

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Ft. Pierce Division

Case Number: 10-14285-CIV-MARTINEZ-LYNCH

TIMOTHY MARDEGAN, as Personal
Representative of the ESTATE OF
AUNALEISE NICOLE WILLIAMS,
Plaintiffs,

vs.

MYLAN, INC., MYLAN
PHARMACEUTICALS, INC., and MYLAN
TECHNOLOGIES, INC.,
Defendants.

**ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' PARTIAL
MOTION TO DISMISS**

THIS CAUSE came before the Court upon Defendants, Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc.'s Partial Motion to Dismiss (D.E. No. 11). Plaintiff Timothy Mardegan ("Plaintiff") has filed suit as personal representative of the estate his deceased daughter, Aunaleise Nicole Williams ("Williams"). Plaintiff filed suit, alleging that Defendants are responsible for the wrongful death of Williams after she used pain patches designed, manufactured and/or distributed by Defendants. Defendants Mylan Inc., Mylan Pharmaceuticals, Inc. and Mylan Technologies, Inc. ("Defendants") now move to dismiss certain claims asserted by Plaintiff. After careful consideration and for the reasons set forth below, the Court grants in part and denies in part Defendant's motion.

I. Relevant Factual and Procedural Background

Plaintiff has alleged that he is a citizen of the State of Florida, and that Williams was a citizen of Florida at the time of her death. (D.E. No. 1, Compl. at ¶ 1). Plaintiff alleges that

Defendant Mylan, Inc. is incorporated under the laws of Pennsylvania with its principal place of business in Pennsylvania but has done and is doing business in Florida. *Id.* at ¶ 2. Defendant Mylan Pharmaceuticals, Inc. is a subsidiary of Mylan, Inc. and is incorporated under the laws of West Virginia with its principal place of business in West Virginia but has done and is doing business in Florida. *Id.* at ¶ 3. Defendant Mylan Technologies, Inc. is also a subsidiary of Mylan, Inc. and is also incorporated under the laws of West Virginia with its principal place of business in Vermont. *Id.* at ¶ 4. Defendant Mylan Technologies, Inc. has done and is doing business in Florida. *Id.*

Plaintiff alleges that Williams was prescribed 50 mcg Mylan (fentanyl transdermal system) patches for pain by Dr. Marion L. Richardson. *Id.* at ¶¶ 9, 12. Plaintiff alleges that

[t]he Patch is applied by the patient and delivers fentanyl th[r]ough the patient's skin. The Defendants design, manufacture, market, and sell the Patch with the intention that it will release a certain amount of fentanyl into a patient at a certain rate, and thus produce a certain level of fentanyl in the blood of the patient. In other words, if a Patch functions as intended and it is properly used by the patient, the patient should not receive a harmful dose of fentanyl.

Id. at ¶ 11. Plaintiff states that Williams "never abused the Patch or used it inappropriately." *Id.* Williams was found dead on June 7, 2009. *Id.* at ¶ 12. At the time of her death, she had a fatal fentanyl blood concentration. *Id.*

On October 26, 2010, Plaintiff filed suit against Defendants alleging strict product liability, negligence, negligent misrepresentation, breach of express warranty, breach of implied warranty of fitness, and Florida wrongful death. Defendants have now moved to dismiss Plaintiff's claims for strict product liability, negligent misrepresentation, breach of express warranty, and breach of implied warranty of fitness pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim upon which relief can be granted.

II. Legal Standard on a Motion to Dismiss

When reviewing a complaint under Rule 12(b)(6), the court is limited to the four corners of the complaint and accepts all well-pleaded allegations as true, viewing the motion in the light most favorable to the non-moving party. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *St. George v. Pinellas Cnty.*, 285 F.3d 1334, 1447 (11th Cir. 2002). “Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1964 (2007) (quoting Fed. R. Civ. P. 8; *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Dismissal, however, is appropriate where “on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action.” *Marshall Cnty. Bd. of Educ. v. Marshall Cnty. Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993).

III. Analysis

Defendants have moved to dismiss Plaintiff's claims for strict product liability, negligent misrepresentation, breach of express warranty, and breach of implied warranty of fitness. The Court addresses each of these arguments in turn, but first addresses the parties' arguments relating to the applicable law.

A. Choice of Law

Defendant has argued that Florida law applies to this action while Plaintiff argues that either West Virginia or Vermont law applies to this action. “A federal court sitting in diversity will apply the conflict-of-laws rules of the forum state.” *Grupo Telvisa, S.A. v. Telemundo Communications Group, Inc.*, 485 F. 3d 1233, 1240 (11th Cir. 2007). Thus, here it is Florida law

that the Court applies to resolve the choice of law question. Under Florida law, choice of law questions are resolved “according to the ‘most significant relationship’ test outlined in the Restatement (Second) of Conflict of Laws.” *Id.*

Section 145 of the Restatement (Second) of Conflict of Laws provides the relevant test, stating that

(1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.¹

(2) Contacts to be taken into account in applying the principles of § 6 to determine

¹Section 6 of the Restatement (Second) of Conflict provides that

(1) A court, subject to constitutional restrictions, 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 expectations,
- (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.

the law applicable to an issue include:

- (a) the place where the injury occurred,
- (b) the place where the conduct causing the injury occurred,
- (c) the domicile, 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.

These contacts are to be evaluated according to their relative importance with respect to the particular issue.

As seen above, section 145 references issues of tort, however, this test is used to apply the more generalized factors in section 6, which “apply to all areas of law which determine choice of law through the most significant relationship test, not just issues of tort.” *Grupo*, 485 F. 3d at 1240.

Thus, this Court must determine which forum has the most significant relationship to the occurrence in light of the four factors listed above. First, the Court determines where the injury occurred. This is generally the “decisive consideration in determining the applicable choice of law.” *Bishop v. Fla. Specialty Paint Co.*, 398 So. 2d 999, 1001 (Fla. 1980). Here, the injury occurred in Florida. More specifically, Plaintiff has alleged that Williams was a resident of Florida and presumably was prescribed and used the patches here in Florida. More importantly, it is undisputed that Williams died in Florida. Thus, this factor weighs in favor of Florida.

Next, the Court must consider the place where the conduct causing the injury occurred. Here, Plaintiff has alleged that it was the design, manufacture, marketing, and selling of the patches that resulted in Williams’s death. It is not clear from the complaint where the patches were designed and manufactured. Plaintiff states in his response that the patches were designed and manufactured in Vermont. The Court assumes that the patches are marketed and sold in all

three states at issue. Moreover, it appears undisputed that the patches were bought in Florida by Williams after they were prescribed by her Florida physician. Thus, the Court finds this factor weighs in favor of both Vermont and Florida.

The Court also considers “the domicile, residence, nationality, place of incorporation and place of business of the parties.” Plaintiff is a resident of Florida. (D.E. No. 1, Compl. at ¶ 1). Williams, the decedent, was also a resident of Florida. *Id.* Plaintiff alleges that Defendant Mylan, Inc. is incorporated under the laws of Pennsylvania with its principal place of business in Pennsylvania but has done and is doing business in Florida. *Id.* at ¶ 2. Defendant Mylan Pharmaceuticals, Inc. is a subsidiary of Mylan, Inc. and is incorporated under the laws of West Virginia with its principal place of business in West Virginia but has done and is doing business in Florida. *Id.* at ¶ 3. Defendant Mylan Technologies, Inc. is also a subsidiary of Mylan, Inc. and is also incorporated under the laws of West Virginia with its principal place of business in Vermont. *Id.* at ¶ 4. Defendant Mylan Technologies, Inc. has done and is doing business in Florida. *Id.* Thus, the only state that all parties have a connection to is Florida. Accordingly, the Court also finds this factor supports applying Florida law as Florida is the only state to which all parties are connected.

Finally, the Court considers “the place where the relationship, if any, between the parties is centered.” Here, it again appears that the parties’ relationship is centered in Florida. It appears that Williams’s only contact with Defendants’ patches was in Florida where she was prescribed the patches, bought the patches, and eventually died allegedly as a result of using the patches. Accordingly, the Court finds that the state with the most significant relationship is clearly

Florida, and this Court will apply Florida law.² The Court now considers Defendants' arguments for dismissal.

B. Claims for Strict Product Liability and Negligent Misrepresentation

First, Defendants have moved to dismiss Plaintiff's claims for strict product liability and negligent misrepresentation for failure to state a claim upon which relief can be granted. Defendants argue that both of these claims are premised on Defendants' failure to warn Williams; however, Defendants argue that Florida applies the learned intermediary doctrine and does not require a prescription drug manufacturer to warn the ultimate user of consumer. In addition, with regard to Plaintiff's negligent misrepresentation claim, Defendants argue that this claim also must be dismissed because as Defendants had no duty warn Williams, Plaintiff will not be able to demonstrate that Williams relied on any alleged representations made by Defendants. The Court agrees in part with Defendants' arguments but will allow Plaintiff to file an amended complaint.

The Court agrees that Florida recognizes the learned intermediary doctrine, which provides that a prescription drug manufacturer's duty to warn of a drug's potential risks is "directed to the physician rather than the patient." *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989). "This is so because the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." *Id.* Thus, pursuant to this doctrine, a prescription drug manufacturer has a duty to provide "an adequate

²The Court disagrees with Plaintiff's argument that the choice of law analysis in this case is split or uncertain.

warning . . . to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.” *Buckner v. Allergan Pharmaceuticals*, 400 So. 2d 820, 822 (Fla. 5th DCA 1981).

Plaintiff responds that these claims should not be dismissed because the warnings provided to Williams’s physician were inadequate. In the complaint, Plaintiff alleges in his strict liability claim that it is in part based on a failure to warn. Plaintiff states in relevant part that

the Williams Patch was defective because it lacked adequate warnings and instructions. There was a risk of harm, which risk is inherent in the Patch or that may arise from the intended or reasonably foreseeable or scientifically discoverable at the time of the exposure. The Mylan Defendants, who exercised substantial control over the content of the warnings and/or instructions, knew, or should have known, of the risks at the time they marketed and sold the Williams Patch, but failed to provide adequate warning and/or instructions. **The Mylan Defendants also failed to adequately communicate to ultimate users, such as Decedent, warnings provided.** The absence of such warnings and/or instructions rendered the product unreasonably dangerous to ultimate users, like Decedent.

(D.E. No. 1, Compl. at ¶ 18) (emphasis added). Thus, in this claim, Plaintiff has alleged a failure to warn the ultimate users and not a failure to warn the physician in accordance with the learned intermediary doctrine. Thus, the Court will grant the motion to dismiss with regard to this portion of the strict liability claim. The Court, however, will allow Plaintiff to amend this claim to allege that Defendants failed to warn Williams’s physician if such allegations are supported by the facts in this case.

In the negligent misrepresentation claim, Plaintiff alleges that Defendants made misrepresentations to the “FDA, Decedent, physicians, pharmacists, as well as the general public.” (D.E. No.1, Compl. at ¶ 28(c)). It is clear that Plaintiff’s claim is too broad and under the learned intermediary doctrine Defendants did not have a duty to warn the general public or the Decedent based on the learned intermediary doctrine. Thus, the Court will also grant the

motion to dismiss as to this claim but again allow Plaintiff to amend this claim to limit its allegation.

Defendants also argue that because the learned intermediary doctrine requires the misrepresentation to have been made to Williams's physician, Williams could not have personally relied upon any of the alleged misrepresentations and cannot state a claim for negligent misrepresentation. Defendants are essentially asking this Court to find that where a plaintiff's negligent misrepresentation claim is based on a misrepresentation regarding a prescription drug, the cause of action is automatically barred by the learned intermediary doctrine. This Court disagrees. *See Lee v. Mylan, Inc.*, No. 5:10-CV-361 (MTT), 2011 WL 1458160, at *4 (M.D. Ga. April 15, 2011) (applying Georgia law, which also has adopted the learned intermediary doctrine, and finding that although the learned intermediary doctrine barred Plaintiff's negligent misrepresentation claims based on a failure "to provide accurate or sufficient information" to the plaintiff's mother it does not bar the plaintiff's claim in its entirety where plaintiff alleged that the defendants "failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/ or the general public that the use of this drug could cause serious injury and/or death."); (*Kline v. Pfizer, Inc.*, No. 08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008) (applying Pennsylvania law, which has also adopted the learned intermediary doctrine, and finding that a negligent misrepresentation claim survives a motion to dismiss where plaintiff alleges a negligent misrepresentation to a plaintiff's physician). Although it is the physician's reliance that will inform the inquiry under this claim, Plaintiff may still make such a claim. Accordingly, Defendants' motion to dismiss is granted as to these claims but leave to amend is also granted as detailed in the ordered and adjudged section below.

C. Claims for Breach of Express and Implied Warranty

Defendants also move to dismiss Plaintiff's claims for express and implied warranty. Defendants argue that under Florida law, a plaintiff must be in privity of contract with a defendant to recover for a breach of warranty and that Plaintiff has failed to allege the requisite privity. Plaintiff has responded arguing not that he can allege privity but that privity is not required. The Court grants Defendants' motion with regard to the implied warranty claim³ and denies it with regard to the express warranty claim.

First, it is clear that under Florida law a plaintiff may not recover on a breach of implied warranty claim absent privity of contract. In *West v. Caterpillar Tractor Company, Inc.*, the Florida Supreme Court found that "[i]f a user is injured by a defective product, but the circumstances do not create a contractual relationship with a manufacturer then the vehicle for recovery could be strict liability in tort. If there is a contractual relationship with the manufacturer, the vehicle of implied warranty remains." 336 So. 2d 80, 91 (Fla. 1976). In *Kramer v. Piper Aircraft Corp.*, the Florida Supreme Court clearly held that "the common law implied warranty claim for personal injury no longer exists under Florida law absent privity . . . where the remedy of strict liability is appropriate." 520 So.2d 37, 39 (Fla. 1988); *see also David v. American Suzuki Motor Corp.*, 629 F. Supp. 2d 1309, 1322-23 (S.D. Fla. 2009) (discussing in detail the evolution of Florida law as applied to implied warranty claims). Here, Plaintiff has not alleged privity of contract and appears to concede in his response that he cannot allege privity of

³In a footnote, Defendants have also argued that Plaintiff has particularly failed to state a claim for breach of implied warranty because Plaintiff cannot allege any of the elements required to support a claim for breach of implied warranty for a particular purpose. Because the Court finds that Plaintiff's claim for breach of implied warranty should be dismissed for other reasons the Court finds it unnecessary to address this alternative argument.

contract. Accordingly, Plaintiff's claim for breach of implied warranty is dismissed.

In contrast, the Court denies Defendants' motion to dismiss with regard to Plaintiff's breach of express warranty claim. Florida law with regard to express warranty claims and the requirement of privity is not as well-settled as the law that applies to breach of implied warranty claims. Although the Florida Supreme Court has never spoken on this issue, the Court acknowledges that several courts have held that absent privity there can be no claim for the breach of an express warranty. *See T.W.M. v. Am. Med. Sys., Inc.*, 886 F.Supp. 842, 844 (N.D. Fla.1995) (stating that "[t]he law of Florida is that to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant."); *Weiss v. Johansen*, 898 So. 2d 1009, 1011 (Fla. 4th DCA 2005) (stating that "in order to recover for the breach of a warranty either express or implied, the plaintiff must be in privity of contract with the defendant."); *Intergraph Corp v. Stearman*, 555 So. 2d 1282, 1283 (Fla. 2d DCA 1990) (stating that "[p]rivacy is required in order to recover damages from the seller of a product for breach of express or implied warranties."). Despite such case law, other courts applying Florida law have found exceptions allowing express warranty claims to proceed even absent privity. *See Fed. Ins. Co. v. Lazzarra Yachts of North Amer., Inc.*, No. 8:09-CV-607-T-27MAP, 2010 WL 1223126, at *6 (M.D. Fla. March 25, 2010) (applying Florida law and finding that a breach of express warranty claim could be brought under the Magnuson Moss Warranty Act despite a lack of privity and stating that "[c]ourts have relaxed the privity requirement where the express warranty was clearly intended to extend coverage to subsequent owners.") *Smith v. Wm. Wrigley Jr. Company*, 663 F. Supp. 2d 1336, 1343 (S.D. Fla. 2009) (applying Florida law and denying a motion to dismiss an express warranty claim on lack of privity based on "the particular facts of

the case”); *Rentas v. DaimlerChrysler Corp.*, 936 So. 2d 747, 751 (Fla. 4th DCA 2006) (allowing an express warranty claim to proceed despite the absence of privity and stating that “[t]his court and other Florida appellate courts have expressly enforced written warranties in suits brought under the [Magnuson-Moss Warranty Act] against manufacturers where privity did not exist between the manufacturer and the vehicle owner.”). Thus, the Court does not find that express warranty claims where there is a lack of privity are automatically barred under Florida law.⁴ Accordingly, the Court denies Defendants’ motion to dismiss as to this claim. Therefore, it is hereby:

ORDERED AND ADJUDGED that

Defendants, Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc.’s Partial Motion to Dismiss (D.E. No. 11) is **GRANTED in part** and **DENIED in part**. In accordance with the Court’s discussion above, the motion is granted in that Plaintiff’s claims for strict product liability and negligent misrepresentation are dismissed without prejudice, and Plaintiff’s claim for breach of implied warranty is dismissed with prejudice. Plaintiff may file an amended complaint **on or before August 16, 2011**. In the amended complaint, Plaintiff may attempt to replead his claims for strict product liability and negligent misrepresentation in accordance with the Court’s discussion above.⁵ In the amended complaint, however, Plaintiff may not assert any new claims, any other new allegations other than that referenced in the

⁴Such denial is without prejudice to Defendants filing a motion for summary judgment arguing that under the particular facts of this case there is no express warranty claim. Such an argument, however, will necessarily involve an examination of the facts and is not appropriately considered in a motion to dismiss.

⁵Plaintiff may not replead his breach of implied warrant claim. This claim is dismissed with prejudice.

discussion in this order, nor may Plaintiff add any new parties. The time to make such amendments to the complaint has passed and is not reopened by this order. *See* (D.E. No. 24 at 5). The Court will also extend the discovery deadline. The parties shall have until **August 29, 2011** to complete all discovery. No other deadlines are affected by this order and the Court's Scheduling Order (D.E. No. 24) remains in full force and effect. The motion to dismiss is denied in all other respects.

DONE AND ORDERED in Chambers at Miami, Florida, this 12 day of August, 2011.



JOSE E. MARTINEZ
UNITED STATES DISTRICT JUDGE

Copies provided to:
Magistrate Judge Lynch
All Counsel of Record