IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORDELIA YOCHAM, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	HON. JEROME B. SIMANDLE Civil No. 07-1810 (JBS/AMD) **OPINION**

APPEARANCES:

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SIMANDLE, District Judge:

I. INTRODUCTION

This products liability matter is before the Court on Defendant's motion for summary judgment under Rule 56(c)(2), Fed. R. Civ. P. [Docket Item 51], and Plaintiff's motion to continue under Rule 56(f), Fed. R. Civ. P. [Docket Item 57]. The principal issues to be decided are whether Texas or New Jersey substantive law will apply to Plaintiff's various claims; what

consequences that state's law will have for whether Plaintiff states a claim under her various cases of action, including whether Plaintiff's failure-to-warn claim is foreclosed because the only available exception to a statutory defense of FDA-approval is preempted by federal law; and whether Plaintiff is entitled to a continuance to take further discovery before opposing the motion. For the reasons explained in today's Opinion, the Court finds that Plaintiff is not entitled to a continuance, that Texas law applies to all of Plaintiff's claims, and that Texas law forecloses some of those claims.

II. BACKGROUND

In 2005, Plaintiff, Cordelia Yocham, was prescribed Lamisil, a prescription antifungal medication to treat her onychomycosis, a fungal nail infection. (Yocham Dep. 141:1-11, 150:12-151:25.) Ms. Yocham alleges that she developed Steven-Johnson Syndrome, a painful and potentially life-threatening medical condition, as a result of having used the Lamisil. (Compl. ¶¶ 10-13.) Lamisil is manufactured and distributed by Defendant, Novartis Pharmaceuticals Corporation, and it is approved by the United States Food and Drug Administration (FDA) as a safe and effective treatment for "onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium)." (Falletta Cert., Ex. B "FDA Approval Letter.") The FDA also approved of the drug's labeling,

and Lamisil remains on the market as an FDA-approved drug. (Id.)

On February 20, 2007, Plaintiff's counsel sent a letter to Defendant threatening a personal injury suit without indicating the nature of the legal claims, followed by copies of Plaintiff's Lamisil prescription, medical records, and photographs of her injuries. (Maloney Cert. Exs. A-C.) Plaintiff then filed this action against Defendant in the Superior Court of New Jersey on April 5, 2007 and Novartis timely removed the action to this Court on April 17, 2007. [Docket Item 1.] Plaintiff's Complaint asserts claims of negligence (Count I), strict liability (Count II), breach of express warranty (Count III), breach of implied warranty (Count IV), fraudulent misrepresentation (Count V), negligent and reckless misrepresentation (Count VI), unjust enrichment (Count VII), defective design and failure to warn under the New Jersey Product Liability Act (Counts VIII and IX), and a New Jersey Consumer Fraud Act claim (Count X).

Ms. Yocham resides in Bollinger, Texas and has lived there since 1966. (Yocham Dep. 42:8-13.) She never sought treatment in New Jersey, and indeed has never been to New Jersey. (Id. 315:3-6.) Ms. Yocham has never had contact with Defendant, never instructed anyone to contact Defendant on her behalf regarding Lamisil or her injuries prior to this lawsuit, and has never seen any literature or written material from Defendant regarding Lamisil. (Yocham Dep. 302:20-304:10.) Defendant is a Delaware

corporation with its principal place of business in New Jersey. (Def.'s Response to Pl.'s Statement of Material Facts.)

Defendant argues that Texas law should govern this case because the drug was prescribed in Texas to a resident of Texas, who received or failed to receive any information about the drug in Texas, and who ingested and was allegedly injured by the drug in Texas. Defendant maintains that Texas law forecloses all of Plaintiff's causes of action.[1] Plaintiff argues that New Jersey law should apply because that is where the drug was researched and where information about the drug was compiled, and that even if Texas law applies, some of her claims are still viable. Finally, Plaintiff asks for a continuance to further develop the evidentiary record, a motion which Defendant opposes.

III. DISCUSSION

A. Summary Judgment Standard

Summary judgment is appropriate when the materials of record "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of

[1] Although Defendant asks for summary judgment as to all of Plaintiff's claims, Defendant does not address Count I (Negligence) or Count II (Strict Liability). It appears that the elements of these claims may substantially overlap with the claims addressed in this motion, but the Court is not prepared to grant or deny summary judgment as to these counts without any argument from the parties as to whether or not these counts have any basis independent from the other counts.

law." Fed. R. Civ. P. 56(c)(2). A fact is "material" only if it might affect the outcome of the suit under the applicable rule of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Summary judgment will not be denied based on mere allegations or denials in the pleadings; instead, some evidence must be produced to support a material fact. U.S. v. Premises Known as 717 S. Woodward Street, Allentown, Pa., 2 F.3d 529, 533 (3d Cir. 1993). However, the court will view any evidence in favor of the nonmoving party and extend any reasonable favorable inferences to be drawn from that evidence to that party. Hunt v. Cromartie, 526 U.S. 541, 552 (1999).

On this motion, the Court takes to be true the facts identified by Defendant as undisputed. This is because Local Civil Rule 56.1(a) requires a summary judgment movant to furnish a Statement of Material Facts not in Dispute citing to evidence in the record, which Defendant in this case did. This rule then requires the non-movant to furnish, with his opposition papers, a responsive Statement of Material Facts addressing each paragraph of the movant's statement, indicating agreement or disagreement and, if not agreed, stating each material fact in dispute and citing to affidavits or other documents in the record of the motion. L. Civ. R. 56.1(a). Plaintiff did not include any response to Defendant's statement of undisputed material facts, and instead offered her own statement discussing separate facts,

to which Defendant duly responded in accordance with the Rule. The local rule provides that "any material fact not disputed shall be deemed undisputed for purposes of the summary judgment motion." Id. This Court has prescribed this procedure because it is necessary to determine under Rule 56(c), recently amended as Rule 56(c)(2), whether there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Rule 56(c)(2), Fed. R. Civ. P. As L. Civ. R. 56.1 now explicitly provides, the consequence of the opponent's failure to address the movant's Statement of Material Facts not in Dispute has long been clear, namely, the movant's facts, duly cited to the record of evidence, are deemed unopposed for purposes of adjudicating the motion. See, e.g., White v. Camden City Bd. of Educ., 251 F. Supp. 2d 1242, 1246 n. 1 (D.N.J. 2003), aff'd, 90 Fed. App'x 437 (3d Cir. 2004). Therefore, to the extent they are supported by record evidence, the facts identified by Defendant as undisputed will be taken as such.

B. Motion to Continue

Rule 56(f) provides that "[i]f a party opposing the motion shows by affidavit that, for specific reasons, it cannot present facts essential to justify its opposition, the court may . . . order a continuance," among other possible forms of relief. 56(f)(2), Fed. R. Civ. P. The Rule requires "that a party

seeking further discovery in response to a summary judgment motion submit an affidavit specifying, for example, what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained." Dowling v. City of Philadelphia, 855 F.2d 136, 140 (3d Cir. 1988). Plaintiff seeks a continuance, arguing that discovery is incomplete.

The motion will be denied because Plaintiff neither provides an affidavit nor otherwise specifies why the information sought in discovery is necessary to enable her to oppose Defendant's motion. See id. ("Dowling did not file a Rule 56(f) affidavit with her response to the City's motion for summary judgment, and therefore, as a procedural matter alone, she has failed to comply with the rule."). The only facts at issue in this motion are those related to the choice of law and the nature of the notice given to Defendant regarding Plaintiff's warranty claims. Plaintiff does not seek discovery on either matter, and indeed there is no dispute over those facts. Perhaps for that reason, while Plaintiff specifically identifies the discovery materials she seeks — papers submitted to the FDA for the approval of Lamisil and a report generated pursuant to the approval process — Plaintiff does not explain how this information would be useful in opposing the present motion. The motion to continue will be denied because Plaintiff has not complied with either the

procedural or substantive requirements of Rule 56(f).

C. Choice of Law

1. Standard

In a diversity case filed in New Jersey, New Jersey choice of law rules govern. See Lebegern v. Forman, 471 F.3d 424, 428 (3d Cir. 2006). In tort cases, New Jersey follows the "most significant relationship" test adopted in the Restatement (Second) of Conflict of Laws as well as the Restatement's default rule that the location of the injury in tort cases determines the law to be applied unless some other location has a more significant relationship. P.V. ex rel. T.V. v. Camp Jaycee, 962 A.2d 453, 460 (N.J. 2008); Restatement (Second) of Conflict of Laws § 146 (1971). In their briefing on this motion, the parties both apply this test to all of Plaintiff's claims. Except for the express warranty claim, this is undoubtedly correct, because all the other claims are considered torts. See Tex. Civ. Prac. & Rem. Code Ann. § 82.001(2) (providing rules for liability in tort for breach of implied warranty and misrepresentation claims); N.J. Stat. Ann. 2A:58C-1(3) (same).

With respect to the express warranty claim, which sounds in contract, the default rule specific to tort law found in the Restatement does not apply as the parties, perhaps inadvertently, suggest. The extent to which the rest of the Restatement applies

is not as clear as in the area of tort, but the Court will apply the Restatement's rules for choice-of-law in contract claims. See Payne v. FujiFilm U.S.A., Inc., Civil Action No. 07-385 (GEB), 2010 WL 2342388, at *6 (D.N.J. May 28, 2010) (citing Agostino v. Quest Diagnostics Inc., 256 F.R.D. 437, 461 (D.N.J. 2009) (Chesler, J.) (applying same test to contract claim)). Although the New Jersey Supreme Court has not explicitly adopted the Restatement's test for contract claims, New Jersey courts have regularly applied the "most significant relationship" test to such claims. See Gilbert Spruance Co. v. Pennsylvania Mfrs. Ass'n Ins. Co., 629 A.2d 885, 888 (N.J. 1993) (citing State Farm Mut. Auto. Ins. Co. v. Simmons' Estate, 417 A.2d 488 (N.J. 1980)).

The Court therefore applies the Restatement's "most significant relationship" test to all the claims. For the tort claims, the Restatement provides that the case will be "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." § 145. The default rule contained in § 146 of the Restatement provides that "the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated

in § 6 to the occurrence and the parties." § 146; Camp Jaycee, 962 A.2d at 461. The standard for contract claims is identical, except the word "transaction" is substituted for "occurrence," § 188, and there is no similar default rule regarding the location of the injury.

Ultimately, both tests involve the significance of the states' relations to the parties and events in light of the principles contained in § 6 of the Restatement, which lists several factors relevant to the choice of law analysis that when "reduced to their essence . . . are: (1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." Camp Jaycee, 962 A.2d at 463 (internal quotation and citations omitted); § 6.

2. Actual Conflict

Before proceeding to the choice of law analysis, the Court must first determine that the state laws are in conflict. Camp Jaycee, 962 A.2d at 460. As the parties concede, there is an actual conflict between the laws of New Jersey and Texas as to each of Plaintiff's claims at issue in this motion. With respect to the failure-to-warn claim, both states have statutes codifying presumptions that warnings approved by the FDA are adequate.

N.J. Stat. Ann. § 2A:58C-4; Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b). But in Texas, the ways this presumption can be overcome are enumerated by the statute, and in this case appear to be limited to a showing that "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." § 82.007(b)(1).

Additionally, Texas, unlike New Jersey, does not permit design defect claims for prescription drugs with otherwise adequate warnings. Compare Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) with Feldman v. Lederle Laboratories, 479 A.2d 374, 382 (N.J. 1984). Conversely, in New Jersey, common law breach of implied warranty and fraud claims are subsumed by the New Jersey Product Liability Act, which creates the sole statutory cause of action for such claims. See Brown ex rel. Estate of Brown v. Philip Morris Inc., 228 F. Supp. 2d 506, 515 (D.N.J. 2002); Reiff v. Convergent Technologies, 957 F. Supp. 573, 583 (D.N.J. 1997).

Finally, while both Texas and New Jersey have adopted the provision of the Uniform Commercial Code requiring notification of breach of warranty, New Jersey courts have held that filing a complaint can serve as adequate notice to satisfy this provision,

Cipollone v. Liggett Group, Inc., 683 F. Supp. 1487, 1498 (D.N.J. 1988) (collecting cases), while Texas courts require notice to be given before suit is filed. See Martin v. Home Depot U.S.A., Inc., 369 F. Supp. 2d 887, 893 (W.D. Tex. 2005) ("[I]t is undisputed Plaintiffs did not give the requisite notice prior to filing suit. Thus, Plaintiffs' express warranty claim fails.").

3. Tort Claims

Having established that the choice of law does make a difference, the question for the tort claims is whether New Jersey has a more significant relationship to the tort and the parties than Texas, the location of injury. § 146. Plaintiff argues that the fact that the injury occurred in Texas was merely fortuitous because the drug is marketed everywhere, and that the conduct causing the injury occurred in New Jersey. Neither proposition is correct as a matter of law, and as discussed below, New Jersey does not have a more significant relationship to the tort than Texas has.

The location of injury in this case was not fortuitous, as that term is used in choice-of-law doctrine. An injury being fortuitous does not mean that the injury-causing conduct did not determine the site of the injury, which is what Plaintiff argues. Instead, "[t]he place of the injury is fortuitous when 'it bears little relation to the occurrence and the parties with respect to

the particular issue.'" Camp Jaycee, 962 A.2d at 463 (quoting § 145 comment e). The Restatement's example of a fortuitous place of injury involves the purchase of an airline ticket to fly from one part of a state to another part, which route happens to overfly a second state, where the plane crashes. § 146 Comment d. In such an instance, although the injury occurred in the second state, that state has no relationship to the parties, and the only relationship to the occurrence is mere chance. See Fu v. Fu, 733 A.2d 1133, 1149 (N.J. 1999) ("The place of an accident, however, may be considered fortuitous only when the driver did not intend or could not reasonably have anticipated being in that jurisdiction at the time of the accident.") In other words, in order to be fortuitous, it must not only be the case that the conduct did not determine the location of the injury — which is true in the great majority of products liability cases — but also that the intentions and decisions of the parties also did not determine it with respect to this particular plaintiff. See Calhoun v. Yamaha Motor Corp., U.S.A., 216 F.3d 338, 347 (3d Cir. 2000) (noting that because the Plaintiff intentionally traveled to Puerto Rico "there was no possibility that Natalie's [boating] accident could have occurred anywhere other than in Puerto Rico."). Where a party is domiciled in the place of injury, purchases the allegedly defective product there, and uses it only there, the place of

injury is not fortuitous. As in Calhoun, in this case Plaintiff's injury could not have occurred anywhere other than Texas. It was not fortuitous that Plaintiff was injured in Texas, her state of residence.

In addition to the injury having occurred in Texas, the conduct causing injury in a prescription drug products liability case, including failure to warn and warranty cases, occurs primarily where the injured party was prescribed and ingested the drug. See Cornett v. Johnson & Johnson, --- A.2d ----, 2010 WL 2867811, at *6 (N.J. Super. Ct. App. Div. July 23, 2010) (citing Bearden v. Wyeth, 482 F. Supp. 2d 614, 620 (E.D. Pa. 2006)). See also Montgomery v. Wyeth, 540 F. Supp. 2d 933, 944 (E.D. Tenn. 2008); Bortell v. Eli Lilly and Co., 406 F. Supp. 2d 1, 5 (D.D.C. 2005). In this case, Plaintiff or her doctor received or failed to receive any representations, warranties, or warnings in Texas, and Plaintiff ingested the drug that allegedly caused her injury in Texas. The Court previously acknowledged that some of the relevant conduct, research of the drug's safety, did occur in New Jersey. But the more relevant conduct at issue is what Defendant revealed to Plaintiff and her doctor about the drug, conduct which occurred, if at all, in Texas. For similar reasons, the parties' relationship is also centered in Texas. Bearden, 482 F. Supp. 2d at 620; Bortell, 406 F. Supp. 2d at 5.

Because the injury non-fortuitously occurred in Texas as a

result of conduct mostly if not exclusively occurring in Texas which was the center of the parties' relationship, the only factor that conceivably weighs against Texas as the state with the "most significant relationship" is Defendant's presence in New Jersey. But even if Plaintiff were not a domiciliary of Texas, more or less mooting this factor, Defendant's New Jersey presence would not outweigh all of the other connections to Texas.

Returning to the ultimate question of the significance of the states' relations to the parties and events in light of the principles contained in § 6 of the Restatement, it is clear that Texas has the more significant relationship. Applying the older governmental interest test, the New Jersey Supreme Court found in a case with a nearly identical choice of law question that the interests of comity, the interests of the parties, the purposes of this field of law, and the respective governmental interests favored the state where the party was allegedly injured by a defective prescription drug. Rowe v. Hoffman-La Roche, Inc., 917 A.2d 767, 776 (N.J. 2007) ("To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in this State's courts completely undercuts Michigan's interests, while overvaluing our true interest in this litigation."); see also

Burleson v. Liggett Group Inc., 111 F. Supp. 2d 825, 829 (E.D. Tex. 2000). The same is true in this case, and therefore Texas law applies.

4. Express Warranty Claim

The analysis of which state has the more significant relationship to the parties and the transaction is largely unchanged with respect to the express warranty claim. Even without the default rule that the location of injury will be the state law that applies, Texas clearly has a more significant relationship to this action than New Jersey.[2] If Plaintiff was offered and accepted the terms of an express warranty, she did so in Texas, where she or her insurance paid the consideration for the product and warranty, and where she was allegedly injured in breach of the warranty. At most, the drafting of the terms would have occurred in New Jersey, which, similar to the research of the drug occurring in New Jersey, does not make New Jersey the state with the most significant relationship to the transaction.

[2] Indeed, the default rule will very rarely make a difference, since it merely provides that the location of injury will provide the law of the case unless some other location has a more significant relationship, essentially restating the more general rule that the state with the most significant relationship to the occurrence will determine the law of the case. The choice-of-law result is only altered by the default rule in cases in which the location of injury has a perfectly equal relationship to the tort as some other state.

D. Preemption of Exception to the Failure-to-warn Defense

Defendant argues that under Texas law it is entitled to a statutory defense to Plaintiff's failure-to-warn claim based on FDA approval of the warnings. Defendant also maintains that the only available exception to the defense, a showing that the FDA has been misled, is preempted by federal law. As explained below, while a tort based exclusively on fraud on the FDA is preempted by federal law, the exception contained in the Texas statute providing a defense to traditional tort claims is not preempted. Summary judgment as to this claim will therefore be denied, as explained below.

1. The Texas Statute

Texas law provides for a defense to liability in failure-to-warn cases involving pharmaceutical products based on the FDA's approval of the drug's labeling:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act

> (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended.

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a). The defense of FDA approval contains several exceptions, and the defendant may nevertheless be found liable if the claimant can establish that "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." § 82.007(b)(1). The term "required information" refers to information required under federal statute and regulations. See Ledbetter v. Merck & Co., Nos. 2005-59499, 2005-58543, 2007 WL 1181991, at *3 (Tex. Dist. Ct. April 19, 2007).[3]

2. FDA Regulations and the *Buckman* Opinion

Under the Supremacy Clause of the United States Constitution, certain kinds of conflict between state and federal laws render the state law unconstitutional. See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-48 (2001). Because the exception to the Texas statutory defense requires the

[3] The Court defers to this Texas court's interpretation of the Texas statute, but not the Texas court's conclusions of constitutional law.

claimant to prove that certain information was required by the FDA and either not provided or misrepresented, Defendant argues that the exception is preempted because it would interfere with the FDA's interpretation and enforcement of its own reporting requirements, and therefore the exception should be severed from the rest of the statute.[4]

The United States Supreme Court has held that traditional product liability torts are not preempted by federal laws governing approval of prescription drugs, Wyeth v. Levine, 129 S.Ct. 1187 (2009), but that torts premised solely on violations of those federal laws are preempted because they "exert an extraneous pull on the scheme established by Congress." Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). The question for this Court is whether Buckman or Wyeth controls this middle case in which a state chooses to require a traditional product liability tort claimant to prove a violation of the federal drug regulations, as one element among others, in order to overcome a defense based on FDA approval of the drug.

In Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), the Supreme Court held that a state court cause of action for injuries caused by misrepresentations made to the FDA was impliedly preempted by the Federal Food, Drug, and Cosmetic Act

[4] Defendant does not argue that Plaintiff cannot prove that the exception applies. Defendant's only argument with respect to the failure-to-warn claim is that the exception is preempted.

(FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, 21 U.S.C. § 301. Id. at 343. The Court began by dispensing with the presumption against preemption that ordinarily applies in cases examining conflict with a federal statute in which the state is regulating a traditional state interest. See Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) ("In all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (internal quotations and citations omitted). The Buckman court found that the presumption against preemption did not apply to a cause of action that was "[p]olicing fraud against federal agencies," since the state has no traditional interest in the relationship between companies and federal agencies. 531 U.S. at 347.

The Court used this fact to distinguish Medtronic, which had held that claims that a defendant had breached common law duties by violating FDA regulations were not preempted by an express provision of the FDA's governing statute. 518 U.S. at 495. The Supreme Court in Buckman wrote that the fraud-on-the-FDA tort at issue in Buckman would not exist but for the federal statute, emphasizing that, unlike in Medtronic, which involved an ordinary

common law claim premised in part on violation of the FDA rules, "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question." Buckman, 531 U.S. at 352-53.

Having determined that the presumption did not apply to fraud-on-the-FDA claims, the Court proceeded to analyze whether allowing the existence of such torts interfered with the federal scheme governing approval of medical devices. Id. at 349. The Supreme Court reasoned that permitting such a tort, based on overlapping and potentially contradictory state interpretations of what was required to be submitted to the FDA, might harm the FDA's careful balancing of competing interests in the approval of medical technology. Id. at 350. Specifically, permitting such torts would interfere with the federal scheme for two reasons. First, exposure to tort liability based on violation of the reporting requirements might discourage companies from submitting useful devices for approval. Id. Second, companies that did decide to submit devices for approval might respond to "fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" by submitting "a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." Id. at 352. The Supreme

Court found that these possible forms of interference were sufficient to find the tort preempted. Id.

3. The Texas Statute is not Preempted

The Circuit Courts of Appeals that have addressed the issue are split over whether federal law preempts the middle case of a traditional tort that also requires proof of fraud on the FDA, and the Third Circuit has not yet addressed the issue. Compare Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961 (6th Cir. 2004) (finding fraud-on-the-FDA exceptions to statutory defenses to be preempted) with Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006) (finding such exceptions not preempted). The Second Circuit opinion in Desiano is the more persuasive of the competing precedents, and the Court finds that Buckman does not apply to the kind of exception in question in this case.

In Garcia, the Sixth Circuit Court of Appeals considered the constitutionality of a Michigan statute that provides for immunity if a drug and its labeling were FDA-approved, with an exception for when the drug company "intentionally withholds from or misrepresents [to the FDA] information concerning the drug that is required to be submitted under [the FDCA], and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." Garcia, 385 F.3d at 965;

Mich. Comp. Laws § 600.2946(5).[5] Citing Buckman, the plaintiff in Garcia had argued that the statute providing the defense was unconstitutional because it required her to prove fraud on the FDA as part of her cause of action against the defendant. Id. Both the district court and Court of Appeals held that the fraud-on-the-FDA exception to the general statutory immunity was preempted by federal law, but that the exception was severable and the general statutory immunity should remain in force. Id.

Neither the Court of Appeals' opinion in Garcia nor the district court opinion it was reviewing examined the rationale of Buckman in great detail in deciding that it extended to the Michigan statute. Although conceding that Buckman addressed a distinguishable factual situation involving a fraud-on-the-agency tort, the Court of Appeals merely adopted the district court's conclusory holding that the exception was preempted because "'Buckman teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.'" Id. at 965-66 (quoting Garcia v. Wyeth-Ayerst Laboratories, 265 F. Supp. 2d 825, 832 (E.D. Mich.

[5] Although the Michigan statute characterizes the FDA-approval provision as a defense, and the Texas statute characterizes it as a rebuttable presumption, the two statutes are functionally identical. The Texas statute does not use the term presumption in the ordinary sense of an evidentiary presumption, Kenneth S. Broun, 2 McCormick On Evid. § 342 (6th ed.), but instead as a kind of default rule for liability with an exception.

2003)). Both Garcia courts apparently took it to be obvious that Buckman forecloses not only fraud-on-the-FDA torts but also ordinary common law torts for which proof of fraud on the FDA is needed to overcome the state's deference to FDA findings.[6]

Considering the same Michigan statute two years later, the Second Circuit Court of Appeals came to the opposite conclusion. Desiano, 467 F.3d at 98.[7] The Court in Desiano found that Buckman did not extend to a tort for which an exception to a statutory affirmative defense involved such misrepresentation or omission. This is because, as the Desiano court explained, Buckman itself relied on the distinction between a tort based solely on fraud on the FDA and other torts. As explained below, the distinction between a fraud-on-the-FDA tort and a traditional common law tort that must prove fraud to overcome an affirmative

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[6] The district court cases cited by Defendant in support of the rule in Garcia are similarly unpersuasive. Some of them are from districts in the Sixth Circuit, and therefore had no occasion to review the reasoning in Garcia, and most were decided prior to Desiano and Wyeth. Of those not controlled by Garcia and which considered Desiano, none offers reasoning for following Garcia beyond conclusory statements that Buckman's concerns apply to traditional torts with added-on fraud elements, and none addresses the actual reasoning given by Desiano for distinguishing Buckman. See, e.g., Lofton v. McNeil Consumer & Specialty Pharmaceuticals, 682 F. Supp. 2d 662 (N.D. Tex. 2010); Ledbetter v. Merck & Co., Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Tex. Dist. Ct. April 19, 2007).

[7] The Second Circuit opinion was ultimately affirmed by the Supreme Court in Warner-Lambert Co., LLC v. Kent, 552 U.S. 440 (2008). But because the affirmance was the result of a 4-4 per curiam order, it is not controlling. Hertz v. Woodman, 218 U.S. 205, 213-14 (1910).

defense means that, unlike in Buckman, the presumption against preemption applies. The distinction also diminishes the Supreme Court's concerns about conflict between the state and federal law.

a. Presumption Against Preemption

The presumption against preemption is a presumption about Congressional intent based on the notion that Congress does not lightly intrude into areas of traditional state control, and therefore a finding of preemption requires the "clear and manifest purpose of Congress." Medtronic, 518 U.S. at 485. There are different degrees of conflict between federal and state laws, varying from minor interference resulting from overlapping obligations to the impossibility of complying with both laws simultaneously. When federal law does not affect states' regulation of their traditional interests, there is no federalism justification for any degree of state interference with the federal scheme. Thus, concern about "an extraneous pull on the scheme established by Congress" is sufficient to find preemption. Buckman, 531 U.S. at 353. When the federal law does affect the state's regulation of its traditional interests, the assumption is that Congress tolerates some degree of interference because of "respect for the States as 'independent sovereigns in our federal system,'" and that Congress would not intend to preempt the state

law absent more direct interference. Wyeth, 129 S.Ct. at 1195 n.3 (quoting Medtronic, 518 U.S. at 485).

Buckman relied on the fact that the state was not regulating in a field which the States have traditionally occupied by providing for a fraud-on-the-FDA tort. Buckman, 531 U.S. at 347. In Buckman, the plaintiff was arguing that any misrepresentation to the FDA can cause liability in itself because a device's approval is a but-for cause of injury from the device. 531 U.S. at 343. Unlike Buckman, the case before this Court involves a traditional state tort narrowed by a state statute such that liability still requires proving that the drug manufacturer failed to meet a state common law duty to warn about the harm actually experienced in addition to proving a misrepresentation or omission to the FDA. Texas law imposes the duty to warn only when injury is likely to result from the manufacturer's failure to warn, see Humble Sand & Gravel, Inc. v. Gomez, 146 S.W.3d 170, 192 (Tex. 2004), a more limited liability distinct from one in which any insufficient or incorrect information about a product is given to the FDA.

This distinction is crucial because it means that the Texas statute is not regulating a company's interaction with a federal agency, but instead deferring to the FDA findings in all but exceptional circumstances in order to narrow its traditional tort duties. Desiano, 467 F.3d at 93-94. It is one of the ways that

Buckman itself distinguished Medtronic in finding that the presumption did not apply. 531 U.S. at 352-53. Buckman did not apply the presumption against preemption because, as the Supreme Court in Wyeth clarified and as the Second Circuit recognized in Desiano, Buckman "involved state-law fraud-on-the-agency claims." Wyeth v. Levine, 129 S.Ct. 1187, 1195 n.3 (2009). In a Buckman situation, With a standalone fraud-on-the-agency claim, the only conduct being regulated by the state is a defendant's interaction with a federal agency. In that circumstance, the state has no traditional interest in policing fraud on a federal agency, and there is therefore no federalism justification for any degree of state interference with the federal scheme regulating such fraud. However, when a state determines that it will defer to the FDA's findings that coincide with findings related to overlapping but pre-existing and more extensive common law duties, the matter falls at least partially within the realm of the regulation of traditional state interests.

Garcia and the cases following it appear to focus on the wrong factual distinction between the fraud-on-the-FDA tort in Buckman and the state statutes setting up FDA approval defenses. Those cases address the distinction in what must be proved between a tort with a sole required element of fraud on the FDA and an exception to an affirmative defense requiring such proof. See, e.g., Garcia v. Wyeth-Ayerst Laboratories, 265 F. Supp. 2d

at 831. They are correct in determining that this is a distinction without a difference, since in either case the party must show that the FDA was misled. But this is not the critical distinction identified in Buckman, which is the difference between a cause of action for which the sole conduct element is fraud on the FDA, so that "they would not be relying on traditional state tort law which had predated the federal enactments in question," Buckman, 531 U.S. at 352-53, and a traditional state tort cause of action for which this showing is but one among others.

b. Diminished Conflict

This difference between a standalone fraud-on-the-agency tort and the Texas statute's traditional tort with a fraud exception to an affirmative defense matters not only to whether the presumption against preemption should apply, but also to the extent of conflict with the federal regime. In essence, under the Texas statute, a pharmaceutical manufacturer may have given an inadequate warning to a plaintiff under traditional state tort law but escape liability so long as it gave the FDA-approved warning, unless the plaintiff also proves that the defendant withheld or misrepresented to the FDA required, material, and relevant information about the performance of the drug in a manner that was causally related to plaintiff's injury. Instead

of relying on the federal agency regulation to create liability, the Texas statute merely defers to those guidelines in creating a limited defense. When proof that the FDA was misled is not the sole conduct element to be proved, the incentives created by requiring this proof are different. The risk that companies will avoid submitting drugs for approval because they might be found liable for violating reporting requirements, and the related risk that companies will drown the FDA in information for those drugs they do choose to submit, are substantially lessened when state tort liability also requires violation of the independent and narrower state duty to warn. With a standalone fraud-on-the-FDA tort, unlike the present case, there is a much higher incentive to avoid any such misrepresentation since there is no fallback defense based on the actual adequacy of the drug's ultimate labeling.

As Desiano points out, regardless of any statute requiring proof of fraud on the FDA to overcome a defense, parties seeking to prove traditional state torts will still try to prove that the FDA was defrauded because it is relevant to what risks were foreseeable and persuasive to jury members. Desiano, 467 F.3d at 97. Consequently, "[r]equiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive." Id. Given the background incentives that are always present so long as misrepresentations

made to the FDA are relevant evidence in a product liability case, the only way to make sense of the concern in Buckman is to understand it to be about the unique increase in incentive created by a tort in which the sole conduct element was such misrepresentation to the FDA. Not surprisingly, identifying the unique incentives created by a standalone fraud-on-the-FDA tort was precisely the position the pharmaceutical appellant articulated at oral argument in Buckman. Desiano, 467 F.3d at 95-96.

The position advanced in Garcia and the cases following it is that regardless of whether proof of fraud on the FDA is the sole element or one of several, having state courts interpret what the FDA requires will interfere with the federal scheme. But those cases fail to account for the difference in incentives created by a standalone fraud-on-the-FDA tort and a traditional tort that must prove fraud to overcome a defense. Absent some actual effect on interactions between drug companies and the FDA caused by the state statute, such as causing the withholding of products or the deluge of information forecast by Buckman, having state courts interpret what information is required by FDA regulations does not interfere with the federal scheme. Thus, since having fraud-on-the-FDA as an added element of a traditional tort claim does not substantially alter the incentives companies have in engaging in the reporting process,

there is no interference with the federal scheme sufficient to overcome the presumption against preemption.

4. Summary

The Court holds that the presumption against preemption applies to the Texas tort reform statute, Tex. Civ. Prac. & Rem. Code Ann. § 82.007, which narrows common law tort duties by deferring to FDA findings when the FDA has not been defrauded. This is so because, unlike a tort for fraud-on-the-agency, the Texas statute involves regulation of traditional state interests. In light of this presumption against preemption, and because the Texas statute, again unlike a standalone tort for fraud-on-the-FDA, does not significantly alter the incentives for whether and how drug companies choose to submit products for FDA approval, the statute is not preempted by the FDCA.

E. Express and Implied Warranty Claims

Defendant argues that it is entitled to summary judgment on Plaintiff's warranty claims because Plaintiff failed to provide the notice required under Texas law. The Texas implementation of the Uniform Commercial Code provides, "Where a tender has been accepted . . . the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Tex. Bus. & Com. Code

Ann. § 2.607(c)(1). Under the Texas interpretation of this law, the notice required by § 2.607 must, at a minimum, be given before the suit is filed. See Martin v. Home Depot U.S.A., Inc., 369 F. Supp. 2d 887, 893 (W.D. Tex. 2005) ("[I]t is undisputed Plaintiffs did not give the requisite notice prior to filing suit. Thus, Plaintiffs' express warranty claim fails.").

The notice need not be detailed, and is merely to inform the seller that something is amiss with the particular transaction, as comment D to the Uniform Code explains:

> The content of the notification need merely be sufficient to let the seller know that the transaction is still troublesome and must be watched. There is no reason to require that the notification which saves the buyer's rights under this section must include a clear statement of all the objections that will be relied on by the buyer, as under the section covering statements of defects upon rejection (Section 2-605). Nor is there reason for requiring the notification to be a claim for damages or of any threatened litigation or other resort to a remedy. The notification which saves the buyer's rights under this Article need only be such as informs the seller that the transaction is claimed to involve a breach, and thus opens the way for normal settlement through negotiation.

Tex. Bus. & Com. Code Ann. § 2.607(c)(1) comment D; Stickle v. Heublein, Inc., 716 F.2d 1550, 1560 (Fed. Cir. 1983) (indicating that Texas law adopts this comment). Consequently, little more is required than for the claimant to indicate that there is a problem with the warranted product that is severe enough to potentially constitute a breach. See, e.g., Carroll Instrument

Co., Inc. v. B.W.B. Controls, Inc., 677 S.W.2d 654, 657-58 (Tex. Ct. App. 1984) (holding that where claimant complained of a "problem," and showed Defendant a rusty part, the requirement of notice was satisfied for a claim of breach of the warranty of fitness).

In this case, Plaintiff identified the specific way in which Lamisil allegedly harmed her, sent over voluminous documentation of her injury, and explicitly threatened suit over the allegedly defective nature of the product. The fact that she did not use the word "breach" or "contract," does not mean that she did not give adequate notice that representations about the safety of the product, implicit or otherwise, made in the course of the transaction had not been kept. Especially in light of the fact that Defendant offers no law or legal arguments to support its conclusory statement that lack of explicit reference to the warranty makes the notice insufficient, the Court is satisfied that summary judgment is inappropriate on this point.

Defendant will, however, be granted summary judgment as to the express warranty claim, because Plaintiff has not adduced evidence of reliance. Under Texas law, an express warranty claim requires some evidence that the claimant relied on the representations in deciding to purchase and use the product. American Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 436 (Tex. 1997). Defendant argues that Plaintiff has failed to demonstrate

that she relied upon any express warranty of safety of the product, and Plaintiff fails to address this argument altogether. Because it is undisputed that Ms. Yocham relied exclusively on the advice of her physician in deciding to use Lamisil (Def.'s Statement of Undisputed Material Facts, ¶ 16-17 (citing Pl.'s Dep 145, 302-04)), and because Plaintiff appears to concede that summary judgment on this point is warranted by not addressing it in her opposition, the Court will grant summary judgment to Defendant with respect to the express warranty claim.

F. Design Defect, Fraud, and Unjust Enrichment Claims

Plaintiff expressly abandons her fraud claims.[8] (Pl.'s Br. 25.) Plaintiff agrees with Defendant that there can be no design defect claim independent from the failure-to-warn claim. (Pl.'s Br. 24-25.) And Plaintiff does not address Defendant's argument that unjust enrichment is not a cause of action under Texas law. Hancock v. Chicago Title Ins. Co., 635 F. Supp. 2d 539, 560 (N.D. Tex. 2009). Accordingly, the Court will grant Defendant summary judgment on all of these counts, including the three fraud counts.

[8] While there are three separate counts for fraudulent misrepresentation, negligent or reckless misrepresentation, and violation of the Consumer Fraud Act, the parties refer generally to Plaintiff's "multiple fraud claims," (Def.'s Br. 19), which the Court understands to refer to all three counts.

IV. CONCLUSION

Texas law applies in this diversity case because, even though Lamisil was researched in New Jersey, Texas has the most significant relationship to the occurrence and the parties. Under Texas law, Defendant is entitled to summary judgment on Plaintiff's express warranty, design defect, and unjust enrichment claims. Defendant is also entitled to summary judgment on the abandoned fraud claims. Defendant is not entitled to summary judgment with respect to Plaintiff's failure-to-warn claim, because the exception to the statutory defense of FDA approval is not preempted by federal law, and Defendant makes no other argument with respect to that claim. Finally, Plaintiff's implied warranty claim survives because the parties' pre-suit correspondence provided adequate notice of the claim under Texas law. The accompanying Order will be entered and the case will be listed for trial.

August 31, 2010
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
United States District Judge