allege[] Essure was manufactured defectively." Defendants argue that the manufacturing defect claims were clearly addressed and dismissed in both the Order On Preemption Demurrer and the Journey Order. For their part, Plaintiffs assert in their opposition that they are not intending to pursue a manufacturing defect claim, but that they have included allegations regarding manufacturing problems with Essure "to bolster and support [their] failure to warn and misrepresentation claims..." Plaintiffs argue that this is consistent with the Journey Order, in which the court permitted some factual allegations to remain in the Journey SAC "to provide background." What Plaintiffs fail to acknowledge, however, is that the court also expressly struck multiple paragraphs of the Journey SAC, some of which appear in either identical or substantially similar form in the Birruete SAC. Accordingly, Defendants are entitled to an order that clarifies that no non-preempted manufacturing defect claim is properly stated. The specific

allegations that do not belong in the SAC at all will be addressed in the context of Defendants' companion Motion To Strike, later in this order.

Defendants also demur to the 1st cause of action "to the extent it alleges failure to conduct adequate post-market surveillance." Here, Defendant argues that Plaintiff has only recently began to assert that this negligence theory has always been part of the case, and that the Order On Preemption Demurrer did not apply to this theory. In Defendants' view, these assertions are incorrect. The Order On Preemption Demurrer (at page 8) expressly recognized that Defendants' preemption arguments were directed to "all of the claims against them," which was clear from Defendants' opening papers and emphasized in their reply at the time. The court agrees. Plaintiff's opposition argument that Defendants' previous demurrer challenged only a limited universe of Plaintiff's claims is not well taken.

Defendant also argues that even if the previous ruling regarding preemption did not apply to this negligence theory, such a claim is preempted, inadequately pled, or both. The SAC does not include allegations that explain how the supposed failures to conduct adequate post-market surveillance caused Plaintiff's injuries. All of the discernible potential theories of causation, i.e., that the inadequate post-market surveillance led to the defective manufacturing of Plaintiff's device, that it led to inadequate warnings being given directly to Plaintiff or her physician, or that it led to Defendants' failure to report adverse information to the FDA, are inadequately pled and preempted.

Recognizing that some of the same allegations in the SAC may apply to Plaintiff's surviving failure to warn claims, Defendants clarify that they are only demurring to "any claim for alleged negligent 'post-market surveillance,' separate and apart from a claim of failure to report adverse events to FDA," i.e., a "stand-alone" negligence post-market surveillance claim.

Notably absent from Plaintiff's opposition is any citation to California decisional authority in which any negligence theory apart from negligent failure to warn based on failure to file adverse event reports with the FDA, as recognized in Coleman v. Medtronic, Inc. (2014) 223 Cal.App.4th 413, 429 ("Coleman"), has survived the preemption analysis. Rather, Plaintiff relies almost entirely on the treatment of a "negligent risk management" cause of action by the court in McLaughin v. Bayer Corp., 2017 WL 697047 ("McLaughlin II"), applying Pennsylvania law. The plaintiffs in McLaughlin II, however, were advancing different theories of causation, and only the theory that Bayer's failure to evaluate and investigate complaints resulted in its failure to report adverse events escaped preemption, based on the alleged breaches of a small subset of the regulations upon which Plaintiff relies, 21 CFR 803.1, 820.198(a)-(c), 803.50(a), (b)(iii), and 803.50(b)(3). (Id, at *6.) Plaintiff here is attempting to cast a far broader net, effectively arguing that all post-market requirements that are reflected in multiple regulations are "inextricably intertwined" with adverse event reporting, and are "integral parts of a cohesive whole."

Plaintiff's arguments are not well taken. The court agrees with Defendants that Plaintiff has not shown and cannot show that a post-market surveillance claim distinct from the claim for failure to report adverse events is parallel to federal law. There is no parallel federal requirement to report on "post market surveillance," and the theory that Defendants should have changed labeling based on post-market surveillance is preempted because there is no federal requirement for a manufacturer to change FDA approved labeling. Accordingly, claims based on allegations of non-compliance with federal regulations that do not have any direct relation to reporting of adverse events to the FDA are preempted. The court also agrees with Defendants that, to the extent any such claims could possibly escape preemption, Plaintiff's factual allegations do not show a cognizable causal link between the alleged failures to comply with a host of post-market regulations and Plaintiff's injuries.

Finally, Defendants' demurrer to the eighth cause of action for loss of consortium, to the extent it alleges loss of consortium predicated on manufacturing defect or post-market surveillance claims, is also well taken.

RULING:

Defendants' demurrer to the 1st and 2nd causes of action to the extent that they allege that Essure was manufactured defectively is SUSTAINED without leave to amend.

Defendants' demurrer to the 1st cause of action to the extent is seeks to state a claim for "negligent post-market surveillance" that is separate and apart from a claim of failure to report adverse events to FDA

is SUSTAINED without leave to amend.

Defendants' demurrer to the 8th cause of action to the extent it alleges loss of consortium predicated on manufacturing defect or post-market surveillance claims is SUSTAINED without leave to amend.

MOTION TO STRIKE:

Defendant also seeks to strike specific phrases and paragraphs in the SAC, as set forth in it separate Motion To Strike ("MTS").

The MTS is GRANTED in part, as follows:

Paragraph 42 - the words "manufacture" and "development" are stricken from the first sentence, and the second sentence is stricken in its entirety.

Paragraphs 43-50 are stricken in their entirety. As argued by Defendants, these paragraphs are essentially the same as those stricken from the Journey SAC, notwithstanding that the heading of the section was changed in the Birruete SAC.

Paragraph 191 - the words "development" and "manufacture" are stricken, and subparagraphs (b), (e) and (f) are stricken.

Paragraphs 206-208 are stricken in their entirety.

Paragraph 185 - references to 21 CFR sections 806; 814.1; 814.3; 814.9; 814.20; 814.37; 814.39; 820.5; 820.20; 820.22; 820.25; 820.30; 820.70; and 820.160 are stricken.

Paragraph 186 is stricken in its entirety.

The court agrees with Defendants that the stricken regulations and sections of the Health & Safety Code have no discernible relevance to Plaintiff's claims, and/or only relate to claims for manufacturing defects or direct failure to warn claims.

The MTS is otherwise DENIED.

Dated: 03/28/2018

Facsimile

Judge Winifred Y. Smith

SHORT TITLE:	CASE NUMBER:
ESSURE PRODUCT CASES	JCCP004887

ADDITIONAL ADDRESSEES

Girard Gibbs LLP
Attn: Gibbs, Eric H.
601 California St., Ste. 1400
San Francisco, CA 94108

-- Third Party --
Yuhl Carr LLP
Attn: Yuhl, Christopher P.
4676 Admiralty Way
Suite 550
Marina del Rey, CA 90292

Girard Gibbs & De Bartolomeo
Attn: DeBartolomeo, A. J.
601 California Street, Suite 1400
San Francisco, CA 94108