SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

LANCE; MIGLIACCIO; BIANCHI; BROWN; BIRRUETE; HYDE & KELLER; JOURNEY, THOMAS & MELGAR; MATTERN; PARADES & MORENO; RIPPERGER; WEBB, Plaintiffs, v. Bayer Essure Inc., Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals, Inc. Defendants.	Case No. RG16809860; RG16809292; RG16813262; RG16813616; RG16809875; RG16812313; RG16810409; RG16809878; RG16804887; RG16804878; RG16809876. ORDER ON PREEMPTION DEMURRER

The Demurrer of Defendants Bayer Essure Inc., Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals, Inc. ("Defendants") on the basis of preemption ("Preemption Demurrer") came on regularly for hearing on July 29, 2016 in Department 21 of this Court, the Honorable Winifred Y. Smith,

presiding. Appearances are reflected in the attendance sheet filed on the date of the hearing.

After full consideration of the moving papers, the opposition thereto, the authorities cited by the parties, as well as arguments presented at the hearing, and the matter having been submitted for decision, and good cause appearing,

IT IS HEREBY ORDERED as follows:

PROCEDURAL BACKGROUND:

Currently before the court are eleven lawsuits against Defendants arising from the use by the plaintiffs of a medical permanent birth control device manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendant called "Essure." Represented in these eleven suits are fourteen women in whom the device was implanted, and six spouses with loss of consortium claims.

Of the eleven suits, four (RG16809860, Lance v. [Defendants]; RG16809292, Migliaccio v. [Defendant]; RG16813262, Bianchi v. [Defendants]; and RG16813616, Brown v. [Defendants]) utilized complaints that are virtually identical to one another, except for the section entitled "Plaintiff's History" (hereafter, "Lance Complaint"). Similarly, the other seven cases (RG16809875, Birruete v. [Defendants]; RG16812313, Hyde & Keller v. [Defendants]; RG16810409, Journey, Thomas & Melgar v. [Defendants]; RG16809878, Mattern

v. [Defendants]; RG16804887, Parades & Moreno v. [Defendants]; RG16804878, Ripperger v. [Defendants]; and RG16809876, Webb v. [Defendants]) utilize complaints that are virtually identical to one another, again with the exception of the section entitled "Plaintiff's History" ("Birruete Complaint").

The Lance Complaint includes causes of action for (1) Negligent Failure to Warn, (2) Negligence, (3) Strict Products Liability, and (4) Fraud. The Negligence cause of action includes alleged breaches of some eight different duties, "(a) manufacturing actual Essure devices that differ from the specifications set forth in the CPMA, its Supplements, the Conditions of Approval and/or other federal regulations; (b) failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products; (c) failing to conduct regular risk analysis of its Essure device, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes and failing to exercise appropriate post-market quality controls; (d) failing to provide the FDA with timely post-approval reports for its six-month, one-year, eighteen-month, and two-year report schedules; (e) failing to comply with applicable federal and state regulations; (f) failing to adequately train Defendants' employees who provide recommendations and advice to physicians who implanted the device; (g) making false, inaccurate and misleading statements concerning the properties and effects of the Essure device; and (h) failing to properly train and educate physicians on the use of the

Essure device. (Lance Complaint, paragraph 111.) The Strict Products Liability cause of action asserts that Essure was defective both because "it did not adequately warn of risks involved in its use" and because "the system differed from Defendants' intended result and design specifications." (Lance Complaint, paragraph 120.)

The Birruete Complaint includes causes of action for (1) Negligent Failure to Warn, (2) Strict Products Liability - Inadequate Warnings; (3) Negligence / Negligence Per Se, (4) Breach of Express Warranty, (5) Negligent Misrepresentation, and (6) Fraud. The Negligence / Negligence Per Se cause of action alleges violations of some twenty sections of the Code of Federal Regulations ("CFR") and some eight violations of California state law, "(a) manufacturing actual Essure devices that differ from the specifications set forth in the CPMA, its Supplements, the Conditions of Approval and/or other federal regulations; (b) failing to conduct regular risk analysis of its Essure device, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes; (c) in failing to properly meet the applicable standard of care by not complying with applicable federal regulations; (d) carelessly and negligently selling and distributing Essure in violation of the CPMA and federal law; (e) negligently incorporating components into Essure that could not stand up to normal usage; (f) failing to exercise reasonable care in its inspecting and testing of the product; (g) failing to exercise

reasonable care in its manufacturing and quality control processes; and (h) failing to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device." (Birreute Complaint, paragraph 174.) Four of the Birruete Complaints also include a cause of action for Loss of Consortium.

By agreement of the parties, Defendants' challenges to the pleadings in these eleven cases have been coordinated.

PREEMPTION LAW:

The Medical Device Amendment ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. section 360k(a)) prohibits the application of state requirements "different from, or in addition to" those imposed by the FDCA. The basic parameters of this "express preemption" are set forth in *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312 ("*Riegel*"). The Food and Drug Administration's ("FDA's") Premarket Approval ("PMA") process constitutes specific federal requirements for purposes of preemption, and reference to a State's "requirements" includes its common law duties (*id*, at 323-324). The concept of implied preemption is set forth in *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341 ("*Buckman*").

Important to the line of authorities on preemption in the medical device arena was the Ninth Circuit Court of Appeals' January 10, 2013 en banc decision in *Stengel v. Medtronic Inc.* (9th Cir. 2013) 704 F.3d 1224 ("*Stengel III*") in which

the court found that the state law negligence claims in that case for failure to warn were not preempted by federal law. The cause of action at issue in *Stengel III* was based on the general duty of reasonable care imposed on product manufacturers under Arizona tort law, specifically "negligence standards [that] impose a duty to produce products with appropriate warning labels" (*Stengel III*, at 1233), and included specific allegations of failure to warn the FDA of adverse events. In concluding that the state law claim was "parallel" to the federal requirements, the *Stengel III* court pointed out that "under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is 'reasonable assurance that the information will reach those whose safety depends on their having it.'" (*Stengel III*, at 1233 [citations omitted].)

The most applicable California state authority on MDA preemption is *Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413 ("*Coleman*"). The *Coleman* court includes a general discussion of the regulation of Class III medical devices, of which Essure is one, including the "rigorous regime of premarket approval" that was found by the *Riegel* court to qualify as imposing "requirements" upon a device that trigger the application of 21 U.S.C. section 360k(a), and lays out its overall views of both express preemption and implied preemption before engaging in a claim by claim analysis. Its discussion of express preemption focuses on the concept of "parallel" claims, a term originating in

Medtronic v. Lohr (1996) 518 U.S. 470 ("*Lohr*") and quoted in *Riegel*, and includes the conclusion that in order to be "parallel" to a federal requirement a state requirement must be "genuinely equivalent" citing the Eleventh Circuit decision in *Wolicki-Gables v. Arrow International, Inc.* (11th Cir. 2011) 634 F.3d 1296, 1300 ("*Wolicki-Gables*"), quoting the Seventh Circuit decision in *McMullen v. Medtronic, Inc.* (7th Cir. 2005) 421 F.3d 482, 489 ("*McMullen*"), in support of this conclusion. (*Coleman*, at 424.) The *Coleman* court's discussion of implied preemption, of course, centers on *Buckman* and includes examples of different interpretations of *Buckman* in decisions by other courts, ultimately finding the narrow interpretation employed in *Stengel III* and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) ("*Hughes*"), as well as in *Bausch v. Stryker Corp.*, 630 F.3d 546, 556-557 (7th Cir. 2010) ("*Bausch*"), to be most persuasive. (*Coleman*, at 426-427.)

The *Coleman* court's discussion of the parameters of MDA preemption culminates in a statement of what it takes to state a state law claim that avoids both express and implied preemption: "a plaintiff 'must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by section 360k(a)); but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)' [citing *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("*Sprint Fidelis*"), quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769,

777 (D.Minn. 2009) ("*Riley*")] ... [or] a state law cause of action 'must be premised on conduct that both (1) violates the FDCA and (2) would give rise to recovery under state law even in the absence of the FDCA.' [citing *Riley*, at 777].)" (*Coleman*, at 427.) The court notes that *Riley* is oft cited in federal court decisions for its discussion of the interplay between express preemption and implied preemption, especially the highly quotable line that immediately precedes the quotations in *Coleman*: "[i]n sum, *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption."

PREEMPTION DEMURRER - Summary of Defendants' Arguments:

Defendants demur to all of the claims against them on the basis that they are expressly preempted by the MDA, impliedly preempted by the MDA, or both. Defendants assert that the Food and Drug Administration ("FDA") issued a Premarket Approval Order ("PMA") for Essure in 2002 and has granted numerous supplemental approvals. Those approvals were in effect at the time of all of the plaintiffs' procedures, and remain in effect today.

In support of the Preemption Demurrer, Defendants rely heavily on orders issued by federal trial courts in two other cases involving Essure, *McLaughlin v. Bayer Corporation*, 2016 WL 1161578 (E.D. Penn.) ("*McLaughlin*") and *De La Paz v. Bayer Healthcare LLC*, 2016 WL 392972 (N.D. Cal.) ("*De La Paz*"), urging this court to rule in a similar fashion.

SUMMARY OF DEFENDANTS' PREEMPTION ARGUMENTS:

For purposes of the preemption analysis, Defendants group the claims in both complaints as (A) claims based on alleged misrepresentations and warranties, (B) claims based on an alleged failure to train physicians, (C) claims based on alleged manufacturing defects, and (D) claims based on an alleged failure to warn.

A) - As to each of the so-called "misrepresentations" alleged in both complaints, Defendant argues that the FDA-approved language in Essure's labeling is "virtually identical." Accordingly, the claims for negligent misrepresentation and breach of warranty are expressly preempted.

B) - Defendants argue that the claims for failure to train physicians are expressly preempted because Plaintiffs fail to allege where the training provided by Defendants deviated from what the FDA required, or any facts tying Defendants' negligence to the physicians' implantation of the device.

C) - Defendants argue that the manufacturing defect claims are expressly preempted because Plaintiffs fail to allege that a deviation from Essure's FDA-approved manufacturing process resulted in a defect in their respective devices that caused their individual injuries; and a claim based solely on Defendants' alleged failure to follow various manufacturing regulations would exist solely by virtue of the MDA, and would thus be impliedly preempted.

D) As to failure to warn, Defendants argue that to the extent the claims are based on the theory that Defendants should have given warnings different from

those approved by the FDA, they are expressly preempted, and Plaintiffs' allegations that Defendants could have unilaterally provided additional warning through the "Changes Being Effective" ("CBE") process do not save their claims, because 21 CFR 814.39(d) permits, but does not require, interim supplemental warnings. Thus, any state law claim that does require such interim supplemental warnings is preempted because it is "in addition to" the federal requirement.

To the extent the failure to warn claims are based on alleged failures to timely file MDR's and to report complaints to the FDA, Defendant argues that they are impliedly preempted under *Buckman* because Plaintiffs have failed to allege facts plausibly demonstrating a causal nexus between those alleged failures and their individual injuries. Defendants further argue that the allegations in the complaints themselves show that the FDA is now in possession of all of the supposedly withheld information, and it has never withdrawn, revoked or suspended its approval of Essure, and that the FDA's recently proposed "boxed warning" contains materially similar warnings to those Defendants already provided to prescribing physicians at the time of Plaintiffs' procedures.

Defendants separately argue that all of Plaintiffs' claims should be dismissed because they fail to adequately plead causation. Plaintiffs fail to identify how they would have learned of adverse events had Defendants reported them prior to their respective procedures, and Defendants assert that even after Defendants provided all of the allegedly withheld information to the FDA, the

FDA chose not to alter the disclosures "to the ultimate users" regarding the percentage of patients who may be injured, the number of adverse events, or the rate of unintended pregnancies. Defendants further argue that Plaintiffs' allegations regarding affirmative misrepresentations, failure to implement an effective physician training program, and violations of federal manufacturing requirements are not coupled with facts that plausibly link those allegations with their injuries.

Finally, Defendants argue that to the extent Plaintiffs' failure-to-train claims are based on the alleged failure "to adequately train implantation physicians in hysteroscopy" they have not alleged facts showing the existence of such a duty.

SUMMARY OF OPPOSITION ARGUMENTS:

Leading off their opposition with their strongest claim, Plaintiffs argue that their failure to warn claims are neither expressly nor impliedly preempted, as there is no conflict between these claims and federal requirements.

Failure to warn FDA -

Plaintiffs assert that Defendants violated numerous federal reporting obligations by failing to notify the FDA of over 32,000 complaints it had received between January 2008 and May 2013, including numerous reportable adverse events, and they did not take steps to add to or strengthen the warnings in the approved Instructions for Use ("IFU") or Patient Information Booklet ("PIB"), even though they could have done so without prior FDA approval through a CBE supplement. The FDA's Draft Guidance and proposed boxed warning and patient

decision checklist make clear that the agency views the current warning accompanying Essure as inadequate.

Plaintiffs further assert that Defendants' argument that Plaintiffs have failed to plead a "causal nexus" between the alleged failures to report adverse events and their individual injuries are not supported by *Coleman*, and that they have adequately alleged causation under state pleading standards.

Plaintiffs further argue that there are considerable differences, in both form and substance, between the FDA's proposed boxed warning and the warnings already provided, and that Defendants' attempt to blame the FDA for not requiring certain labeling changes misrepresents the assignment of responsibility for adequate labeling under the FDCA. (Citing *Wyeth v. Levine*, 555 U.S. 555, 570-571.) Under both federal and state law, the responsibility for the content of the labels is born by the manufacturer, not the FDA.

Failure to warn doctors and patients -

Plaintiffs argue that a state law duty to update warnings in response to new safety information would not be "different from, or in addition to" federal requirements, because federal law itself requires medical devices to carry adequate warnings. 21 U.S.C. section 352(f)(2) provides that a device is misbranded unless its label bears adequate warnings, and 21 U.S.C. section 331 prohibits sale of misbranded devices. Plaintiff further argues that express preemption under the MDA only exists where FDA has established device-specific federal requirements.

(Citing Brief for U.S. as Amicus Curiae, Medtronics, Inc. v. Stengel, No. 12-1351, 2014 WL 2111719, at 8-9 ["Stengel Amicus Brief"].)

Fraud, misrepresentation and warranty -

Plaintiffs argue that their fraud, misrepresentation and warranty claims are not preempted because (a) the PMA does not establish any device-specific requirements as to product warranties (relying again on the Stengel Amicus Brief) and express warranties are not state requirements, but rather contractual commitments voluntarily undertaken by the warrantor; and (b) because the alleged misrepresentations are not "virtually identical" to language approved by the FDA.

Manufacturing defect -

Plaintiffs argue that their manufacturing defect claims are parallel claims that escape preemption since they are premised on the assertion that the medical device at issue did not conform to the design requirements of the CPMA or FDA manufacturing regulations. For preemption purposes, it is sufficient for Plaintiffs to allege that these manufacturing violations were the proximate cause of their injuries.

Failure to train physicians -

Plaintiffs assert that their allegations that Defendants negligently trained their implanting physicians in violation of both the training requirements imposed as part of the CPMA approval and Defendants' duty of care under state law are sufficient, for pleading purposes.

Plaintiffs further assert that they have adequately pled causation. They allege that the FDA publishes all adverse event reports in a searchable Internet database ("MAUDE") that physicians and the general public can use, and that if Defendants had fulfilled their duty to report adverse events in a timely fashion, the FDA would have issued its draft guidance before Plaintiffs and their physicians made the decision to use Essure.

Finally, Plaintiffs argue that they have adequately pled Defendants' duty to train physicians, as they allege that Defendants undertook to train physicians in the use of the Essure device, including the hysteroscope required for implantation.

DISCUSSION:

Failure to Warn -

Although they are not presented as separate causes of action in either complaint, Plaintiffs' failure to warn claims fall into two distinct categories. First is Plaintiffs' claim of Defendants' failure to warn the FDA. The essence of Defendants' arguments regarding this claim is well-captured in footnote 16 of their opening Memorandum of Points and Authorities, wherein Defendants submit that "*Coleman* and *Stengel* are wrongly decided." The court disagrees.

Citing *Stengel III*, at 1233 and *Hughes*, at 771, the *Coleman* court concluded that to the extent Coleman's claims for failure to warn were based on Medtronic's failure to file adverse event reports with the FDA, they were not subject to express or implied preemption. (*Coleman*, at 429.) For purposes of this

portion of its ruling, the *Coleman* court concluded that there was no reason to treat strict liability failure to warn under California law any differently from the negligence claim under Arizona law at issue in *Stengel III*, and that California law, like Arizona law, recognizes a duty to convey warnings through a third party (such as the FDA) where that is the only available method to warn doctors and consumers. (Ibid, citing, e.g., *Persons v. Salomon North America, Inc.* (1990) 217 Cal.App.3d 168, 178.)

To the extent that Plaintiffs' failure to warn claims, whether pled in negligence or in strict liability, are based on the allegations of Defendants' failures to comply with its reporting obligation to the FDA, they are factually indistinguishable from the claims asserted in *Coleman*. Accordingly, these claims are neither expressly nor impliedly preempted. Furthermore, while both the *Coleman* court and the *Stengel* court acknowledged that the plaintiffs in each of those cases would face a "causation hurdle" in proving their case (*Coleman*, at 429 and *Stengel III* at 1235) neither court used the term "causation hurdle" in connection with the articulation of a pleading requirement, and both found the allegations in the complaints at issue in those cases sufficient for pleading purposes. The court arrives at the same conclusion here.

Second is Plaintiffs' claim of failure to warn doctors and patients directly, which claim does not fall within the authority of *Stengel* and *Coleman*. Indeed, as the *Stengel* concurrence pointed out, "any attempt to predicate the Stengels' claim

on an alleged state law duty to warn doctors directly would have been expressly preempted under 21 U.S.C. section 360k, which forbids state-imposed requirements that are 'different from, or in addition to' the requirements imposed by federal law. [citations]" The court is not persuaded by Plaintiffs' attempt to characterize Defendants' alleged failures to update their labeling as "parallel" to a violation of 21 U.S.C. section 352(f)(2), or by their reliance on the Stengel Amicus Brief for the proposition that this claim would have no preemptive effect. (See, e.g., *McLaughlin*, at *4, fn.5.) The court finds that to the extent Plaintiffs' state law claims for failure to warn are based on the theory that Defendants should have given warnings directly to doctors and patients different from those approved by the FDA, they are expressly preempted. (*Coleman*, at 427-428.)

Fraud and Breach of Warranty -

There is no dispute that the claims for breach of warranty, which are only found in the Birruete Complaint, the claims for fraud, found in both complaints, and the claims for negligent misrepresentation, also found in both (a part of the negligence cause of action in the Lance Complaint), are all based on the same factual allegations of specific statements allegedly made by Defendants in advertising materials. Following the model suggested by the court in *McLaughlin* (*McLaughlin*, at *15, fn.20), Defendants have presented the alleged misrepresentations and approved labeling statements in chart form and ask that the court evaluate the similarity between the two and render findings as to all. The

court notes that the *McLaughlin* court concluded that the breach of warranty claims in that case were not preempted because they did not arise from state requirements (*McLaughlin*, at *11), and "that Plaintiffs can potentially allege cognizable and parallel misrepresentation claims at least insofar as they allege that Bayer made false or misleading statements in unapproved advertising or other promotional materials that were inconsistent with specific statements in approved FDA materials that undermined the approval and required statements in those materials" (*id*, at *15). It dismissed the breach of warranty and fraud claims under the federal pleading standards, which are inconsistent with California pleading standards, and allowed the negligent misrepresentation claims to go forward. (*McLaughlin*, at *17.)

As noted above in connection with failure to warn claims, the court rejects Plaintiffs' reliance on the Stengel Amicus Brief. These claims will not escape preemption solely on the basis that they do not implicate any preemptive device-specific federal requirements. The court also recognizes that Plaintiffs' ultimate success in avoiding preemption for breach of warranty will rest on findings that the challenged contractual commitments are different from the FDA-approved statements (*Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 797 ["*Kanter*"]), as will their success on all of their misrepresentation claims. The court concludes, however, that the exercise of comparing and contrasting the language of the alleged misrepresentations with the language of the FDA approved materials

is not appropriate in the context of a demurrer. The court notes in this regard that *Kanter* arose in the context of a summary judgment motion.

Manufacturing Defect -

Plaintiffs' opposition arguments with respect to their manufacturing defect claims miss the primary point of Defendants' challenge. While it is accurate to state, as this court did in its April 20, 2016 order in *Price v. St. Jude Medical, et al.* (RG15765815, "*Price*"), that a manufacturing defect cause of action that parallels the federal requirements in a PMA, thereby escaping preemption, may be based on allegations that the medical device failed to comply with the specific processes and procedures that were approved by the FDA (*Coleman*, at 435), Defendants correctly argue here that neither the Lance Complaint nor the Birruete Complaint include allegations of a specific defect in Essure devices generally, let alone in the Essure device that was implanted in each of the named Plaintiffs, attributable to any of the design or manufacturing processes that Defendants are alleged to have failed to comply with. Plaintiffs' claims in this case are distinguishable from the claims in *Price* and the claims in the cases upon which *Price* relied (e.g., *Coleman*). And while the *McLaughlin* court declined to hold that the manufacturing defect claims in that case were expressly preempted, it dismissed those claims because of the lack of allegations that a defectively manufactured product was implanted in any of the plaintiffs or that any alleged manufacturing defect actually caused any of the Plaintiffs' injuries. (*McLaughlin*, at *23.)

Notwithstanding that this court is not bound by *McLaughlin* or the federal pleading standard in play in that case, it concludes that Plaintiffs have failed to adequately allege facts that state a state law cause of action for negligent or strict liability product defect.

Negligent Training of Physicians -

Similarly, although the court agrees with the concept that a claim that escapes preemption could be based on allegations that Defendants failed to comply with training requirements included in the PMA (e.g., *McLaughlin*, at *6), Plaintiffs fail to counter Defendants' other primary argument that neither of the complaints include any factual allegations that tie the alleged negligent training to their injuries. Notably, none of the Plaintiffs allege that the doctors who performed the implantation procedures made any mistakes in doing so, let alone that any such mistakes could be attributed to negligent training or a lack of training. Accordingly, a state law cause of action is not stated.

RULING:

Defendant's Demurrer is OVERRULED as to all of Plaintiffs' claims for failure to warn, whether framed in negligence or strict liability. These claims are not preempted, and Plaintiffs' causation allegations are sufficient, for pleading purposes.

Defendants' Demurrer to Plaintiffs' claims for breach of express warranty, fraud and negligent misrepresentation are OVERRULED. To the extent that these

claims are based on statements in promotional materials that were inconsistent with specific statements in approved FDA materials, they are not preempted, and the evaluation of such inconsistency will not be done in this context.

Defendants' Demurrer to Plaintiffs' claims for manufacturing defect, whether framed in negligence or strict liability, is SUSTAINED. While the court recognizes that such claims are not necessarily preempted, Plaintiffs' factual allegations are insufficient to state a cause of action. Leave to amend is GRANTED.

Defendants' Demurrer to Plaintiffs' claims for Negligent Training of Physicians is SUSTAINED. While the court recognizes that such claims are not necessarily preempted, Plaintiffs' factual allegations are insufficient to state a cause of action. Leave to amend is GRANTED.

Defendants' Demurrers to the derivative Loss of Consortium causes of action are OVERRULED.

The parties' respective unopposed requests for judicial notice are GRANTED.

Any amended complaints pursuant to leave granted herein must be filed and served no later than August 15, 2016. Responsive pleadings thereto must be filed and served within the statutory time after service thereof.

August 4, 2016
Date

Winifred Y. Smith
Judge of the Superior Court

Superior Court of California, County of Alameda
Department 21, Administration Building

Case Number: RG16809860, RG16809292, RG16813262, RG16813616, RG16809875, RG16812313, RG16810409, RG16809878, RG16804887, RG16804878, RG16809876

Case Name: Lance VS Bayer Corp., an Indian Corporation

RE: ORDER ON PREEMPTION DEMURRER

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown at the bottom of this document, and that the mailing of the foregoing and execution of this certificate occurred at 1221 Oak Street, Oakland, California.

Executed on August 2, 2016

Executive Officer/Clerk of the Superior Court

By *Christopher Wright*
Deputy Clerk

Motley Rice LLC
Breanne V. Cope
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

Sidley Austin Brown & Wood LLP
Alycia A. Degen
555 West Fifth Street
Suite 4000
Los Angeles, CA 90013

Gibbs Law Group LLP
Eric H. Gibbs
One Kaiser Plaza, Suite 1125
Oakland, CA 94612

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