United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SUSAN GALINIS, et al.,

Plaintiffs,

v.

BAYER CORPORATION, et al.,

Defendants.

Case No. 09-cv-04980-SI

ORDER DENYING DEFENDANT'S *DAUBERT* MOTIONS AND DENYING IN PART AND GRANTING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 57, 58, 59

This action is before the Court upon remand from the Southern District of Illinois, where the Honorable David R. Herndon for many years oversaw the multi-district litigation ("MDL") *In re: Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, No. 09-md-02100-DRH-PMF. This case, brought by plaintiffs Susan Galinis and Richard Galinis, is now here for disposition of several pending motions and, if needed, trial. Defendant Bayer HealthCare Pharmaceuticals Inc. ("Bayer") has filed two motions for exclusion of expert testimony and a motion for summary judgment. Docket Nos. 57 ("*Daubert* Mot. No. 1"), 58 ("*Daubert* Mot. No. 2"), 59 ("Mot. Summ. J."). Plaintiffs filed opposition briefs. Dkt. Nos. 101 ("Opp'n to *Daubert* Mot. No. 1"), 115 ("Summ. J. Opp'n"), 116 ("Opp'n to *Daubert* Mot. No. 2").[1] Plaintiffs then filed supplemental briefing on May 7, 2019, to alert the Court to prior rulings on *Daubert* motions in the MDL. Dkt. Nos. 117, 118. Defendant filed reply briefs on May 31, 2019. Dkt. Nos. 125 ("Reply

[1] On May 6, 2019, plaintiffs filed a notice of errata that a number of the citations in their original briefs at Dkt. Nos. 102 and 103 were incorrect and that certain exhibits filed in support of the briefs were erroneous or incomplete. Dkt. Nos. 113, 114. Plaintiffs then filed corrected opposition briefs. Citations in this Order to plaintiffs' oppositions are to the corrected briefs at Dkt. Nos. 115 and 116. Citations to the exhibits are to the corrected exhibits at Dkt. No. 114 or, if applicable, to the exhibits filed in support of the original opposition briefs at Dkt. No. 104.

re: *Daubert* Mot. No. 1"), 126 ("Reply re: *Daubert* Mot. No. 2"), 127. The motions came on for hearing on June 13, 2019. Having carefully considered the papers filed and the arguments made, the Court hereby rules as follows.

BACKGROUND

In October 2009, Susan Galinis and Richard Galinis brought this action against Bayer. Susan had suffered a stroke after she began taking a birth control pill manufactured by Bayer.[2] She had gone to see her OB/GYN, Dr. Mary Ann Co-Asino, on April 30, 2008. Pls.' Ex. 4.1 ("Luciani Rpt.") at 8. Susan had a history of endometriosis, which caused severely painful menstrual periods. She had tried various treatment methods over the years, including surgical interventions. Since the late 1990's, she had also taken Toradol (or its generic equivalent, ketorolac) on the days of her period to manage the pain. Def.'s Ex. 3 ("Galinis Dep.") at 121:9-13.[3]

At Susan's April 2008 appointment, Dr. Co-Asino prescribed Bayer's Yasmin birth control pill. Yasmin is a type of combined oral contraceptive ("COC") that contains the progestin drospirenone ("DRSP") and ethinyl estradiol. Pls.' Ex. 7.1 ("Stier Rpt.") at 2-3. Dr. Co-Asino gave Susan instructions to take one active tablet of Yasmin daily for 12 weeks followed by a 7 day tablet free interval, with the goal of suppressing Susan's menstrual periods, and thereby eliminating the accompanying pain. Luciani Rpt. at 9; Def.'s Ex. 4 ("Prescription Records") at 3; Pls.' Ex. 9 ("Co-Asino Dep.") at 64:21-65:13.[4] Such use of Yasmin was an "off-label" but standard use of the drug.[5]

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[2] Unless otherwise specified, references in this Order to "plaintiff" are to Susan Galinis alone, and references to "plaintiffs" are to Susan and Richard Galinis. For clarity, at times this Order refers to plaintiff Susan Galinis by her first name.

[3] The parties dispute whether Susan was still taking Toradol at the time of her stroke. Defendant says the ER records show she was taking it. Def.'s *Daubert* Mot. No. 2 at 2; Def.'s Ex. 5 ("ER Records") at 00042. Susan testified at her deposition that she doesn't recall if she was taking Toradol at the time of her stroke, but that she would not have been taking it unless she had her period. Galinis Dep. at 121:9-25, 123:9-124:25.

[4] For exhibits that lack page numbers, the Court cites to the page number provided by the ECF stamp at the top of the page.

[5] The Ninth Circuit has explained, "Off-label use of a drug is legal, and is 'generally based on published scientific reports purporting to show a beneficial effect of the drug in such indications

Luciani Rpt. at 10. Susan filled the prescription for Yasmin that same day. Prescription Records at 3. The record is unclear as to precisely how long Susan took Yasmin. She testified that she took it from the time she filled the prescription on April 30 up until she had the stroke in June, but she also testified that she took it for only thirteen days, and that she had her stroke on the fourteenth day. *See* Galinis Dep. at 190:24-191:16. She could not recall whether her doctor had instructed her to delay taking Yasmin until after her period was over. *Id.* at 191:17-22.

On June 7, 2008, Susan suffered a cerebral artery ischemic stroke. ER Records at 4. In the complaint, plaintiffs allege that "[a]s a result of using Defendants' product Yaz, Plaintiff sustained serious side effects including, but not limited to, a stroke in June of 2008, ongoing physical pain, diminished cognition, mental anguish, diminished enjoyment of life, significant lifestyle changes, permanent scarring, medical, health, incidental and related expenses, medical monitoring and/or medications, and the fear of developing additional health consequences." Dkt. No. 1 ¶ 72. Plaintiffs bring, among other claims, a claim for strict product liability failure to warn.

LEGAL STANDARD

I. *Daubert* Motions

"[T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Federal Rule of Evidence 702 permits the introduction of expert testimony only if: (1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue," (2) "the testimony is based on sufficient facts or data," (3) "the testimony is the product of reliable principles and methods," and (4) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The proponent of the expert testimony has the burden of proving the proposed testimony is admissible. *Lust ex rel. Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). "Although the district court

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or patient populations.'" *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1230 n.2 (9th Cir. 2017), *cert. denied sub nom., Teva Pharm. USA, Inc. v. Wendell*, 138 S. Ct. 1283 (2018).

must perform a gatekeeping function, a trial court 'not only has broad latitude in determining whether an expert's testimony is reliable, but also in deciding *how* to determine the testimony's reliability.'" *United States v. Gadson*, 763 F.3d 1189, 1202 (9th Cir. 2014) (citation omitted); *see also Daubert*, 509 U.S. at 597.

II. Summary Judgment

Summary judgment is proper if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The moving party, however, has no burden to produce evidence showing the absence of a genuine issue of material fact. *Id.* at 325. Rather, the burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence to support the non-moving party's case. *Id.*

Once the moving party has met its burden, the burden shifts to the non-moving party to "designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324 (quoting then Fed. R. Civ. P. 56(e)). To carry this burden, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "The mere existence of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

In deciding a summary judgment motion, the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor. *Id.* at 255. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for summary judgment . . . ." *Id.* However, conclusory, speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact and defeat summary judgment. *Thornhill Publ'g Co., Inc. v. Gen. Tel. & Elec. Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). The evidence the parties present must be admissible. Fed. R.

Civ. P. 56(c)(4).

The parties agree that in this action based on diversity jurisdiction, the substantive law of the state of California applies. *See Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

DISCUSSION

I. *Daubert* Motions

Defendant has filed two motions to exclude expert testimony under *Daubert*.

A. Motion to Exclude Testimony of Dr. Luciani (Dkt. No. 57)

Defendant first moves to exclude the rebuttal opinion "proffered by plaintiffs' OB/GYN expert Richard Luciani regarding Bayer's supposed withholding of information about adverse events, which Dr. Luciani admits is supported by no evidence whatsoever." *Daubert* Mot. No. 1 at 1. Plaintiffs say this motion is moot, as Dr. Luciani will not testify that Bayer withheld information about adverse events. Rather, plaintiffs say "Dr. Luciani will testify that if Bayer did indeed withhold information about adverse clotting events suffered by Yasmin users, then (i) Bayer's conduct fell below the standard of care that OB/GYNs expect of drug manufacturers, and (ii) that information about adverse clotting events would be material to OB/GYNs like him, giving them the option of changing their prescribing habits." Opp'n to *Daubert* Mot. No. 1 at 1. Plaintiffs state that whether Bayer withheld information "is the province of other experts, such as Dr. Suzanne Parisian" and that "Dr. Luciani is permitted . . . to rely on the opinions of other experts that Bayer has indeed withheld information about adverse clotting events, and to apply his expertise to those facts." *Id.* at 2. In reply, defendant states Dr. Luciani should be precluded from offering this opinion because he "has no basis of his own to opine on Bayer's conduct[]" and he "failed to disclose any reliance on another expert's findings in support of his rebuttal opinion[.]" Reply re: *Daubert* Mot. No. 2 at 1, 4.

Dr. Luciani's rebuttal report contains the following:

> In reviewing all reports and information presented to me, it appears that Bayer withheld from the prescribers information about adverse events with regard to Yasmin. Since the physician relies on the manufacturer to prescribe their product,

> this information regarding any adverse events would be extremely important to the prescribing physician who would not have expected this information to be withheld. Had the adverse information ie. increased risk of Yasmin [sic] been provided to me as a prescribing Ob/Gyn, it would have given me the option of either changing my prescribing habits or at the very least having a detailed discussion with my patients regarding the safety of this product compared to other oral contraceptives and/or alternative drugs with less risk.

Dkt. No. 57-1 ("Luciani Rebuttal Rpt.") at 2-3. At his deposition, Dr. Luciani testified, "There is no way of me able to be – actually be able to tell that" Bayer had any information that it withheld from physicians. Dkt. No. 57-2 ("Luciani Dep.") at 41:19-23. Dr. Luciani also testified, "I would give a generic opinion, which I've already given, that if in fact Bayer had the information that there was [sic] questionable side effects of the pills Yaz and Yasmin, . . . and based on the internal draft of the VTE Crisis Report, that this would be, in my mind as a practicing physician, less than a honorable way for a drug company to deal with physicians based on questions about products. I think that would be the comment that I would make and I would go probably no further than that." *Id.* at 41:4-15.

The Court will DENY this motion, without prejudice to renewal at the time of trial. First, plaintiffs have stated that Dr. Luciani will not present the testimony that originally prompted defendant to file this motion; that is, Dr. Luciani will not testify that Bayer withheld information about adverse events regarding Yasmin. Second, defendant has long been aware of the basis for Dr. Luciani's rebuttal opinion. Dr. Luciani testified that he read Dr. Parisian's report as part of his review,[6] and he testified at his deposition that he "would give a generic opinion" from his perspective as a practicing physician, "if in fact Bayer had the information . . . ." *See id.* at 41:4-15. At the hearing, defendant characterized this motion as more a problem of discovery than anything else, saying Dr. Luciani's failure to disclose Dr. Parisian's findings as the basis of his rebuttal opinion precluded defendant from being able to depose him on this further. However, defendant has long known that Dr. Parisian's report formed the basis for Dr. Luciani's rebuttal opinion and

[6] Plaintiffs anticipate that Dr. Parisian will testify that Bayer withheld information about adverse clotting events from the United States Food and Drug Administration ("FDA"). At the hearing, plaintiffs clarified that at Dr. Luciani's deposition he incorrectly referred to another expert, the epidemiologist, as having information regarding adverse event reports.

has apparently not sought to re-take his deposition.[7] Finally, defendant has presented no evidence to show that Dr. Luciani is not qualified as a medical expert to offer his opinion regarding the standard of care that OB/GYNs expect of drug manufacturers or regarding what information is material to OB/GYNs when prescribing medications. Should the evidence at trial fail to support Dr. Luciani's testimony, defendant may renew its motion.

B. Motion to Exclude Expert Testimony on VTE Studies and Expert Testimony that Yasmin Has a Higher Stroke Risk Than Other Oral Contraceptives (Dkt. No. 58)

Defendant's second *Daubert* motion seeks to exclude two types of expert testimony: (1) expert testimony on studies regarding venous thromboembolism ("VTE"), which defendant says is irrelevant; and (2) expert testimony that Yasmin has a higher stroke risk than other oral contraceptives, which defendant says is unreliable.

1. VTE Studies

Defendant argues that the Court should exclude expert testimony on VTE studies because plaintiff suffered from an arterial thromboembolism ("ATE"), not a VTE, and that because plaintiff's injury was not a VTE, any testimony relying on VTE studies is irrelevant under *Daubert*. Plaintiffs argue that their expert testimony should not be excluded. They say that defendant never identifies which VTE studies it seeks to exclude and that "modern research" no longer considers ATEs and VTEs to be separate pathophysiological entities but "that the same biological trigger is responsible for activating clotting pathways in veins and arteries." Opp'n to *Daubert* Mot. No. 2 at 3. In essence, what the parties dispute is how to characterize the injury plaintiff suffered. Defendant argues for a narrow characterization, that plaintiff suffered an ATE and not a VTE. Plaintiffs argue that the injury was a blood clot, which in her case led to an ATE, but in other cases could lead to a VTE, depending on whether the clot is located in an artery or a vein.

[7] At the hearing, defendant stated it did not learn that Dr. Luciani planned to rely on Dr. Parisian's opinion until it received plaintiffs' opposition brief to this motion. Plaintiffs filed their opposition brief in August 2017. *See* Dkt. No. 67.

Plaintiffs' epidemiology expert, Dr. April Zambelli-Weiner, Ph.D., M.P.H., explains the difference between VTEs and ATEs in this way:

> Thrombosis is defined as the formation of a blood clot (thrombus) within a blood vessel which leads to the obstruction of blood flow to vital organs and may cause infarction [or tissue necrosis]. An embolism occurs when the thrombus breaks away from the blood vessel wall and is transported to other areas through circulation. Whether the thrombosis is arterial or venous depends on the location of the formation of a thrombus, whether it occurs in an artery or a vein. All thrombotic and thromboembolic events (TTEs) consist of (1) arterial thromboembolic events (ATEs) or (2) venous thromboembolic events (VTEs).

Pls.' Ex. 8.1 ("Zambelli-Weiner Rpt.") at 9.

Defendant says the problem is one of "fit," citing *Daubert*. There, the Supreme Court explained that expert testimony, among other criteria, must be "helpful" to be admissible. 509 U.S. at 591 (citing Fed. R. Evid. 702). "This condition goes primarily to relevance." *Id.* "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591-92. In other words, in determining whether expert testimony is admissible under the Federal Rules, the court must, in addition to assessing "whether the reasoning or methodology underlying the testimony is scientifically valid[,]" also determine "whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. The Ninth Circuit has explained,

> The relevancy bar is low, demanding only that the evidence "logically advances a material aspect of the proposing party's case." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*"). Relevancy depends on the particular law at issue because "[e]xpert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry." [Citation.] Here, California state products liability law requires only that a plaintiff show that the defendant's conduct was "more likely than not" a substantial factor in causing the injury in order to prove specific causation. *See Saelzler v. Advanced Grp. 400*, 25 Cal.4th 763, 107 Cal.Rptr.2d 617, 23 P.3d 1143, 1152 (2001).

Messick v. Novartis Pharm. Corp., 747 F.3d 1193, 1196-97 (9th Cir. 2014).

In this instance, the Court will not exclude the testimony regarding VTE studies wholesale. Defendant does not challenge any particular study's methodology or reliability, but rather argues that the studies cannot be applied to the facts here. Not so. Under California products liability law, plaintiff will need to prove whether defendant's conduct was more likely than not a substantial factor in causing her injury. *See Messick*, 747 F.3d at 1196-97; *see also Smith v. Bubak*, 643 F.3d 1137

(8th Cir. 2011) (evaluating relevance of expert's reliance on scientific paper through lens of state proximate cause statute that required patient to show whether a certain treatment would more likely than not cause her to improve). The VTE studies to which plaintiffs' experts cite are relevant to this question. Plaintiffs' experts have considered studies finding that, while VTE and ATE "have traditionally been viewed as distinct conditions, . . . recent epidemiological studies have suggested associations between venous thromboembolism, arterial thromboembolism . . . and atherosclerosis." *See, e.g.*, Pls.' Ex. 8.2 ("Zambelli-Weiner Suppl. Rpt.") at 7, 12. Moreover, Dr. Zambelli-Weiner clarifies in her supplemental report that she "considered two separate endpoints as part of this evaluation: (1) All thrombotic and thromboembolic events (TTEs) and (2) arterial thrombotic events (ATEs) only." *Id.* at 3. She thus asserts that she did not improperly conflate ATEs and VTEs, as defendant's expert has charged. *Id.*

As support for its position, defendant cites to *Rider v. Sandoz Pharmaceuticals Corporation*, 295 F.3d 1194 (11th Cir. 2002). There, the Eleventh Circuit found it was not an abuse of discretion for the district court to exclude expert testimony after finding as insufficiently "reliable scientific evidence to support a decision that bridged the gap between the conclusion that Parlodel [the drug in question] caused other injuries, which might include ischemic stroke, and the conclusion that Parlodel was a probable cause of the hemorrhagic strokes suffered by plaintiffs." *Id.* at 1196. The appellate court explained, "Ischemic strokes occur as a result of lack of blood flow to the brain. Hemorrhagic strokes occur as a result of bleeding within the brain. Thus, although the two conditions share a name, they involved a wholly different biological mechanism." *Id.* at 1202. The plaintiffs there presented no testimony to support their theory that whatever caused an ischemic stroke could cause a hemorrhagic stroke, and their causal chain also suffered from a host of other deficiencies, including the fact that the active ingredient of Parlodel could cause "vasodilation and hypotension, precisely the opposite of what the plaintiffs allege." *Id.* at 1201. The differences between ischemic and hemorrhagic stroke in that case and what plaintiffs have presented here regarding the related biological mechanisms underpinning both VTE and ATE make *Rider* distinguishable.

Defendant does not cite to any VTE study or proposed expert testimony in particular that it

seeks to have excluded. Meanwhile, plaintiffs' experts collectively rely on hundreds of studies in rendering their opinions, and the Court will not (and indeed, cannot, on the current record) parse each study to try to discern which are the ones defendant finds problematic. The Court will not exclude VTE studies as categorically irrelevant. Defendant may present its own expert testimony to refute plaintiffs' experts' conclusion, but that does not make testimony based on these studies irrelevant.

2. Risk of Stroke

Defendant also argues that plaintiffs' experts should be precluded from testifying that Yasmin has a higher stroke risk than other oral contraceptives. Defendant argues that "[e]very study that has looked at the question has concluded that the overall population of Yasmin users are at no greater risk of stroke than users of other birth control pills." *Daubert* Mot. No. 2 at 7. Defendant states that "Plaintiffs point to just one data point in one study, by Dr. Sidney, that found that one subgroup in the study population—'new users' of Yasmin over the age of 35—had a higher incidence of stroke compared to women taking certain other pills[,]" and that this study does not apply to plaintiff because she was not a "new user" since she had been prescribed birth control pills previously. *Id.* at 8. According to defendant, the Dr. Sidney study is therefore irrelevant to this case. By extension, defendant argues that expert testimony relying on the study to draw conclusions about plaintiff's particular case are therefore unreliable. Reply re: *Daubert* Mot. No. 2 at 4-5. The only other basis for plaintiffs' expert testimony on this point, defendant states, are studies looking at levels of activated protein C ("APC") and sex-hormone binding globulin ("SHBG"), which according to defendant are "inadmissibly speculative and unreliable." *Daubert* Mot. No. 2 at 9.

Plaintiffs anticipate that Dr. Zambelli-Weiner will testify that Yasmin is causally related to an increased risk of ATEs when compared with other oral contraceptives. Plaintiffs argue that Dr. Zambelli-Weiner found Dr. Sidney's "FDA-funded study provided the most reliable epidemiological evidence of ATE-specific risk[,]" that Dr. Zambelli-Weiner found "five studies funded by or otherwise associated with Bayer" were less reliable, and that it is "not the Court's role to choose between competing epidemiologic studies, much less to decide which study's design is

most probative." Opp'n to *Daubert* Mot. No. 2 at 2-4. Plaintiffs also urge the Court to allow their experts (Drs. Goldberg, Griffin, and Stier) to testify about "Yasmin's effect on APC resistance and SHBG[, which] has previously been found admissible (in the VTE cases) . . . ." *Id.* at 2. In support, plaintiffs have filed supplemental briefing attaching Judge Herndon's prior *Daubert* rulings that allowed testimony regarding APC resistance and SHBG in cases where plaintiffs suffered a VTE after taking Yasmin.

a. Epidemiological Studies

The Court finds that the Dr. Sidney study is relevant to this case. Dr. Sidney's study looked at "more than 573,000 new users of CHCs [combined hormonal contraceptives,]" with "new user" "defined as first exposure to any study CHC or comparator CHC during the 2001 – 2007 study period and no previous use of any CHC . . . during the study period." Pls.' Ex. 33 at 3. Dr. Zambelli-Weiner explains in her report why she finds a new user study to be more reliable than a prevalent user design:

> New users are study participants who are initiating therapy for the first time; prevalent users are individuals enrolled in a study who have been on the study drug – or a related drug – for some prior period of time. The inclusion of prevalent users in observational epidemiological studies becomes problematic when the risk relationship between the drug and the outcome of interest is not constant over time. Specifically, prevalent users are a selected subset of the population and are not representative of the general user population because patients who have experienced adverse events and can't tolerate the drug have already been screened out. Further, including prevalent users can significantly underestimate the rate of the event if events occurring early in the course of treatment are not captured.

Zambelli-Weiner Rpt. at 20. Moreover, Dr. Zambelli-Weiner explained, and defendant has not disputed, that risk of thrombotic outcomes from oral contraceptive use "is highest during the initial period of use and decreases steadily over time." *Id.* at 29. Thus, studies of users who have been using birth control pills for an extended period would not account for users who suffered thrombotic events early on. *Id. (*citing a "recent Japanese study . . . that 50% of thrombotic events occurring in COC users happened within the first 90 days of use . . ."). In her review, Dr. Zambelli-Weiner "identified 8 studies reporting information concerning the risk of ATEs in connection with DRSP-COC exposure[.]" *Id.* at 28. Only one, the Dr. Sidney study, employed a new user design.

The Court finds that defendant has improperly oversimplified the matter. Even if plaintiff would not be considered a "new user" within the meaning of Dr. Sidney's study, that does not mean the study may not form the basis for plaintiffs' expert opinions or that opinion testimony based on the study is unreliable. The appropriate course is to allow the parties' experts to testify as to how the results of the study do or do not apply to plaintiff, given the "new user" design.

Defendant further argues that Dr. Sidney's "new user" design is not more reliable than prevalent user studies because the Agency for Healthcare Research and Quality has said that a prevalent user design may be justified in certain circumstances. Reply re: *Daubert* Mot. No. 2 at 6 (citing Def.'s Ex. 31 at 64). In fact, the relevant portion of that report reads:

> There are well-recognized advantages in studying new initiators of treatments, which is why the new user design is considered the gold standard in pharmacoepidemiology. Specifically, a new user design prevents under-ascertaining of early events and avoids problems arising from confounders that may be affected by treatment in prevalent users. It also prevents bias arising from prevalent users being long-term adherers who may also follow other healthy behaviors. . . .
>
> Inclusion of prevalent users may be justified, however, when outcomes of interest are extremely rare or occur after long periods of use, so that a new user design may not be feasible.

Def.'s Ex. 31 at 64. Contrary to defendant's implication, this report does not find that a prevalent user study is preferable when outcomes of interest are rare, such as with an ATE.

Ultimately, defendant does not take issue with the underlying methodology of Dr. Sidney's study.[8] Rather, defendant argues the study is simply irrelevant here. The Court finds otherwise.

b. APC Resistance and SHBG

Additionally, defendant argues the Court must exclude testimony that Yasmin carries a

[8] Defendant raises a new argument for the first time in its reply brief, saying that Dr. Sidney's conclusions are additionally "unreliable on their face." Reply re: *Daubert* Mot. No. 2 at 6. Defendant cites the study's "peculiar finding[]" that "Yasmin increases VTE risk for those younger than 35, but protects against VTEs for those 35 and up" and that "Yasmin has no impact on ATE risk for subjects younger than 35, but . . . increased the risk for those 35 and older." *Id.* The Court will not consider arguments raised for the first time in a reply brief, and, in any event, finds that this argument goes more to the weight of plaintiffs' expert testimony than it does to admissibility. Defendant may make this argument before the jury but the Court will not exclude any testimony on these grounds.

higher risk of stroke than other birth control pills because "Plaintiffs' other expert testimony is based on non-epidemiological studies that do not evaluate stroke risk in humans." *Daubert* Mot. No. 2 at 9. According to defendant, "Plaintiffs rely on lab studies looking at levels of something called activated protein C (APC) resistance in women taking birth control pills" as well as "studies of changes in sex-hormone binding globulin (SHBG) in women taking birth control pills" and that plaintiffs wrongly argue that these changes are suggestive of or predict a higher stroke risk. *Id.*

Plaintiffs counter that *Daubert* does not require that a causation opinion be based on an epidemiologic study and that "[t]estimony regarding biologically-plausible mechanisms by which a drug may cause the alleged injury is one of the more common varieties of causation evidence." Opp'n to *Daubert* Mot. No. 2 at 16. According to plaintiffs, their experts will testify that "[p]eer-reviewed experimental studies have found that Yasmin markedly increases both APC resistance and SHBG levels, and does so more than second-generation oral contraceptives[,]" that "[i]ncreased APC resistance reflects a reduction in the body's ability to prevent excessive clot formation, while increased SHBG levels reflect higher estrogenicity, which is known to stimulate coagulation factors and inhibit anticoagulant factors[,]" and that "[h]igher APC resistance and higher SHBG levels are thus associated with a higher risk of both VTEs and ATEs." *Id.* at 17.

As an initial matter, plaintiffs are correct that expert scientific testimony is not excludable solely because it is based on non-epidemiological studies. *See Wendell*, 858 F.3d at 1236 (neither animal nor epidemiological studies "are necessary for an expert's testimony to be found reliable and admissible") (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1229 (9th Cir. 1998)). Defendant concedes as much in its reply brief. *See* Reply re: *Daubert* Mot. No. 2 at 7. This had been the main thrust of defendant's argument, which states that plaintiffs' testimony regarding APC resistance and SHBG should be excluded because plaintiffs cannot point to any studies showing an association between these levels and increased stroke risk. Defendant changes its position slightly in its reply brief, saying that this testimony does not "fit" the question at hand because, according to defendant, while there are at least some studies showing an association between these biological triggers and VTE, there are no such studies showing an association to stroke. *See id.* at 8. The question of "fit" is one of relevance, not reliability, and as explained above the Court will not exclude VTE studies

as irrelevant to the facts of this case. Additionally, at the hearing, plaintiffs pointed to studies that their expert Dr. Griffin cited linking APC resistance to ATE and ischemic stroke. *See* Pls.' Ex. 3.1 at 8.

Ultimately, plaintiffs' proposed expert testimony is admissible under *Daubert*. Drs. Goldberg, Griffin, and Stier will provide their medical and scientific knowledge about APC resistance and SHBG to explain some of the biological mechanisms that may be at play here. Defendant may cross-examine them or present its own expert testimony in contradiction, but the focus under *Daubert* is "on the principles and methodology" employed by the expert and "not the conclusions they generate." *See Daubert*, 509 U.S. at 595; *see also Daubert II*, 43 F.3d at 1318 ("[T]he test under *Daubert* is not the correctness of the expert's conclusions, but the soundness of his methodology."). Although defendant repeatedly states that testimony regarding APC resistance and SHBG must be excluded as "unreliable," defendant does not in fact attack plaintiffs' experts' testimony on methodological grounds. Instead, defendant argues the evidence should be excluded because "[n]one of this evidence even purports to evaluate whether women taking Yasmin actually suffered strokes at a different rate than women taking other pills." *Daubert* Mot. No. 2 at 10. But that is not the test of admissibility. The Court's gatekeeping function is to determine "whether [the expert's] testimony has substance such that it would be helpful to a jury." *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013). The fact that one expert's testimony, standing alone, "might not establish causation" does not make that report inadmissible. *Whitlock v. Pepsi Americas*, 527 Fed. App'x 660, 661 (9th Cir. 2013). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citing *Rock v. Arkansas*, 483 U.S. 44, 61 (1987)).[9]

[9] Defendant also makes a cursory request that the Court exclude any reliance on adverse event reports but without identifying in which expert reports or where in those reports this issue arises. *See Daubert* Mot. No. 2 at 9-10 (citing, inter alia, Def.'s Ex. 25 ("Parisian Dep.") at 72:25-73:16 ("You can't calculate an incidence rate from the FDA's [adverse event reporting] database . . .")). It is unclear from the Court's review that plaintiffs' experts are using the adverse event reports in the manner that defendant finds objectionable. At the hearing, defendant conceded that the use of adverse event reports plays a role in this case generally, and plaintiffs conceded that adverse event reports cannot be used in certain ways, such as for statistical analyses. The Court

Accordingly, the Court DENIES defendant's motion to exclude expert testimony regarding VTE studies or expert testimony that Yasmin has a higher stroke risk than other oral contraceptives.

II. Summary Judgment

As the parties describe it, "Plaintiff's strict liability failure-to-warn claim is the heart of her case against Bayer . . . ." Summ. J. Opp'n at 19. Defendant moves for summary judgment, largely on the basis of what defendant describes as a lack of proof of causation on strict liability failure to warn. Defendant argues that plaintiffs' strict liability claim fails because they cannot show: (1) that Yasmin has a higher stroke risk than other birth control pills; (2) that defendant knew of or could have known of any increased risk at the time plaintiff was prescribed Yasmin; and (3) that a different warning would have avoided plaintiff's stroke. Defendant also argues it is entitled to summary judgment on the remaining claims.

Plaintiffs oppose, though they state they will not pursue claims for design defect, failure to test, or commercial bribery. *Id.* at 19. Plaintiffs intend to pursue conspiracy as a theory of liability and will seek punitive damages, but they concede that these are not stand-alone causes of action. *Id.* Plaintiffs state that they are pursuing the following claims: strict liability failure to warn, negligent failure to warn, fraudulent concealment, fraudulent misrepresentation, negligent misrepresentation, breach of express and implied warranties, and loss of consortium. In their brief, plaintiffs do not address defendant's argument for summary judgment on claims premised on a manufacturing defect or general negligence.

A. Strict Products Liability – Failure to Warn

The California Supreme Court has held that manufacturers are strictly liable for injuries caused by failure to warn of risks that were known or reasonably scientifically knowable at the time they manufactured and distributed the product. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1108 (1996) (citing *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991)). This

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therefore declines to rule in defendant's favor on this point at this time.

strict liability applies to manufacturers of prescription drugs. *Id.* at 1109. A plaintiff seeking to hold a manufacturer strictly liable for failure to warn must prove that no warning was provided or that the warning was inadequate, *and* that the inadequate warning caused her injury. *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (applying California law), *aff'd*, 358 F.3d 659 (9th Cir. 2004). Where a plaintiff sues a drug manufacturer, "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." *Motus*, 358 F.3d at 661.

Here, summary judgment is inappropriate because defendant has failed to demonstrate the absence of a genuine issue of material fact on all three of the points it raises. First, there is an issue of material fact as to whether Yasmin has a higher stroke risk than other birth control pills. As discussed in regard to defendant's *Daubert* motion, plaintiffs' epidemiology expert Dr. Zambelli-Weiner is prepared to testify that Yasmin has a higher stroke risk than other birth control pills, based in part on the findings of Dr. Sidney's FDA-funded study of more than 573,000 new users of combined hormonal contraceptives. Whether to credit Dr. Zambelli-Weiner's opinion over that of defendant's experts, who presumably will testify that no such higher stroke risk exists, is a factual determination for the jury.

Second, plaintiffs are prepared to offer expert testimony to show that Bayer knew or should have known of a clotting risk above that of other birth control pills before plaintiff was prescribed Yasmin in 2008. For instance, Dr. Suzanne Parisian, M.D., a former Chief Medical Officer in the Office of Health Affairs of the FDA, has opined that "Bayer had access to internally gathered hemostasis information which described the procoagulant tendency (increased risk of clotting) of DRSP"[10] and that this tendency was seen in Bayer's internal studies conducted between 2000 and 2001, 2003 and 2005, and 2005 and 2008. Pls.' Ex. 6.2 at 14-15. Plaintiffs' experts have also cited to the results of a study published in the Journal of Thrombosis and Haemostasis in 2004, in which the researchers concluded, "In our study, DRSP-containing OC [oral contraceptives] users were less sensitive to APC than LNG [levonorgestrel]-containing OC users, which predicts an increased risk

[10] "DRSP" refers to drospirenone, the progestin used in Yasmin.

of thrombosis. Therefore, even in the absence of clinical outcome data, we advise not to prescribe DRSP-containing combined OC as a first choice for women starting OC." *See* Pls.' Ex. 25 at 2061-62. In a strict liability failure to warn case, "[t]he actual knowledge of the individual manufacturer, even if reasonably prudent, is not the issue. We view the standard to require that the manufacturer is held to the knowledge and skill of an expert in the field; it is obliged to keep abreast of any scientific discoveries and is presumed to know the results of all such advances." *Carlin*, 13 Cal. 4th at 1113 n.3. Defendant has failed to show the absence of an issue of material fact here.

Finally, defendant argues that "Plaintiffs cannot prove that any different warning—either for stroke or VTE—would have made any difference in plaintiffs' case . . . ." Mot. Summ. J. at 14. According to defendant, plaintiff's prescribing OB/GYN, Dr. Co-Asino, does not rely on warning labels when prescribing drugs, "[s]he was not deterred from prescribing another drug [Toradol] with a heightened stroke warning at the same time she prescribed Yasmin[,]" and "[s]he was aware of the stroke risk from Yasmin at the time, and continues to prescribe Yasmin to this day, which remains on the Kaiser formulary because the Kaiser pharmacy committee continues to believe that Yasmin's benefits outweigh its risks." *Id.*

In *Wendell v. GlaxoSmithKline LLC*, the Ninth Circuit reversed the district court's entry of summary judgment for the defendant drug manufacturer, finding there was a genuine issue of material fact as to whether warnings from the manufacturer would have changed the prescribing physician's conduct. In that case, the parents of a 21-year-old patient who died from a rare form of cancer (Hepatosplenic T-cell lymphoma, or HSTCL) sued the manufacturers of the drugs he had taken for many years as treatment for his inflammatory bowel disease. *Wendell*, 858 F.3d at 1230. The Ninth Circuit did not find it dispositive that the prescribing doctor testified that it was not his "regular practice to look at drug labeling," where he also testified that when he does read drug labels it is "one of the things that is part of [his] decision-making process." *Id.* at 1238. Moreover, the doctor had changed his prescribing practices for one of the other drugs that his patient was taking after its manufacturer "began circulating warnings—both a black box warning and a Dear Health Care Provider letter" about the risk of that drug and HSTCL. *Id.* Instead, the doctor began prescribing Humira, which did not have a warning about HSTCL and which the doctor therefore

believed had "a better safety profile." *Id.* The Ninth Circuit explained, "This change in prescribing practices which can, at least in part, reasonably be attributed to the lack of warning for Humira creates a question of material fact as to whether the presence of a warning on" the drug of the manufacturer for whom the district court entered summary judgment "would have changed Dr. Rich's prescribing practices as to" the patient. *Id.* at 1238-39. The Ninth Circuit also pointed to evidence that the doctor "changed his prescribing practices generally after learning of incidents of HSTCL in patients" taking a combination of the drugs in question. *Id.* at 1239. Instead of prescribing a combination of drugs, he now "uses only monotherapy." *Id.*

The factual disputes at issue in *Wendell* are similar to those at issue here. As with the doctor in *Wendell*, there is evidence in the record that Dr. Co-Asino changed her prescribing practices after she received information about a potential for higher rates of blood clots with use of Yasmin than with other birth control pills. At some point after plaintiff's stroke, Kaiser Pharmacy Services issued a "Drug FAQs for Clinicians" regarding Yasmin and the risk of VTE.[11] The FAQs stated, in part, "Recent studies suggest that Yasmin or Yaz may have a higher risk of causing blood clots compared to some typical birth control pills because they contain the progestin hormone called drospirenone. These study results differ from older studies which showed the risk of blood clots for birth control pills with drospirenone to be similar to that of typical birth control pills." Pls.' Ex. 24 at 4; *see also* Co-Asino Dep. at 40:23-41:5. At her deposition, Dr. Co-Asino testified to the following:

> Q. And had you been given this information or had this update about the higher risk with Yasmin, would you have prescribed Yasmin to Susan in 2008?
>
> [Objection.]
>
> The Witness: If I have this information, I would not prescribe it.

Co-Asino Dep. at 41:24-42:5. She further testified that she stopped prescribing Yasmin to her patients "as soon as I got this information." *Id.* at 43:4-6. "I stopped prescribing it unless I have a patient who insists to be on it. There are, I'll say, occasional patients who have been on it for a long

[11] Plaintiffs state this happened a year after Susan's stroke, but the FAQs exhibit that plaintiffs attach to their brief is labeled as a "draft" and is undated. *See* Pls.' Ex. 24. Defendant attaches the same document to its briefing. *See* Def.'s Ex. 37.

time and have no issues and would refuse to be switched in spite of extensive counseling about the new studies about Yasmin." *Id.* at 43:12-17.

Defendant argues that the FAQs Kaiser issued related to an increased risk of VTE, not of stroke, but Dr. Co-Asino agreed at her deposition that she does not differentiate between types of blood clots when counseling patients:

> Q. So when considering the risk of clots, you don't differentiate between whether a clot occurred in a vein or an artery. Correct?
>
> [Objection.]
>
> The Witness: As an OB/GYN, we do not make that determination. It is the neurologist.
>
> . . .
>
> Q. When you discuss with patients the risk of stroke, you don't differentiate between the type of stroke.
>
> [Objection.]
>
> Q. Do you?
>
> A. No.
>
> Q. Because a clot is a clot. Correct?
>
> [Objection.]
>
> The Witness: Yes.

Id. at 45:3-21. Dr. Co-Asino's deposition testimony is enough to create a factual dispute regarding whether a heightened warning would have caused her to prescribe a different birth control pill.

The disputed facts here are distinct from those presented in *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001), *affirmed* 358 F.3d 659 (9th Cir. 2004), on which defendant relies. There, the district court granted summary judgment for the defendant, and the Ninth Circuit affirmed, where the widow of a patient who committed suicide after being prescribed Zoloft sued the drug manufacturer for failure to adequately warn of the risks of suicide. The prescribing doctor testified at his deposition that he didn't review the package insert for Zoloft until after his patient died and that he didn't rely on statements by or materials from Pfizer sales representatives in deciding to prescribe Zoloft. He stated he was aware of some claims that that these types of drugs (SSRIs) were

linked to increased suicide rates, but he discounted those claims based on his personal experience. *Motus*, 196 F. Supp. 2d at 989. He testified at his deposition, "My personal belief is that SSRIs do not cause people to commit suicide." *Id.* Nothing in his testimony or in the evidence was equivocal, and the district court found the plaintiff could "point[] to no evidence establishing that Dr. Trostler would have acted differently had Pfizer provided an adequate warning . . . ." *Id.* at 999.

By contrast, in addition to the testimony cited above, Dr. Co-Asino testified that after plaintiff's stroke she stopped prescribing Yasmin except at the request of a patient. Co-Asino Dep. at 71:13-21. She also testified that when there is a product label change, Pharmacy Services brings it to the clinician's attention, and she agreed that "if there was a label change for Yasmin prior to 2008, then [she] would have been advised of it." *Id.* at 53:9-25. The evidence plaintiffs have presented here is much more like that in *Wendell*, where the doctor changed his prescribing practice after a drug manufacturer began issuing new warnings, than that in *Motus*, where even after his patient's death the doctor continued to hold to his "personal belief" that the drug he prescribed did not cause suicide.

Because defendant has failed to show the absence of a genuine issue of material fact, the Court DENIES defendant's motion for summary judgment on strict liability failure to warn.

B. Other Claims

In their opposition brief, plaintiffs agree they will not pursue claims for strict liability design defect, strict liability failure to test, and civil conspiracy, and commercial bribery. They agree that punitive damages is not a stand-alone cause of action. And at the hearing, they conceded as well that they will not pursue claims based on a manufacturing defect and that general negligence remains in the case only as an element of their negligent failure to warn claim and not as its own claim for relief. Accordingly the Court GRANTS defendant's motion for summary judgment as to these claims.

Defendant argues that plaintiffs' claim for negligent failure to warn fails for the same reason the strict liability claim fails, and further argues that plaintiff Richard Galinis's loss of consortium claim must fail because it is derivative of Susan's claims. Because the Court has denied defendant's

motion for summary judgment on the strict liability failure to warn claim, the Court likewise DENIES the motion as to the negligent failure to warn and loss of consortium claims.

In addition to the reasons it cites in support of its motion for summary judgment on strict liability failure to warn, defendant states there is no genuine issue regarding plaintiffs' claims for fraudulent concealment, negligent misrepresentation, and fraudulent misrepresentation. According to defendant, "plaintiffs cannot point to any evidence that creates a genuine issue as to whether Bayer concealed or misrepresented information about Yasmin's stroke risk, whether Bayer intended reliance on any concealment or misrepresentation, or whether plaintiff's prescribing physician actually so relied." Mot. Summ. J. at 16. In response, plaintiffs point to a variety of evidence, including testimony by their expert Dr. Parisian, who opined that "Bayer's DRSP-OC product labels and its communications with prescribers in the United States about these products are misleading and fail to adequately warn of increased risks for thrombotic arterial events." *See* Pls.' Ex. 6.2 at 17. Dr. Parisian also found, for instance, that "Bayer learned in 2003 FDA's Office of Drug Safety Review of Yasmin and COC recommended that the COC labels including Yasmin based on the seriousness of the thromboembolic risks strengthen the warnings for prescribers against off-label use.[] Based on the risk in the FDA's database for COCs, FDA recommended that the label warnings be strengthened to describe serious increased thromboembolic risks for women under 40 years of age with no risk factors. . . . FDA was able to identify the risk of thrombotic events was greatest for Yasmin when compared to three other approved COCs with other progestins. . . . Bayer identified by 2004 a similar increased pattern of risk for ATE/VTE thrombotic events for Yasmin compared to the three other COCs consistent with the findings of the FDA." Pls.' Ex. 6.3 at 72. Dr. Parisian also cited to 2005 minutes from defendant's Corporate Strategic Marketing G&A, listing as an "opportunity": "Promote off-label use of Yasmin in extended regimen in order to grow sales and bridge to Yaz extended." *Id.* at 73-74.

Defendant does not address this nor any of plaintiffs' evidence in its motion or reply. Construing the evidence in favor of plaintiffs, as the non-moving party, the Court finds defendant has failed to show an absence of evidence to support claims for fraudulent concealment, negligent misrepresentation, and fraudulent misrepresentation. The Court DENIES defendant's motion for

summary judgment on these claims.

Defendant also states the warranty claims must fail because plaintiffs did not provide pre-suit notice of the breach. Mot. Summ. J. at 15 n.2. However, as plaintiffs note, this requirement does not apply where the plaintiff is a customer suing a manufacturer with whom the plaintiff did not deal directly. *See Sanders v. Apple, Inc.*, 672 F. Supp. 2d 978, 988-89 (N.D. Cal. 2009) (California state law requiring pre-suit notice to seller "is not required where the action is against a manufacturer and is brought 'by injured consumers against manufacturers with whom they have not dealt'") (quoting *Greenman v. Yuba Power Prods.*, 59 Cal. 2d 57, 61 (1963)). By failing to address the warranty claims in its reply brief, defendant appears to have conceded this point. The Court DENIES defendant's motion for summary judgment on the warranty claims.

CONCLUSION

For the foregoing reasons and for good cause shown, the Court hereby DENIES defendant's *Daubert* motions to exclude expert witness testimony. The Court GRANTS IN PART and DENIES IN PART defendant's motion for summary judgment. The Court GRANTS the motion for summary judgment on plaintiffs' claims for strict liability design defect, strict liability failure to test, civil conspiracy and commercial bribery, general negligence, strict liability manufacturing defect, and punitive damages, though at trial plaintiffs may still pursue punitive damages and claims based on a conspiracy theory or negligence theory. The Court DENIES the motion for summary judgment on plaintiffs' claims for strict liability failure to warn, negligent failure to warn, fraudulent concealment, negligent misrepresentation, fraudulent misrepresentation, breach of express and implied warranty, and loss of consortium.

IT IS SO ORDERED.

Dated: June 28, 2019

SUSAN ILLSTON
United States District Judge