UNITED STATES DISTRICT COURT
THE SOUTHERN DISTRICT OF FLORIDA
CASE NO. 2:17-CV-14302-ROSENBERG/MAYNARD

DENNIS MCWILLIAMS,
LORI MCWILLIAMS,

Plaintiffs,

v.

NOVARTIS AG, *a global healthcare company*,
NOVARTIS PHARMACEUTICALS CORPORATION,
a Delaware corporation,

Defendants.
_____/

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT

This Cause is before the Court on Defendant Novartis Pharmaceuticals Corporation's Motion for Summary Judgment. DE 61. Plaintiff Dennis McWilliams suffered a stroke while taking Defendant's drug, Tasigna, for his chronic myeloid leukemia. Mr. McWilliams alleges that his stroke was caused by Defendant's drug and that Defendant did not properly warn about the risks associated with its drug. Mr. McWilliams and his wife, Plaintiff Lori McWilliams, brought a three-count Amended Complaint alleging: (1) strict product liability under a failure to warn theory; (2) negligence under a failure to warn theory; and (3) loss of consortium for Mrs. McWilliams. DE 19. Plaintiffs seek both compensatory and punitive damages. *Id.* at 13.

Defendant has now filed a Motion for Summary Judgment. DE 61. Plaintiffs responded, DE 63, and Defendant replied, DE 75. For the reasons set forth below, Defendant's Motion is granted in part and denied in part.

I. BACKGROUND[1]

In June 2007, Plaintiff Dennis McWilliams was diagnosed with PH+ chronic myeloid leukemia ("CML"). DE 62 ¶ 10. CML is a rare cancer of the blood. *Id.* ¶ 1. Patients with CML usually have a genetic mutation, known as the Philadelphia chromosome (Ph), which causes production of the mutant "BCR-ABL protein." *Id.* ¶ 2. THE BCR-ABL protein causes white blood cells to proliferate uncontrollably. *Id.* ¶ 3. In 2001, Defendant's drug Gleevec (imatinib) was approved for commercial use in patients with PH+ CML. *Id.* ¶ 4. Gleevec is a type of medication called a tyrosine kinase inhibitor (TKI), which works by targeting and inhibiting the BCR-ABL protein created by the Philadelphia chromosome. *Id.* ¶ 5. In October 2007, Defendant's drug Tasigna (nilotinib), another TKI inhibitor, was approved by the FDA for patients who became resistant or intolerant to Gleevec. *Id.* ¶ 7. In 2010, Tasigna was approved to treat patients with newly diagnosed CML. *Id.* ¶ 8.

Following Mr. McWilliams's diagnosis in 2007, his oncologist, Dr. Sanjiv Walia, prescribed Gleevec. *Id.* ¶ 11. Mr. McWilliams responded to Gleevec. *Id.* ¶ 13. In May 2011, Dr. Walia ordered for the first time a quantitative Polymerase Chain Reaction (qPCR) test on Mr. McWilliams; this test determines BCR-ABL levels with greater precision. *Id.* ¶ 14. The test revealed that Mr. McWilliams had an abnormal BCR-ABL level. *Id.* ¶ 15. In June 2011, Dr. Walia switched Mr. McWilliams to Tasigna. *Id.* ¶ 16. On August 25, 2013, Mr. McWilliams suffered a stroke. *Id.* ¶ 17. Mr. McWilliams had several risk factors for stroke, including a history of smoking, hypertension, obesity, a significant family history of coronary artery disease and stroke, and hyperlipidemia. *Id.* ¶ 33.

[1] The facts in this section are undisputed, unless indicated otherwise.

Dr. Walia testified that all medications have side effects and that prescribing physicians have to weigh the benefits and the risks in making prescribing decisions. *Id.* ¶ 19. He continues to prescribe Tasigna today "with careful warning." DE 64 ¶ 25. Dr. Walia testified that he has met at some point with Defendant's sales representative. DE 62 ¶ 66.

The parties dispute when medical literature was first published regarding an association between Tasigna and atherosclerotic-related vascular disease. Defendant states that there were no scientific publications that evaluated cases of stroke in patients taking Tasigna when Mr. McWilliams began taking the drug in June 2011. *Id.* ¶ 34. Plaintiffs contend that as early as 2010 and continuing through 2013, there were multiple reports of patients developing atherosclerotic-related vascular disease. DE 64 ¶ 34.

Tasigna was approved initially by the Food and Drug Administration ("FDA") on an accelerated basis. DE 62 ¶ 38. As part of the accelerated approval process, the FDA required Defendant to provide updated safety and efficacy data on Tasigna on an annual basis. *Id.* ¶ 40. In July 2011, Defendant proposed to the FDA adding peripheral arterial occlusive disease (PAOD) to its Medication Guide for patients and to the Adverse Reaction section of the label. *Id.* ¶ 43. The FDA told Defendant that it should not add PAOD to its Medication Guide for patients if it did not also include PAOD on its label for doctors. DE 64 ¶ 45.

In March 2013, Defendant informed the FDA that the Canadian government had required revisions to the Canadian Product Monograph in August 2012 to include information regarding cerebrovascular events observed in Defendant's clinical trials. DE 62 ¶ 48. In April 2013, Defendant notified the FDA that the Canadian government was requiring that letters be sent to health care providers informing them of the changes to the Canadian Product Monograph. *Id.* ¶ 49.

On October 25, 2013, the FDA requested that Defendant add "vascular occlusive events" to the Tasigna label in the Warnings and Precautions section. *Id.* ¶ 52. On October 31, 2013, the FDA requested that the manufacturer of a leukemia chemotherapy drug, Inclusig, suspend marketing because of cardiovascular and arterial adverse events. *Id.* ¶ 54. Defendant notes that the FDA revised the boxed warning for Inclusig and found that "similar rates of serious vascular events have not been observed in several other drugs of this class." *Id.* ¶ 55.

In January 2014, the FDA reported the results of the Post-Mark Safety Summary of Tasigna and stated that it was evaluating adverse event reports of cerebrovascular incidents. *Id.* ¶ 58. That same month, the FDA approved the addition of a new Warning and Precautions section regarding cardiac and vascular events. *Id.* ¶ 60. The section included incidence of PAOD, ischemic cerebrovascular events, and ischemic heart disease-related events. *Id.* In February 2014, Defendant confirmed with the FDA that it did not need to send a letter to healthcare providers regarding the January 2014 label change. *Id.* ¶ 64. To date, the FDA has not requested that Defendant send a letter to health care providers regarding cardiovascular adverse events. *Id.* ¶ 65.

Plaintiffs' Amended Complaint contains claims for strict product liability and negligence under failure to warn theories and for loss of consortium for Mrs. McWilliams. DE 19. Defendant has now moved for summary judgment. DE 61.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The existence of a factual dispute is not by itself sufficient grounds to defeat a motion for summary judgment; rather, "the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A dispute is genuine if "a reasonable trier of fact could return judgment for the non-moving party."

Miccosukee Tribe of Indians of Fla. v. United States, 516 F.3d 1235, 1243 (11th Cir. 2008) (citing *Anderson*, 477 U.S. at 247–48). A fact is material if "it would affect the outcome of the suit under the governing law." *Id.* (citing *Anderson*, 477 U.S. at 247–48).

In deciding a summary judgment motion, the Court views the facts in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *See Davis v. Williams*, 451 F.3d 759, 763 (11th Cir. 2006). The Court does not weigh conflicting evidence. *See Skop v. City of Atlanta*, 485 F.3d 1130, 1140 (11th Cir. 2007). Thus, upon discovering a genuine dispute of material fact, the Court must deny summary judgment. *See id.*

The moving party bears the initial burden of showing the absence of a genuine dispute of material fact. *See Shiver v. Chertoff*, 549 F.3d 1342, 1343 (11th Cir. 2008). Once the moving party satisfies this burden, "the nonmoving party 'must do more than simply show that there is some metaphysical doubt as to the material facts.'" *Ray v. Equifax Info. Servs., LLC*, 327 F. App'x 819, 825 (11th Cir. 2009) (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). Instead, "[t]he non-moving party must make a sufficient showing on each essential element of the case for which he has the burden of proof." *Id.* (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). Accordingly, the non-moving party must produce evidence, going beyond the pleadings, to show that a reasonable jury could find in favor of that party. *See Shiver*, 549 F.3d at 1343.

III. ANALYSIS

Defendant makes the following arguments in its Motion for Summary Judgment: (1) Plaintiffs' state law failure-to-warn claims are preempted; (2) Plaintiffs failed to establish a prima facie case for their failure-to-warn claims; (3) Plaintiffs are not entitled to punitive

damages; and (4) because Defendant is entitled to summary judgment on Plaintiffs' failure-to-warn claims, Plaintiffs' derivative claim for loss of consortium also fails. The Court addresses each argument in turn.

A. Preemption

Defendant argues that Plaintiffs' state law claims are preempted because (1) Defendant could not have added a warning to the box label without prior approval from the FDA and (2) there is clear evidence that the FDA would have rejected a warning of stroke had Defendant proposed it. DE 61 at 12–17. Plaintiffs respond that Defendant cannot meet its burden on the impossibility preemption defense because it has not offered clear evidence that the FDA would not have approved a warning about stroke. DE 63 at 14–19.

The Supremacy Clause preempts state law that is directly in conflict with federal law. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011); U.S. Const., Art. IV, cl. 2. Impossibility preemption occurs where "it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc.*, 564 U.S. at 618 (citation omitted). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citation omitted).

Although the FDA retains authority to approve or require amendments to a drug manufacturer's label, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with drafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009) (citations omitted). A manufacturer can change the warnings on a label in two different ways. First, "manufacturers can

implement 'major changes' to a label by filing a so-called 'Prior Approval Supplement' ('PAS'). . . . [A] PAS change requires prior FDA approval before it can be implemented." *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 274 (3d Cir. 2016) (citing 21 C.F.R. § 314.70(b)). Second,

> the "Changes Being Effected" ("CBE") regulation permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. Under the CBE regulation, the manufacturer may, upon filing a supplemental application with the FDA, change a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction"; it need not wait for FDA approval. To add a warning to the Warnings and Precautions section through a CBE submission, "there need only be 'reasonable' evidence of a causal association with the drug, a standard that could be met by a wide range of evidence."

In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d at 273 (citations omitted).

In *Wyeth*, the Supreme Court noted that "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications." 555 U.S. at 571. The Court held that "where there is 'clear evidence that the FDA would not have approved a change' to the label, federal law preempts state-law claims premised on the manufacturer's failure to make that change." *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d at 283 (quoting *Wyeth*, 555 U.S. at 571). The Supreme Court has noted that "[i]mpossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 571.

Here, for Defendant to succeed on its impossibility pre-emption defense, it needs to present clear evidence that the FDA would not have approved a change to the label of Tasigna to add stroke if Defendant had proposed one. Defendant offers several pieces of evidence that it argues show that the FDA would not have approved adding a warning for stroke to the label.

Defendant notes that, in October 2013, the FDA requested that the manufacturer of a leukemia chemotherapy drug, Inclusig, suspend marketing because of cardiovascular and arterial adverse events. DE 61 at 14 (citing DE 62 ¶ 54). Defendant notes that the FDA revised the boxed warning for Inclusig and found that "similar rates of serious vascular events have not been observed in several other drugs of this class." DE 62 ¶ 55. Defendant argues that "[i]f FDA had wanted to add a boxed warning for Tasigna, it could have done so at the same time that it updated the Iclusig label." DE 61 at 14. This is not clear evidence that the FDA would not have approved a change to the label of Tasigna to add stroke if Defendant had proposed one. It does not follow that, because the FDA did change the label of one drug, the FDA would not have approved a change to the label of Tasigna.

Defendant argues that "FDA could have also required—but did not—a boxed warning for stroke in January 2014, following the addition of Cardiac and Vascular Events to the Warnings and Precautions section of the Tasigna label." DE 61 at 14. It is unclear to the Court how the FDA's decision to add Cardiac and Vascular Events to the Warnings and Precautions section of the label two months after Mr. McWilliams's stroke is strong evidence that the FDA would not have approved a change to the Tasigna label at an earlier date.

Defendant also points to the following facts as evidence that the FDA would not have approved a change to the Tasigna label to add stroke: (1) that the FDA did not suggest that PAOD, a different medical problem from stroke, be added to the label; (2) that the FDA did not request that stroke be added to the Warnings and Precautions section in March 2013 when Defendant informed the FDA that Canadian regulators had requested that the Product Monograph include a warning about cerebrovascular events reported in Defendant's clinical trials; and (3) "[w]hen FDA did reach out to NPC about updating the Warnings and Precautions

section of the Tasigna® label on October 25, 2013, FDA requested that NPC propose language to warn of the risk of vascular occlusive events generally, not stroke specifically." *Id.* at 16. The FDA's approval of the label is not clear evidence that the FDA would not have approved a change to the Tasigna label to add stroke if Defendant had proposed it. *See Wyeth*, 555 U.S. at 558–59 (rejecting Defendant's argument that the FDA's approval of its label provided Defendant with a complete defense to Plaintiff's tort claims).

The cases cited by Defendant in which the Courts found that the plaintiffs' claims were preempted are distinguishable because they had much clearer evidence that the FDA had investigated the particular medical event at issue and had determined that there was insufficient evidence to support adding or modifying a warning on a drug's label. For example, in *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163 (S.D. Cal. 2016), the Court found that there was clear evidence that the FDA would not have approved a warning of the risk of pancreatic cancer because the FDA had repeatedly conducted a targeted review of the risk and had not found a causal relationship. 187 F. Supp. 3d at 1173–74. The Court noted that "[t]he FDA has consistently considered pancreatic cancer rick and concluded evidence of a casual association was indeterminate, and therefore insufficient to support a reference to pancreatic cancer." *Id.* The Court stated that the FDA had published an article in the *New England Journal of Medicine*, in which it explicitly stated its finding of the lack of causal association between the drug and pancreatic cancer. *Id.* at 1165.

The other cases cited by Defendant had similarly clear evidence that the FDA had considered the particular medical event at issue and had determined that a label change was not appropriate. *See Rheinfrank v. Abbott Labs.*, 119 F. Supp. 3d 749, 766 (S.D. Ohio 2015) ("The Court finds the FDA's February 2006 decisions that developmental delay warnings 'should not

be incorporated into [Depakote] labeling' and the FDA's 2008 belief that 'the data do not provide sufficient evidence to support [Depakote] labeling changes at this time' constitute 'clear evidence' that when confronted by the issue in 2003, the FDA would have rejected an attempt to add a developmental delay warning."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1273–74 (W.D. Okla. 2011) ("Wyeth's evidence also reflects the FDA's continued rejection of enhanced suicidality warnings for antidepressants during the time period following approval of Effexor. On three occasions prior to Mr. Dobbs's 2002 suicide, the FDA rejected citizen petitions asking it to strengthen the suicidality warnings for Prozac, an antidepressant regulated under the same SSRI classification as Effexor. On each occasion, the FDA rejected the requests, finding insufficient scientific evidence of an association between the SSRI and suicidality."). Accordingly, Defendant has not presented clear evidence that the FDA would not have approved a change to the label of Tasigna to add stroke if Defendant had proposed one and Plaintiffs' claims are not preempted.

B. The Elements of Plaintiffs' Failure-to-Warn Claims

Under Florida law, "[s]trict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product." *Colville v. Pharmacia & Upjohn Co. LLC*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008). Defendant argues that it should be granted summary judgment as to each element. The Court addresses each element in turn.

i. Adequacy of the Warnings

In order to establish the first element—that the warnings were inadequate—Plaintiff must prove that "the defendant did not adequately warn of a particular risk that was known or

knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Wolicki-Gables v. Arrow Intern.*, Inc., 641 F. Supp. 2d 1270, 1286 (M.D. Fla. 2009) (citation omitted).

Defendant argues that Plaintiffs cannot meet their burden to show that the risk was known or knowable during the June 2011 through December 2013 time period when Mr. McWilliams was taking the drug because "[n]o articles were available in June 2011, and there were no published reports of patients treated with Tasigna® experiencing strokes until the publication in March 2013 of two letters reporting on one patient each." DE 61 at 11. Plaintiffs respond that, in 2012, Defendant was notified by Canadian regulators of an association between Tasigna and atherosclerotic disease and that Defendant was consistently informed of patients suffering vascular disease. DE 63 at 12–13.

In viewing the facts in the light most favorable to Plaintiffs, *see Davis*, 451 F.3d at 763, there is evidence to suggest that the risk was known or knowable to Defendant. Plaintiffs point to Health Canada's conclusion in 2012 that there was an association between Tasigna and the development and exacerbation of atherosclerotic-related disease. DE 64-30 at 2.[2] Plaintiffs also

[2] The Court notes that Defendant has filed a Motion in Limine seeking for the Court to exclude evidence or argument concerning foreign regulatory actions as irrelevant, misleading to the jury, and unfairly prejudicial to Defendant. DE 58 at 4. Defendant argues that the evidence is irrelevant and prejudicial because "foreign regulations and standards for medication labeling differ from those in the United States." *Id.* Plaintiffs respond that the evidence is highly probative to Defendant's knowledge of the association between Tasigna and atherosclerotic-related disease. DE 71 at 1–5. Although the Court will issue a separate order on the Motion in Limine, the Court grants in part and denies in part Defendant's Motion for the Court to exclude evidence or argument concerning foreign regulatory actions. The Court follows the approach of the Court in *Mahaney ex rel. estate of Kyle v. Novartis Pharm. Corp.*, 835 F. Supp. 2d 299 (W.D. Ky. 2011):

point to a 2011 article discussing patients developing Arterial Occlusive Disease while taking Tasigna, DE 64-9, and to several reports informing Defendant of patients suffering strokes, *see* DE 64-5 at 1; DE 64-15 at 4. Because there is a dispute of fact as to whether the risk was known or knowable, the Court denies summary judgment on this element for Defendant.

ii. Proximate Cause

"Plaintiff establishes proximate cause by showing that the inadequacy of the warnings was a substantial factor in bringing about [Plaintiff's] injury." *Kirchman v. Novartis Pharm. Corp.*, No. 8:06-cv-1787-T-24-TBM, 2014 WL 2158519, at *5 (M.D. Fla. May 23, 2014). Defendant argues that Plaintiffs cannot meet their burden on proximate cause because they cannot "provide evidence that [Mr. McWilliams's] prescribing physician would have not prescribed Tasigna® or would have recommend that McWilliams stop taking Tasigna® if a different warning regarding the risk of stroke had been provided." DE 61 at 10. According to Defendant, Plaintiffs cannot meet their burden as to proximate cause because Mr. McWilliams's doctor still prescribes Tasigna to patients. Plaintiffs respond that "Florida law does not require a showing that the treating physician would have declined to prescribe the drug if he or she had

---

> NPC is an international company, whose headquarters is in Switzerland. Because the company transcends international boundaries, the labeling in other countries could bear on what information the company's executives were privy to and when they recognized the alleged connection between [Tasigna] and [stroke]. The Court will permit this evidence, as it may bear on NPC's knowledge and the notice it had of [Tasigna]'s side effects.
>
> Plaintiff may not use this information to show NPC violated the FDA's regulations. Differing regulatory schemes and objectives in other nations should not impact those which governed [Tasigna]'s use in the United States. Thus, any attempt by Plaintiff to color the FDA requirements with those of other countries would be improper.

Id. at 318. *See Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 5258858, at *3–4 (S.D. Ohio Sept. 10, 2015).

known of the association at the time of prescription," DE 63 at 9, and that the evidence here is that Dr. Walia would have informed Mr. McWilliams of the risk had Dr. Walia been properly informed, *id.* at 11.

The Court agrees with Plaintiffs. Under Florida law, the learned intermediary rule states that "the manufacturer's duty to warn of [the drug's] dangerous side effects was directed to the physician rather than the patient." *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989). This does not mean, however, that Plaintiffs must prove that Mr. McWilliams's doctor has stopped prescribing Tasigna in order to show that the inadequacy of Defendant's warning was a substantial factor in Plaintiff's injury. *See Kirchman*, 2014 WL 2158519, at *5. Here, Dr. Walia has testified that he continues to prescribe Tasigna today "with careful warning." DE 64-17 at 19, 69:10–14. Dr. Walia's testimony that his warning has changed since learning more about Tasigna is similar to the doctor's testimony in *Kirchman*. In that case, the Court denied summary judgment where the plaintiff's prescribing physician testified that a different warning would not have changed the physician's decision to prescribe; it would, however, "have changed his prescribing practices by giving different warnings or instructions" to the patient. *Kirchman*, 2014 WL 2158519, at *5. Dr. Walia's testimony also distinguishes this case from *Chase v. Novartis Pharm. Corp.*, 740 F. Supp. 3d 1295 (M.D. Fla 2006), a case on which Defendant relies, *see* DE 75 at 3–4. In *Chase*, the prescribing doctor unequivocally testified that the revised warning about a drug's side effect would not have changed the doctor's prescribing decision in any way. *Id.* at 1298. Accordingly, there are genuine issues of material fact as to whether the allegedly inadequate warning was a proximate cause of Mr. McWilliams's injury and the Court denies summary judgment on this element for Defendant.

iii. Injury

"In order to establish medical causation in a toxic tort case such as this one, a plaintiff must show both that exposure to the alleged toxic substance can cause a particular disease (general causation), and that exposure to the alleged toxic substance was a cause of his or her individual injury (specific causation)." *Guinn v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1239, 1242 (M.D. Fla. 2009) (citation omitted). In its Motion for Summary Judgment, Defendant states that it has moved to exclude Plaintiffs' specific and general causation experts and that it is entitled to summary judgment if the Court excludes these experts.

1. Specific Causation

Defendant filed a motion to exclude the testimony of Dr. Robert Wagmeister, Plaintiff's expert on specific causation. DE 60. Plaintiffs responded, DE 66, and Defendant replied, DE 73. The Court denied Defendant's Motion as to Dr. Wagmeister. DE 89. Accordingly, there is a triable issue as to specific causation and Defendant's Motion for Summary Judgment as to specific causation is denied.

2. General Causation

Defendant filed motions to exclude the testimony of Plaintiffs' general causation experts, Dr. Singh, DE 56, and Dr. Weiss, DE 59. The Court granted in part and denied in part Defendant's Motion to Exclude Dr. Singh. DE 90. The Court stated that "Dr. Singh is permitted to testify; he may not, however, testify that Tasigna is causally associated with atherosclerosis characterized as 'severe' or 'rapidly progressive.'" *Id.* at 10. The Court granted in part and denied in part Defendant's Motion to Exclude Dr. Weiss. DE 91. The Court excluded Dr. Weiss's opinion that Tasigna is causally associated with atherosclerotic-related conditions, including accelerated and severe vascular occlusive disease. *Id.* at 3–5. Although the Court excluded Dr. Weiss's general causation opinion, it did not exclude Dr. Singh's general causation

opinion. Accordingly, there is a triable issue as to general causation and Defendant's Motion for Summary Judgment as to general causation is denied.

C. Punitive Damages

Defendant argues that Plaintiffs are not entitled to punitive damages. It argues that New Jersey law applies which prohibits an award of punitive damages in products liability actions where the drug that caused the harm was subject to preapproval by the FDA.[3] DE 61 at 18 (citing *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 774 (N.J. 2007)). Defendant states that the conduct allegedly giving rise to punitive damages occurred in New Jersey, where it is headquartered. DE 61 at 13. Plaintiff responds that Florida law applies because Defendant engaged in conduct in Florida to persuade doctors to prescribe Tasigna over Gleevec. DE 63 at 19. Florida law allows for punitive damages when plaintiffs can show by clear and convincing evidence that the defendant committed intentional misconduct or acted with gross negligence. Fla. Stat. § 768.72. [4]

A federal court sitting in diversity applies the conflict of law rules of the forum state. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). Before beginning a conflict of law analysis, a court should determine whether a conflict of laws truly exists. *Fioretti v. Mass.*

[3] There is one statutory exception to this prohibition on punitive damages "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C-5. Courts, however, have found this exception to be preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). *See McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 276 (N.J. Super. Ct. App. Div. 2008). Plaintiffs do not argue that this exception applies. Thus, the Court does not need to analyze whether the exception is preempted under *Buckman*.

[4] Defendant argues in the alternative that, "[e]ven if the Court finds that Florida law applies, plaintiffs are still not entitled to recover punitive damages because they cannot show by clear and convincing evidence that NPC committed 'intentional misconduct' or acted with 'gross negligence.'" DE 61 at 19 (citing Fla. Stat. § 768.72). Because the Court finds that New Jersey law governs, it does not reach this argument.

Gen. Life Ins. Co., 53 F.3d 1228, 1234–35 (11th Cir. 1995). Here, there is a conflict between the punitive damages laws of New Jersey and Florida; Plaintiffs cannot recover punitive damages under New Jersey law but could under Florida law if they show by clear and convincing evidence that the defendant committed intentional misconduct or acted with gross negligence. *Compare* N.J. Stat. Ann. § 2A:58C-5 ("Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration."), *with* Fla. Stat. § 768.72 ("A defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence.").

Given the conflict, the Court must next determine which state's law to apply. Florida's conflict of law test utilizes the "significant relationship" test for torts. *See Bishop v. Fla Specialty Paint Co.*, 389 So. 2d 999 (Fla. 1980); *Lacy v. BP, PLC*, No. 11-civ-21855, 2015 WL 3952593, at *1–2 (S.D. Fla. June 29, 2015). This requires the Court to determine which state has the most significant relationship to the particular issue, punitive damages in this case. The Court is to consider the contacts in § 145 of the Second Restatement of Conflict of Laws, along with the general framework established in § 6. Section 145 instructs that the following contacts should be considered: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." Restatement (Second) of Conflict of Laws § 145 (1971). The significant relationship test utilizes the following framework:

> (1) A court, subject to constitutional restriction, will follow a statutory directive of its own state on choice of law.

> (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include:
>
> (a) the needs of the interstate and international systems,
> (b) the relevant policies of the forum,
> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
> (d) the protection of justified expectation,
> (e) the basic policies underlying the particular field of law,
> (f) certainty, predictability and uniformity of result, and
> (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6 (1971). In personal injury cases, the assumption is that the law of the place of injury governs, unless another state has a more significant relationship to the issue. Restatement (Second) of Conflict of Laws § 146 (1971).

The Court's analysis is about which state's law should govern the issue of punitive damages. "In a conflict-of-laws inquiry, the fact that one state has the greatest interest in applying its punitive damage rule to a particular dispute does not necessarily mean that the same state will have the greatest interest in applying its compensatory damage rule. . . . [T]he question of which state retains the greatest interest in applying its punitive damage rule should be analyzed separately from the question of which state retains the greatest interest in applying its compensatory damage rule." *Judge v. Am. Motors Corp.*, 908 F.2d 1565, 1571 n.6 (11th Cir. 1990).

The Court finds that New Jersey law applies to the issue of punitive damages. Several of the contacts in § 145, including the domicil of Plaintiffs and the place where the relationship between the parties is centered, point towards the application of Florida law. Several of the contacts, however, point towards the application of New Jersey law, including the domicil of Defendant and the place where the conduct causing the injury occurred.

The Court recognizes that the place of injury was Florida; thus, there is an assumption that Florida law applies. *See* Restatement (Second) of Conflict of Laws § 146. The Restatement, however, notes that "if the primary purpose of the tort rule involved is to deter or punish misconduct . . . , the state where the conduct took place may be the state of dominant interest and thus that of most significant relationship." Restatement (Second) of Conflict of Laws § 145, cmt. c. Punitive damages are designed to deter and punish the defendant; not to compensate the plaintiff. Accordingly, the state where the conduct took place—New Jersey—has a more significant relationship.

Plaintiffs argue that Defendant's conduct occurred in Florida in addition to New Jersey because Defendant marketed Tasigna in Florida to doctors, including to Mr. McWilliams's prescribing physician. The Court, however, agrees with Defendant that "the alleged sales and marketing strategies originated from NPC's New Jersey headquarters, and plaintiffs have not identified any way in which those strategies were implemented differently in Florida than in any other state." DE 75 at 11. Accordingly, New Jersey law applies to Plaintiffs' punitive damages claim. Because New Jersey law does not allow for punitive damages in this case, Defendant's Motion for Summary Judgment as to Plaintiffs' punitive damages claim is granted.

D. Plaintiffs' Loss of Consortium Claim

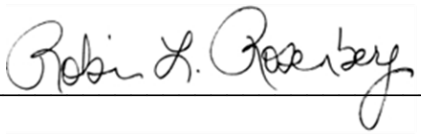
Defendant argues that Plaintiff Lori McWilliams's claim for loss of consortium must fail because it is derivative of Plaintiff Dennis McWilliams's substantive causes of action. As the Court denied Defendant's Motion for Summary Judgment as to Mr. McWilliams's substantive causes of action, it also denies Defendant's Motion for Summary Judgment as to Mrs. McWilliams's loss of consortium claim.

II. CONCLUSION

For the foregoing reasons, it is hereby **ORDERED AND ADJUDGED** that:

1. Defendant's Motion for Summary Judgment [DE 61] is **GRANTED IN PART AND DENIED IN PART**;
2. Defendant's Motion for Summary Judgment is granted as to Plaintiffs' request for punitive damages but is denied in all other respects.

DONE AND ORDERED in Chambers in West Palm Beach, Florida this 9th day of July, 2018.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE