

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 613

DELTACINE VIS.	
COORDINATION PROCEEDING SPECIAL TITLE [RULE 3.550(c)]	Case No. CJC-16-004863 JUDICIAL COUNCIL COORDINATION PROCEEDING NO. 4863
PRADAXA® CASES	
This document relates to:	ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT, OR IN THE
Rosemary Lawson San Francisco Superior Court Case No.: CGC-17-559611	ATERNATIVE, FOR SUMMARY ADJUDICATION
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INTRODUCTION

The above-entitled matter came on regularly for hearing on October 22, 2019. A court reporter was present. The appearances are as noted in the record. Following the hearing on October 22, 2019, the Court issued an order requesting further briefing on an isolated issue. Each party made timely, supplemental submissions.

Having reviewed and considered the argument and written submissions of all parties and being fully advised, the Court grants Defendants' motion for summary judgment, or in the alternative, summary adjudication ("MSJ/MSA").¹

¹ Because the Court separately considers the parties' preemption arguments in its order on Defendant's motion for summary judgment based on federal preemption, the Court does not consider the parties' arguments within the MSJ/MSA on federal preemption. (Compare MSJ, 10-13 and Reply, 4:21-5:2 with Oppo., 20:26-21:28.)

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Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") moved for summary judgment or, in the alternative, summary adjudication, on Plaintiff Rosemary Lawson's ("Plaintiff") claims for strict liability failure to warn, negligent failure to warn, negligent misrepresentation, fraud and intentional misrepresentation, and punitive damages pursuant to Code of Civil Procedure section 437c, subds. (c) & (p). Defendant McKesson Corporation ("McKesson") joined the motion.² (See Motion, 1, fn. 1.)

Pradaxa is a prescription drug Defendant BI manufactures, and the Food and Drug Administration ("FDA") approved in October 2010, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. (See Declaration of Wayne A. Wolff ISO Defendants' Motions for Summary Judgment (Oct. 8, 2019) ["Wolff Decl."], Joint Appendix ["J.A."] Ex. 205 ["Complaint"], ¶¶ 13-14; Wolff Decl., J.A. Ex. 100 ["Pradaxa (Oct. 2010) Label"] at 1.)

Plaintiff was diagnosed with atrial fibrillation in January of 2010. (See Plaintiff's Separate Statement of Facts in Opposition to BI's MSJ/MSA ["Plaintiff's SSDF"] No. 1.) Plaintiff's prescribing physician and cardiologist, Dr. Khan³, testified that he was familiar with the risks and warnings contained in the Pradaxa label at the time he prescribed Pradaxa to Plaintiff in November of 2010, and that he discussed these risks with Plaintiff. (Khan Depo., at 50:13-51:2, [Dr. Khan generally was familiar with the risks and warnings prior to recommending Pradaxa to Plaintiff], 51:3-52:4 and 150:21-151:7 [Dr. Khan knew the FDA approved only two doses of Pradaxa, with the appropriate dose to be determined by

² BI and McKesson are collectively referred to as "Defendants."

³ Plaintiff repeatedly refers to Mr. John Kitchell, Physician's Assistant, as her prescribing doctor. (See Oppo., 6:26-7:1 [citing Plaintiff's SSF No. 8], 10:13-12:9 [citing Plaintiff's SSF Ns. 56-72].) However, the undisputed facts reveal that Dr. Khan was the doctor who evaluated Plaintiff and recommended she take Pradaxa, and Mr. Kitchell is in fact *not* a doctor. (See Wolff Decl., J.A. Ex. 223, Gauhar Khan, M.D. (5/22/19) Depo. ["Khan Depo."], at 22:19-24:5; see also Plaintiff's SSDF No. 8.) As discussed in more detail, *infra*, case law makes clear that only *the prescribing and/or treating physicians*' potential change in behavior is relevant to the causation analysis here. (See *Georges v. Novartis Pharmaceuticals Corp.* (C.D. Cal., Nov. 2, 2012) 2012 WL 9083365, at *6.)

Further, and most importantly, while Plaintiff repeatedly refers to Mr. Kitchell and his experience with Pradaxa and Ms. Lawson in the facts section of Plaintiff's Oppo., Plaintiff's entire argument section is devoid of any reference to Mr. Kitchell. (See Oppo., 14-19 [discussing Dr. Khan, only].) Thus, any evidence on Mr. Kitchell's purported changes in this prescription decision or informed consent discussions are irrelevant.

the patients' renal function], 55 [Dr. Khan was informed that if a patient, like Plaintiff, were taking amiodarine (a p-gp inhibitor) that he did not need to adjust her Pradaxa dose]; 57:9-21 and 99:1-14 [Dr. Khan knew Pradaxa increased the risk of significant bleeding, including fatal and intracranial bleeding, and would have discussed this with Plaintiff], 68:16-69:21 and 165:24-166:10 [Dr. Khan knew there was no reversal agent for Pradaxa at the time he prescribed it to Plaintiff, and is confident he would have discussed this fact with Plaintiff], 90:19-91:2 [Dr. Khan knew the concomitant use of NSAIDS and aspirin could further increase the risk of bleeding while on anticoagulation therapy, and Dr. Khan would have instructed Plaintiff to avoid them], 99:15-21 [Dr. Khan knew Pradaxa had an increased risk of bleeding for patients over 75, as compared to Warfarin, and would have discussed this with Plaintiff], 100:20-23 [Dr. Khan knew, and would have discussed with Plaintiff, that Pradaxa was not monitored with blood tests], 101:3-5 [Dr. Khan knew, and would have discussed with Plaintiff, the need to look out for signs of bleeding while taking Pradaxa].)

Specifically, and as outlined immediately above, Dr. Khan informed Plaintiff that Pradaxa carried a risk of bleeding, including intracranial and fatal bleeding, which is increased in patients such as Ms. Lawson, who is over the age of 75 and a female. (Khan Depo., at 99:1-21, 110 [Dr. Khan was aware that Ms. Lawson's age and gender put her at an increased risk of bleeding while on Pradaxa]; Plaintiff's SSDF Nos., 95-96.) Dr. Khan also informed Plaintiff that Pradaxa did not have a product-specific reversal agent, and that Pradaxa was not monitored with blood tests. (*Id.* at 68:16-69:21, 100:20-23, 165:24-166:10.) Dr. Khan testified he followed the dosing instructions, and prescribed Plaintiff the 150 mg dose twice daily because she had normal kidney and renal function. (*Id.* at 51:21-56:17 [Dr. Khan prescribed 150 mg of Pradaxa twice daily after assessing Ms. Lawson's kidney and renal function, which was measured by creatine clearance and accounted for one's weight, age, and gender], 115:6-116:20 [Dr. Khan analyzed the risks and benefits and prescribed Pradaxa based on pre-2010 dosing guidelines].)⁴

Plaintiff began taking Pradaxa in January of 2011. (Wolff Decl., J.A. Ex. 207, PFS at 10.) She

⁴ There is evidence that Dr. Khan did not recall the specific informed consent discussion with Ms. Lawson. (See Plaintiff's SSDF 93-99.) However, this is a non-issue. Indeed, Plaintiff admits that "[t]here is no reason to believe that Dr. Khan deviated from his normal risk/benefit discussion when discussing Pradaxa with Ms. Lawson," which included the risks discussed in the two paragraphs, *supra*. (Oppo., 17:10-24.)

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testified that she relied on her doctors to decide the best medications for her and trusted their medical judgment to make those decisions for her. (Wolff Decl., J.A. Ex. 221 ["Lawson Depo."], at 16:9-12, 66:11-67:4.)⁵

On March 14, 2016, Plaintiff was admitted to Doctors Medical Center for an intracranial hemorrhage. (Wolff Decl., J.A. Ex. 224, Belinda Kea, M.D. Depo., at 13:17-21.) There was no subsequent required surgery, the hospital administered two doses of the Pradaxa reversal agent to Ms. Lawson, and Ms. Lawson was stable throughout her hospitalization. (*Id.* at 24:18-12, 46:1-13, 65:4-16.) Plaintiff's expert, Dr. Rosengart, opined that the elevated levels of Pradaxa concentrations (which were higher than the 215 nanograms per milliliter) in Plaintiff's blood more likely than not caused her intracranial bleed. (Plaintiff's SSDF No. 73.) Dr. Rosenhart opined further that the elevated Pradaxa levels were due to Plaintiff's age, strong p-gp inhibitor use (i.e. amiodarone), weight, gender, intrapatient variability, and reduction in renal function.⁶ (*Id.*) Ms. Lawson had mild to stage two renal impairment at the time of her intracranial bleed. (See Plaintiff's SSDF, No. 66.)

Plaintiff filed the instant case on June 19, 2017, asserting claims for strict liability failure to warn,

⁵ While Plaintiff also testified that if Dr. Khan informed her of the risk of serious, sometimes fatal, bleeding, she "probably" would have refused Pradaxa or "might have told . . . him no" (see Lawson Depo, 75:12-16, 77:1-6 [emphasis supplied]) the undisputed evidence shows that (1) Dr. Khan did inform Plaintiff of these risks (see Khan Depo., 99:1-14), and (2) Plaintiff does not recall what risks were specifically discussed with her at the time of prescription. (See Lawson Depo., 73:13-17, 76:6-12.) Thus, as discussed infra, Plaintiff's speculative testimony precludes the Court from finding a triable issue of material fact on causation. (See Ochoa v. Pacific Gas & Electric Co. (1998) 61 Cal.App.4th 1480, 1485— 1486 [He opined that the stroke, 'was more probably a complication from the internal mammary visualization procedure than a coincidence.' The appellate court held that this testimony 'is at best speculative and conjecture and falls short of meeting the 'probability' standard of proximate cause." [emphasis supplied].) Other case law also makes clear that in order to defeat summary judgment, Plaintiff must testify that she would have refused the prescription if she had known certain information relevant to her injury. (See e.g., Hill v. Novartis Pharmaceuticals Corp. (E.D. Cal. 2012) 2012 WL 600416, at *4 [denying summary judgment because prescribing physician, who had become aware after he prescribed the drug to plaintiff that the drug could cause problems with a person's jaw, testified that he now discloses that fact to his patients, and plaintiff testified she would not have taken the drug had she been made aware of the same].) Thus, testimony that she "probably" or "might have" refused to take Pradaxa had she known relevant information relating to potentially fatal bleeding is insufficient.

⁶ The at-issue label had specific warnings that Pradaxa can cause serious, and sometimes fatal bleeding, and also warned of increased risks of bleeding based on renal impairment, concomitant use of p-gp inhibitors (like amiodarone), age (including geriatric patients), and concomitant use of other drugs. (See "Pradaxa (Oct. 2010) Label" at 1, 3-6].) Further, the label advised that Pradaxa is administered based on renal function, *not* by monitoring of anticoagulation tests or plasma levels (like Warfarin). (See *id.*)

negligent failure to warn, negligent misrepresentation, fraud and intentional misrepresentation, and punitive damages. (See generally, Complaint.) Plaintiff alleged that the warnings accompanying Pradaxa were deficient because BI failed to adequately warn prescribing physicians "that there was no reversal agent that could stop or control bleeding in patients;" "that Pradaxa has a narrow therapeutic window, and that it should be dose adjusted to patients to minimize their risk of bleeding;" "that approximately ten percent of patients are 'super absorbers' who eliminate Pradaxa from their bodies slower than other patients;" and "that the risks of Pradaxa outweigh the benefits in patients 80 years of age or older." (*Id.*

During his deposition, Plaintiff's counsel cross-examined Dr. Khan and presented to him various medical literature, references to BI company documents, and regulatory documents. (MSJ, 3:2-3.) Dr. Khan testified that none of the additional risk information or documents presented to him would have changed his decision to prescribe Pradaxa to Plaintiff, or the informed consent discussion he had with her about Pradaxa. (Khan Depo., 116:4-118:1 [presently, Dr. Khan stands by his decision to prescribe Plaintiff the 150mg dose of Pradaxa, and his risk benefit information communication to Plaintiff even after her intracranial hemorrhage, and believes it was the best medication for her in March of 2016], 167:24-168:23 [Dr. Khan stood by his decision to prescribe Pradaxa even after all additional risks and documents were presented to Dr. Khan during deposition].)

However, Dr. Khan also testified that had he known that there was a mechanism to monitor and measure the Pradaxa plasma concentrations in the blood, that he would have wanted to know that such measuring/monitoring was possible, and would have *measured* a patient's Pradaxa concentrations to see if they ran a risk of a major bleed. (See Plaintiff's' SSDF Nos. 20-21, 26, 76, 85; see also *id.* at Nos. 22, 27, 77, 86 [testifying that if Dr. Khan knew there were documents showing that there was large variability in plasma concentrations, that would have "an impact" on whether or not to prescribe Pradaxa].) With respect to monitoring specifically, Dr. Khan testified that he was unaware that the risk of bleeding increases substantially above 215 nanograms per milliliter, and he would have wanted to be aware of that fact at the time he prescribed Pradaxa. (See *id.* at Nos. 18-19, 47.) Dr. Khan further testified that if he knew that there were 543 deaths associated with the use of Pradaxa in May of 2012, he "probably" would have ceased Ms. Lawson's Pradaxa prescription. (See *id.* at Nos. 32-35, 54, 87; see also *id.* at No. 35 [if

Dr. Khan knew that Pradaxa caused more deaths and major bleeds than Warfarin, Dr. Khan would take that into consideration when prescribing Pradaxa].) Dr. Khan also testified that he would have wanted to be made aware of a therapeutic range for Pradaxa, if one existed, and if he knew this information, "he would have adjusted" his risk/benefit calculation in determining whether to prescribe Pradaxa. (See *id.* at Nos. 36-41, 74-75, 82-83, Reply, 2:13-18.) Lastly, Dr. Khan testified that he would have adjusted his risk/benefit analysis if knew the levels at which major bleeding increases and benefits remain constant (also known as the therapeutic range). (See Plaintiff's SSDF Nos. 23, 39, 30, 53, 75, 73.)⁷

EVIDENTIARY OBJECTIONS

Defendants object to various pieces of Plaintiff's evidence to the extent such evidence is (1) immaterial to the disposition of the MSJ/MSA, (2) duplicative of prior evidence, or (3) not a fact, but rather an improper hypothetical or legal argument. (See Defendants' Responses to Plaintiff's SSDF, Nos. 1-114.) The Court overrules Defendants' objections. Defendants' objections go to the weight to be given to the Plaintiff's evidence, not its admissibility (and the Court will not consider irrelevant facts at summary judgment). The Court need not consider the remainder of Defendants' objections, as they are immaterial to the Court's analysis below. (See Defendants' Responses to Plaintiffs' SSDF, Nos. 115-136; Code of Civ. Proc. § 437c(q).).

Plaintiff does not object to any of Defendants' supporting evidence. (See generally, Plaintiff's Statement in Response to BI's Separate Statement of Undisputed Facts ISO BI's MSJ/MSA ["Plaintiff's Response to BI's SSF"] (Sept. 10, 2019).)

LEGAL STANDARD

In the words of Code of Civil Procedure Section 437c, "any party may move for summary judgment in any action or proceeding if it is contended that the action has no merit or that there is no defense to the action or proceeding." The party moving for summary judgment "bears the burden of persuasion that there is no triable issue as to any material fact and that he is entitled to a judgment as a matter of law." (Aguilar v. Atlantic Richfield Co. (2001) 25 Cal.4th 826, 850.) Moreover, the moving party also "bears an initial burden of production to make a prima facie showing of the nonexistence of any

⁷ As discussed in Discussion and Analysis Part II.A, *infra*, the legal relevance of the facts in this paragraph are what prompted the request for further briefing. (See Order After Defendant's (1) Motion For Summary Judgment, or in the Alternative, for Summary Adjudication and (2) Motion for Summary Judgment on the Basis of Federal Preemption (Oct. 22, 2019) ("Further Briefing Order").)

triable issue of material fact." (Id.)

A defendant moving for summary judgment carries his burden of persuasion and/or production by "present[ing] evidence that would require such a trier of fact not to find any underlying material fact more likely than not. In the alternative, he may simply point out - he is not required to present evidence - that the plaintiff does not possess, and cannot reasonably obtain, evidence that would allow such a trier of fact to find any underlying material fact more likely than not." (*Id.* at 845.)

If the moving party carries his burden of production, "he causes a shift, and the opposing party is then subjected to a burden of production to make a prima facie showing of the existence of a triable issue of material fact." (*Id.* at 850.) But if the moving party fails to carry his initial burden, he would not be entitled to judgment as a matter of law, and would have to present his evidence to a jury. (*Id.* at 851.)

DISCUSSION AND ANALYSIS

Defendants moved for summary judgment or, in the alternative, summary adjudication on Plaintiff's strict liability failure to warn claim, as well as Plaintiff's other claims for negligent failure to warn, negligent misrepresentation, and fraud and intentional misrepresentation, on the grounds that Plaintiff cannot establish proximate causation. Defendants also seek summary adjudication of Plaintiff's punitive damages claim on the grounds that Plaintiff cannot meet her burden of proof to recover punitive damages under Connecticut's "reckless disregard" standard. For the reasons stated below, the Court concludes that Plaintiff cannot demonstrate that Pradaxa is a proximate cause of her injury.

Accordingly, Defendants are entitled to summary judgment on Plaintiff's claims, and the issue regarding punitive damages is moot.⁸

I. Background Law

To establish a failure to warn claim, a plaintiff must prove that the inadequacy or absence of the warning caused the plaintiff's injury. (Webb v Special Elec. Co., Inc. (2016) 63 Cal.4th 167, 181.)

⁸ BI also moved for summary judgment on Plaintiff's design defect and failure to test claims to the extent Plaintiff asserts such claims. (See MSJ, 10:2-9 [claiming no evidence of a design defect and preemption of such claim], 13:4-21 [failure to test claim].) However, Plaintiff makes clear she is not asserting any design defect or failure to test claims apart from her failure to warn claim. (See Oppo., 20-22 ["Plaintiff's claims of inadequate testing relate directly to [Defendants'] failure to warn about the dangers of Pradaxa"]; see also Reply, 1 [noting Plaintiff's concession that she is not pursuing a design defect claim], 4:5-20 [arguing Plaintiff conceded that her failure to test claim is indistinct from her failure to warn claim].)

Legal or proximate cause is a "flexible concept" that generally "refers to the basic requirement that there must be some direct relation between the injury asserted and the injurious conduct alleged." (*Paroline v. U.S.* (2014) 572 U.S. 434, 444.) "[P]roximate cause is ordinarily concerned, not with the fact of causation, but with the various considerations of policy that limit an actor's responsibility for the consequences of his conduct." (*State Dept. of State Hospitals v. Sup. Ct.* (2015) 61 Cal.4th 339, 353.) Indeed, "rules of legal cause...operate to relieve the defendant whose conduct is a cause in fact of the injury, where it would be considered unjust to hold him or her legally responsible." (*Id.*) Where reasonable minds cannot differ, the question of proximate cause is one of law, not of fact. (*Id.*)

Under the learned intermediary doctrine, the question is whether different or additional warnings would have altered the conduct of the prescribing physician. (*Motus v. Pfizer, Inc.* (9th Cir. 2004) 358 F.3d 659, 661; see also *Carlin v. Sup. Ct.* (1996) 13 Cal.4th 1104, 1116 [California courts apply the learned intermediary doctrine to warning claims arising from the use of prescription medications]; *Tucker v. Wright Medical Technology, Inc.* (N.D. Cal., Mar. 19, 2013) 2013 WL 1149717, at *12 ["A manufacturer of a prescription drug is obligated warn *physicians*, not patients, of potential side effects associated with its pharmaceutical products."].)

"[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." (Id. [citing Motus, supra, 358 F.3d at 661] [emphasis supplied].)

II. Application⁹

As stated above, Plaintiff alleges BI failed to adequately warn prescribing physicians "that there was no reversal agent that could stop or control bleeding in patients;" "that Pradaxa has a narrow therapeutic window, and that it should be dose adjusted to patients to minimize their risk of bleeding;" "that approximately ten percent of patients are 'super absorbers' who eliminate Pradaxa from their bodies slower than other patients;" and "that the risks of Pradaxa outweigh the benefits in patients 80 years of age or older." (Complaint, ¶ 22, 24.) To prevail on her claims, Plaintiff must show a sufficient causal connection between Defendants' alleged failure to warn and Plaintiff's injury.

⁹ The Court notes that no party cited California state court cases to support its arguments. Thus, the Court does not have any binding precedent on the causation issue. Rather, the Court must rely on federal, mainly unpublished opinions, which are persuasive.

Defendants present evidence demonstrating that additional warnings would not have altered the conduct of Plaintiff's prescribing physician. Here, Dr. Khan testified that none of the additional risk information regarding Pradaxa presented to him by Plaintiff's counsel during his deposition, which included information relating to measuring and/or monitoring plasma concentrations, would have changed his decision to prescribe Pradaxa to Plaintiff, or the kind of informed consent discussion he had with her about the drug.¹⁰ This evidence is sufficient to demonstrate that Defendants' alleged failure to warn did not proximately cause Plaintiff's injury.

Plaintiff relies upon Dr. Khan's testimony that he would have measured Plaintiff's concentration levels had he been informed he could do so. ¹¹ In essence, Plaintiff argues that had Dr. Khan measured Plaintiff's concentration levels, as he testified he would have done had he been informed he could do so, he would have discovered that Plaintiff's Pradaxa levels were elevated or her renal function was reduced (as testified to by Plaintiff's expert), and would have then prescribed Plaintiff a lower dose of Pradaxa or a different anticoagulant as a result. Based on Dr. Khan's testimony, however, whether he would have prescribed Plaintiff a lower dose of Pradaxa or a different anticoagulant is dependent on whether he would have concluded that Plaintiff's Pradaxa levels were so high or her renal function was so reduced such that a change in her prescription was warranted. In this respect, Plaintiff's theory for proximate causation is speculative as there is no evidence to suggest that *Dr. Khan* would have reached that conclusion even if

Defendants dispute that any change in Dr. Khan's informed consent discussion is relevant to the causation inquiry. (See MSJ, 6:11-7:8.) The Court disagrees. Absent any new, compelling case law to the contrary, the Court is persuaded by Judge Wiss's previous holding that the prescribing and/or treating doctor's informed consent discussion is relevant to the causation inquiry. (See Wolff Decl., J.A. 419 [Fourzon Order Denying Motion for Partial Summary Judgment], at 7:26-8:13.) Nonetheless, the Court agrees with Judge Wiss's analysis, and concludes separately that the prescribing and/or treating doctor's informed consent discussion is relevant to the causation inquiry. (Stanley v. Novartis Pharm. Corp. (C.D. Cal. 2014) 11 F.Supp.3d 987, 1003.) Regardless, Dr. Khan's testimony unequivocally demonstrates that Dr. Khan would not have communicated different information to Plaintiff Lawson if Dr. Khan had additional warnings.

¹¹ As discussed *infra*, in *Narain* the prescribing doctor testified that he would have followed the warning "had he been instructed to do so *in the label*." (see J.A., Ex. 201; see also Khan Depo., 127:23-128:16 [testimony regarding measuring].) While at first glance it appears Dr. Khan may not have testified regarding *labeling* instructions specifically, the deposition testimony reveals that his testimony is sufficiently tethered to the *label*. (See *id*. ["If the FDA said check it I would have checked it for sure."].)

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he had measured Plaintiff's blood concentrations. 12

In supplemental briefing, Plaintiff argues courts have found triable issues of fact on causation where the "plaintiff shows that their physician would have used monitoring tests if adequately warned to do so." (Plaintiff's Supp. Brief (Oct. 28, 2019), 4 [emphasis added] [citing Holley v. Gilead Sciences, Inc. (N.D. Cal. 2019) 379 F.Supp.3d 809, 830].) Thus, because the testimony of Dr. Khan shows that he would have "monitored¹³ to ensure [Plaintiff] was within the safe therapeutic range," Plaintiff insists she has demonstrated a triable issue of fact on causation. (See Plaintiff's Supp. Brief, 2-4.) On the other hand. Defendant argues the same result in *Narain* should follow here. (See Defendant's Supp. Brief (Oct. 28, 2019), 5-7 [citing J.A., Ex. 201 [Narain Order Granting Defendants' Motion for Summary Judgment].) In Narain, and similar to the evidence discussed in the preceding paragraph, Plaintiff pointed to the physician's testimony that he (1) would have monitored Plaintiff if he had been instructed to do so in the label, and (2) "probably" would have prescribed a lower Pradaxa dose had the monitoring revealed the Plaintiff was over-anticoagulated. While, as with Narain, Dr. Khan stated he would have measured his patients' blood concentrations to see if his patients' were at a risk of a major bleed if there was a method of doing so, unlike Narain, there is no corresponding testimony that Dr. Khan would have "probably" prescribed a different dose or anticoagulant for Ms. Lawson (if he found her blood concentration levels to be high). ¹⁴ In sum, Dr. Khan's testimony does not show that a particular warning, such as a warning to measure blood concentration levels, would have prevented Plaintiff's brain bleed.

¹² As noted in footnote 7, *supra*, the legal relevance of all other warning information identified *supra*, at 5:18-6:7 is addressed in Part II.A, *infra*.

¹³ Here, the Court notes that, specifically, Dr. Khan testified that he *would* have wanted to *measure* the concentration levels of Pradaxa, if possible, to ensure there was no risk of a major bleed. (See Khan Depo., 127:23-128:16.) However, there is no similar testimony that he "would have" *monitored* Plaintiff. Thus, it appears Plaintiff uses "monitoring" and "measuring" interchangeably. The Court assumes that this is accurate for purposes of this motion.

¹⁴ Based on footnote 13, *supra*, the Court also disagrees with Defendant's statement that "[t]hough Dr. Khan testified that he would have adjusted his risk-benefit discussion in response to additional information posed by Plaintiff's counsel, he never testified that he would have taken a 'next step' as exemplified in the cited cases above – i.e. *chosen to monitor*." (Defendant's Brief, 6:26-7:2 [emphasis supplied].) Regardless, *Narain* did not find a choice to monitor (or similarly here, a choice to measure) dispositive on the causation analysis. *Narain* assumed that the doctor's testimony about monitoring was true, and still found causation too speculative. The same follows for Dr. Khan's "measuring" testimony (especially in light of the even more attenuated testimony here as compared to *Narain*, as discussed in this paragraph).

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Further, as stated in the preceding paragraph, Plaintiff Lawson has not provided similar evidence to the one case cited in Holley (In re Xarelto (Rivaroxaban) Products Liability Litigation (E.D. La., Apr. 17, 2017) 2017 WL 1393480, at *1-3 [applying Louisiana law]¹⁵), addressing the issue of monitoring. Indeed, in In re Xarelto, "Plaintiffs point[ed] to evidence that both doctors would have used PT tests had they been adequately instructed to do so, and therefore would have been equipped to adjust treatment to avoid injury. Specifically, for Plaintiff Orr, Dr. Bui, her neurosurgeon, would have known Ms. Orr was not anticoagulated and would have proceeded with her surgery much sooner. Because of the delay, however, Ms. Orr experienced significant medical issues." (Id. [emphasis supplied].) Unlike In re Xarelto, and as stated supra at 9:8-10:1, there is no evidence that, had Dr. Khan measured Plaintiff's blood concentration levels, he would have known Ms. Lawson's blood concentration levels were too high/she ran a risk of a major bleed, would have provided a lower dose of Pradaxa or a different anticoagulant, and/or would have taken steps to prevent her brain bleed. While Holley's and In re Xarelto's discussion that triable issues of fact may exist where "plaintiffs have presented evidence that their physicians would have used monitoring tests if adequately warned to do so," the evidence presented in In re Xarelto provided for all of the necessary links in the causal chain; whereas the evidence here does not. (Compare In re Xarelto, supra, 2017 WL 1393480, at *2 [quoted language above] with at 9:8-10:1, *supra*.)

Plaintiff relies upon the expert testimony of Dr. Rosengart who opined that the elevated levels of Pradaxa concentrations in Plaintiff's blood more likely than not caused her intracranial bleed. (Plaintiff's SSDF No. 73.) However, regardless of Dr. Rosengart's opinions, what matters to the causation inquiry in this case is *Dr. Khan's* opinions, that is, as the learned intermediary 16, whether *Dr. Khan* would have changed his course of treatment or provided different warnings to Plaintiff. As stated above, nothing in the record establishes that Dr. Khan would have concluded, if Dr. Khan had measured Plaintiff's blood concentration levels, that Plaintiff had elevated Pradaxa concentrations in the blood, such that Dr. Khan

¹⁵ While the Court analyzes *In re Xarelto* here, it notes that it does not address California law.

¹⁶ While Plaintiff argues that, "[n]eglecting to educate physicians, via the drug label or otherwise, prohibits a defendant from asserting that the physician is a learned intermediary," Plaintiff cites to no case law to support this argument. (See Oppo., 14:26-15:5)

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would have changed his course of treatment or provided different warnings to Plaintiff. It is this absence of evidence that is fatal to Plaintiff here. (See Aguilar, supra, 25 Cal.4th at 845; see generally Defendant's Response to Plaintiff's SSDF ["Plaintiff has adduced no testimony that any of her warnings criticisms would have caused Dr. Khan to change his prescribing decision or his patient counseling of Ms. Lawson." [emphasis added].) As such, the Court finds that Plaintiff failed to establish that additional warnings would have altered Dr. Khan's conduct. (See Motus, supra, 358 F.3d at 661; see also Stanley, supra, 11 F.Supp.3d at 1003 [finding a genuine issue of material fact as to causation and failure to warn where, "Dr. Molina and Dr. Nakamura both testified that they would have [had] a different conversation with their patients regarding the risks and benefits in taking bisphosphonates [had they known of the undisclosed risks]. Additionally, Dr. Molina testified that he would now prescribe the drug in a more conservative manner, which would include dental monitoring."] [emphasis supplied]; Motus v. Pfizer Inc. (C.D. Cal. 2001) 196 F.Supp.2d 984, 999, aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.) (9th Cir. 2004) 358 F.3d 659 ["Ms. Motus points to no evidence establishing that Dr. Trostler would have acted differently had Pfizer provided an adequate warning about the alleged risk that Zoloft causes those who ingest it to commit suicide."].) Consequently, Plaintiff fails to demonstrate that any alleged failure to warn caused Plaintiff's injury. 17

While Plaintiff asks this Court to find that a triable issue of material facts exists because (1) Dr. Khan's past actions with a similar drug, Warfarin, indicates he would have communicated additional warnings to Ms. Lawson in 2010 (see Oppo., 17:8-18:3 [citing Plaintiff's SSDF Nos. 93-99] [arguing mainly, that "a jury could certainly infer that if he discussed the importance of monitoring before prescribing Warfarin, he would have likewise discussed the importance of monitoring with Pradaxa if he had the important safety information that [BI] failed to disclose to prescribing physicians such as Dr. Khan], and Reply, 3:8-16), and that (2) as an "engaged patient," Plaintiff would have made different decisions had she had additional information regarding the risks of taking Pradaxa (see Oppo., 18:4-19:15 [citing Plaintiff's SSF Nos. 100-114] [arguing that a jury could certainly find that Ms. Lawson was an informed patient, who would not take medication without consideration, simply because her doctor gave it to her.], Reply 3:17-4:2), such arguments are insufficient under the law.

Indeed, Plaintiff's one cited case (*Stanley, supra*, 11 F.Supp.3d at 1003) undermines Plaintiff's argument, and confirms that definitive testimony from the prescribing doctor that the (1) doctor would not have prescribed the drug, or (2) had a different informed consent conversation, is required. Other cases are in accord, and add that Plaintiff must also definitively testify that she would not have taken the drug had she been informed of certain risks that were causally connected to her injury. (See e.g., *Georges, supra*, 2012 WL 9083365, at *5-6 [citing several district court cases denying summary judgment where the plaintiff provided evidence that the physician would have changed a prescription or treatment procedure]; *Hill, supra*, 2012 WL 6004161, at *4 [denying summary judgment because prescribing physician, who

A. Supplemental Briefing

As noted, *supra*, the Court requested further briefing on whether Dr. Khan's testimony noted at pp. 5:18-6:7, *supra*, creates a triable issue of fact. (See Further Briefing Order, 2:12-4:5.) In sum, the supplemental briefing demonstrates that Plaintiff fails to sufficiently show a causal connection between additional warnings and information Dr. Khan would have liked to have known, and Plaintiff's actual injury.¹⁸

1. Analysis¹⁹

Plaintiff argues here that a physician's "conduct" is not limited to the decision not to prescribe the drug. (Plaintiff's Supp. Brief (Oct. 28, 2019), 4.) Indeed, courts have found triable issues of fact on causation where the "plaintiff shows that their physician would have used monitoring tests if adequately warned to do so²⁰, or that they would have altered their prescription practices in a manner that may have prevented the injury." (Id. [emphasis added]; [citing Holley v. Gilead Sciences, Inc. (N.D. Cal. 2019) 379 F.Supp.3d 809, 830].) Plaintiff further insists that "[c]autioning the patient about risks factors or

had become aware after he prescribed the drug to plaintiff that the drug could cause problems with a person's jaw, testified that he now discloses that fact to his patients, and plaintiff testified she would not have taken the drug had she been made aware of the same].) Because Plaintiff cannot establish that either she or Dr. Khan would have taken different action if they knew of the additional warning information, her arguments are lacking.

What's more, a triable issue of fact does not exist where, as here, the evidence amounts to conjecture and lacks the quality in order for the Court to conclude that a triable issue of material facts exists as to causation. (*Nardizzi v. Harbor Chrysler Plymouth Sales, Inc.* (2006) 136 Cal.App.4th 1409, 1415.)

¹⁸ Plaintiff devotes significant portions of its supplemental briefing to arguments that (1) were not expressly authorized by this Court, and (2) are nearly identical to arguments made in its initial briefing (which the Court rejects in footnote 17, *supra*.) (Compare Plaintiff's Supp. Brief, 4-8 with Oct. 22, 2019 Order [additional briefing], MSJ Oppo., 17:8-18:3 [arguing mainly, that "a jury could certainly infer that if he discussed the importance of monitoring before prescribing Warfarin, he would have likewise discussed the importance of monitoring with Pradaxa if he had the important safety information that [BI] failed to disclose to prescribing physicians such as Dr. Khan], and *id*. at 18:4-19:15 [arguing that a jury could certainly find that Ms. Lawson was an informed patient, who would not take medication without consideration, simply because her doctor gave it to her].)

¹⁹ The primary issue with the federal cases here is that (1) they are unclear as to whether Plaintiff must show the warnings "would have" or "may have" prevented Plaintiff's injury; and (2) they often lack the requisite factual specificity to be able to adequately compare them to the case at bar.

²⁰ Because this is addressed in Part II, *supra*, the Court does not address it here.

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reducing the dose²¹ may constitute changes in prescriptions practices." (Plaintiff's Supp. Brief, 2 [citing *Holley, supra*, 379 F.Supp.3d at 831.)²² Because the testimony of Dr. Khan shows that he would have (1) "made a more informed risk/benefit analysis before he prescribed [Pradaxa to Ms. Lawson]", (2) monitored to ensure [Plaintiff] was within the safe therapeutic range²³, and (3) Dr. Khan "may" not have prescribed Pradaxa to Plaintiff at all, Plaintiff insists she has demonstrated a triable issue of fact on causation. ²⁴ (See Plaintiff's Supp. Brief, 2-4.)

However, Defendant is correct on the relevant background law here. Upon a review of the case the legal inquiry on causation is not, as Plaintiff suggests, "whether the prescribing physician would have changed his conduct or the manner in which his would have prescribed the drug if he had received the warning or risk information of which he was unaware at the time." (Plaintiff's Supp. Brief, 2.) Such a standard is too broad. Rather, the change in a physician's conduct or prescription procedures must have sufficiently prevented the Plaintiff's injury, and/or be sufficiently connected to the injury. (See *Motus, supra*, 196 F.Supp.2d at 991 ["A plaintiff asserting causes of action based on a failure to warn must

²¹ There is no testimony here about reducing Ms. Lawson's dose.

²² Plaintiff also cites to the Court's decision in *Fourzon*. (*Id.* at 2 [*Fourzon* Order Denying Motion for Partial Summary Judgment], at 6-8.). Yet, *Fourzon* does not assist Plaintiff here. In *Fourzon*, the court found triable issues of fact existed because (1) the prescribing physician said he *would have had* a different informed consent discussion with the Plaintiff if he was provided certain warnings; and (2) Plaintiff testified that he would have taken Warfarin instead of Pradaxa if he knew one in five patients are over or under dosed. The issues in *Fourzon* do not bear on the Court's request in supplemental briefing, and none of the probative facts in *Fourzon* are present here.

²³ Because this is addressed in Part II, *supra*, the Court does not address it here.

²⁴ Though Plaintiff again points to Dr. Khan's testimony that if he knew that there were 543 deaths associated with the use of Pradaxa in May of 2012, he "probably" would have ceased Ms. Lawson's Pradaxa prescription, such testimony in too attenuated under the law. (See *Motus, supra*, 196 F.Supp.2d at 995–996 ["The burden [is] on the plaintiff to demonstrate that the additional non-disclosed risk *was sufficiently high that it would have* changed the treating physician's decision to prescribe the product for the plaintiff."] [emphasis supplied].) Thus, Plaintiff's attempt to argue at the hearing that Dr. Khan's use of the word "probably" creates a triable issue of fact on whether it is "more likely than not" that Dr. Khan would have changed his prescription decision fails. In sum, it is plainly too speculative. Regardless, Dr. Kahn still unequivocally testified that, even after knowing the 543 death statistic, he stood by his decision to prescribe Pradaxa to Ms. Lawson.

Further, the fact that Dr. Khan "may" not have prescribed Pradaxa to her at all is insufficient to create a triable issue of fact. The case law makes clear that Plaintiff must demonstrate that Dr. Khan would have decided not to prescribe Pradaxa to Ms. Lawson if he was provided with additional warnings, and Dr. Khan testified unequivocally to the contrary.

injury."] [emphasis supplied].)²⁶

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²⁵ Had Dr. Khan testified that the risk/benefit information discussed at 5:18-6:7, *supra*, *would have* changed how he (1) prepared Ms. Lawson for Pradaxa (by way of an informed consent discussion, or in the types of tests he would have ordered for Ms. Lawson while taking Pradaxa), or (2) his actual prescription decision, the result may be different here. (See *id*.)

²⁶ Apart from *Holley*'s cited cases, the Court agrees with Defendant's claim that *Holley* itself does not assist the Court's analysis here. (See Defendant's Brief, 3:17-4:4.)

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With respect to Plaintiff's first argument on Dr. Khan's risk/benefit analysis (see 5:18-6:7, supra), Defendant shows that a physician's desire for certain additional risk information, without more (and specifically without a sufficient causal connection to the actual injury Plaintiff suffered), is insufficient to support causation. (See Defendant's Supp. Brief, 4-5 [citing Nix v. SmithKline Beecham] Corp. (D. Ariz., Sept. 5, 2007) 2007 WL 2526402, at *3] [applying California law] [finding the following testimony insufficient on causation: "Dr. Hoehne did testify that he would have liked to have known more about deaths associated with Serevent and that generally the lack of accurate information about potential side effects makes it difficult to perform a risk-benefit analysis."] [emphasis added]; see id. ["But merely raising the possibility that Dr. Hoehne might have acted differently is not enough to satisfy Plaintiffs' burden of proof on causation." [emphasis supplied]; Gaghan v. Hoffman-La Roche *Inc.* (N.J. Super. Ct. App. Div., Aug. 4, 2014) 2014 WL 3798338, at *15-16 [applying California law] ["But Gaghan's counsel could not get Dr. Hartman to testify that he would have warned Gaghan of an IBD side effect if the Roche warnings had been as plaintiffs' evidence and argument would have required."].)²⁷ Though a New York state case, Gaghan makes clear that California law requires that, if a doctor testifies he would have wanted to know certain risk-benefit information prior to prescription, a doctor must then also testify that the doctor would have communicated the risk-benefit information to the patient (or as noted, *supra*, footnote 25, would have concretely prepared the patient in a different way). As with the prescribing doctor in *Gaghan*, Dr. Khan's did not state that he would have communicated any additional risk-benefit information to Ms. Lawson. Rather, as noted, *supra*, his testimony demonstrates the opposite.

While Defendant's other cited cases seem to be in accord, they do not apply California law. However, some of these jurisdictions do apply the learned intermediary doctrine (or assume it applies), so they may be instructive. (See, Defendant's Supp. Brief, n. 2 [citing Hanson v. Boston Scientific Corp. (S.D.W. Va., Apr. 12, 2016, No. 2:13-CV-10653) 2016 WL 1448868, at *5 ["Assuming...in her risk/benefit calculus."]; Hoffman v. Boston Scientific Corp. (S.D.W. Va., Oct. 6, 2015) 2015 WL 5842785, at *5 ["Indeed, such evidence requires a reasonable juror to speculate, based only on mere possibility, that Dr. Crouch would have altered his decision to prescribe the product simply because of 'cause for concern.""]; Vanderwerf v. SmithKlineBeecham Corp. (D. Kan. 2008) 529 F.Supp.2d 1294, 1312 ["Dr. Creek clearly testified that even today, he would still prescribe Paxil for Mr. Vanderwerf. The speculative argument that Dr. Creek "may not" have used Paxil "in a certain individual" does not raise a genuine issue of material fact whether Dr. Creek would have declined to prescribe Paxil for Mr. Vanderwerf if he had received any of the three warnings which plaintiffs propose."]; see also id. at 1313 [discussing monitoring claim, and how Plaintiff failed to present any evidence that additional monitoring would have prevented suicide]]].)

In sum, unlike the cited cases, here, Dr. Khan testified that even with additional warnings information, he still would have prescribed Ms. Lawson Pradaxa and would not have changed his informed consent discussion with Ms. Lawson. Further, Dr. Khan did not testify that he would have reduced her prescribed dosage or not prescribed Pradaxa if he (a) knew about additional risk factors, or (b) had measured Plaintiff's blood concentration levels.

B. Conclusion.

For all of the foregoing reasons, the Court finds that there is no genuine issue of material fact as to causation and the failure to warn.

II. Plaintiff's Other Claims.

Plaintiff's other claims for negligent failure to warn, negligent misrepresentation, fraud and intentional misrepresentation, also fail for lack of causation because these claims are based on the same facts as Plaintiff's failure to warn claims. (See MSJ, 9:19-10:1; see, e.g., *Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1481-83 ["We conclude the directed verdict on negligent failure to warn was correct because the strict liability verdict foreclosed a finding of negligent failure to warn...[T]he manufacturer's strict liability duty to warn is greater than its duty under negligence, and thus negligence requires a greater showing by plaintiffs"]; *Motus, supra,* 358 F.Supp.2d at 999 [granting defendant's motion for summary judgment finding that plaintiff's claims for wrongful death, fraud, and breach of warranty are premised on the failure to warn claim].) Accordingly, Defendants are entitled to summary judgment on Plaintiff's claims, and the summary adjudication regarding punitive damages is moot. (Compare MSJ, 16:21-23:15 and Reply 6-14, with Oppo., 25-34.)²⁸

CONCLUSION AND ORDER

For all of the foregoing reasons, Defendants' motion for summary judgment is granted.

IT IS SO ORDERED.

Dated: November 8, 2019

Judge of the Superior Court

²⁸ Defendants separately argue that Plaintiff's claims fail because the Pradaxa warnings were adequate as a matter of law. (Compare MSJ, 14:1-16:20 and Reply, 5:3-26 with Oppo., 22-25.) Because the Court finds that summary judgment is warranted based on causation alone, the Court need not reach this issue.

CERTIFICATE OF ELECTRONIC SERVICE

(CCP 1010.6(6) & CRC 2.260(g))

I, KEITH TOM, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On November 8, 2019, I electronically served the ATTACHED DOCUMENT(S) via File&ServeXpress on the recipients designated on the Transaction Receipt located on the File&ServeXpress website.

Dated: November 8, 2019

T. Michael Yuen, Clerk

By:

KEITH TOM, Deputy Clerk