IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MARADEAN KERSEY,	:	
	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO.
	:	1:09-CV-898-RWS
DOLGENCORP LLC d/b/a Dollar General and/or Dollar Corp., *et al*.,	:	
	:	
Defendants.	:	
	:	
	:	

ORDER

This case comes before the Court on Defendants Dolgencorp, LLC d/b/a Dollar General and/or Dollar Corporation, Dolgencorp, Inc. d/b/a Dollar General and/or Dollar Corporation (collectively, "Dollar General"), and Defendant Faria Limited, LLC d/b/a Sheffield Pharmaceuticals or Sheffield Laboratories' (collectively, "Faria") Motion for Summary Judgment [48]. After a review of the record, the Court enters the following Order.

I. Background

Defendant Faria manufactures a wide variety of generic products including: creams, ointments, sun screens, pet products, first-aid products,

personal lubricants, body washes, shampoos, and conditioners. Def.'s SMF, Dkt. No. [48-3] at ¶ 6. Relevant here, Faria produces the Dollar General Maximum Strength Muscle Rub Cream ("Rub Cream") for Defendant Dollar General to sell in its stores. Id. at ¶¶ 8-9. The Rub Cream is an over-the-counter external analgesic which is the national brand equivalent of Ben-Gay® or Icy Hot®. Id. at ¶¶ 11-12. Since 2002, Faria has manufactured over eight million tubes of the Rub Cream, six million of which were sold through Dollar General. Id. at ¶¶ 14-15. Prior to this case, Faria had never received a complaint, allegation, or notice of physical injury sustained from the use of the Rub Cream. Id. at ¶ 16.

The Rub Cream contains the following warning on its external box packaging:

> Warnings:
> -For external use only.
> -Use only as directed.
> -Keep out of reach of children to avoid accidental poisoning.
> -Discontinue use if excessive irritation o[f] the skin develops.
> -Do not bandage tightly, apply to wounds or damaged skin or use with a heating pad.
> -If condition worsens, of if symptoms persist for more than 7 days or clear-up and occur again within a few days, discontinue use of this product and consult a doctor.
> -If swallowed, get medical help or contact a Poison Control Center right away.

Id. at ¶ 29.

Maradean Kersey, Plaintiff, was diagnosed with diabetes in 1994 and has severe diabetic neuropathy as a result of her condition. Id. at ¶¶ 1-2. This neuropathy has affected Ms. Kersey's feet, specifically causing foot ulcers, broken bones, and necessary surgeries to be performed to correct the incurred results. Id. at ¶ 4.

Plaintiff began using the Defendants' Rub Cream sometime in 2006 or 2007. Id. at ¶ 40. In May 2008, the Plaintiff purchased two tubes of the Rub Cream and applied the cream several times over that weekend. Id. at ¶¶ 30, 32. After applying the cream, she put on socks and shoes. Id. at ¶ 31. On May 27, 2008, the Plaintiff sought medical attention for foot ulcers at the East Georgia Regional Medical Center's Comprehensive Wound Healing Center where she was treated by Dr. John E. Martin, Sr. Id. at ¶ 33. Dr. Martin diagnosed the Plaintiff with "multiple diabetic ulcers secondary to chemical burns." Pl.'s Res. SMF, Dkt. No. [61] at ¶ 34. However, Dr. Martin did not complete a biopsy to confirm his diagnosis and at his deposition, confirmed that he did not have an opinion to a degree of medical probability that the Rub Cream caused the Plaintiff's injuries. Dep. Martin, Dkt. No. [53] at 100:11-21, 104:2-18. As well,

he noted that the injuries had a "potential friction element" as well, but he "was not sure." Id. at 90:14-21.

Based upon these injuries, the Plaintiff originally filed this action in the State Court of Fulton County, and Defendants subsequently removed. Dkt. No. [1]. Plaintiff alleges the Defendants' product caused the Plaintiff's foot injuries. To that end, the Plaintiff has brought four counts against the Defendants: 1) product liability sounding in negligence; 2) product liability sounding in strict liability; 3) breach of express warranty; and 4) breach of implied warranty. The Defendants have now brought a motion for summary judgment. The Court will consider the arguments in turn.

II. Discussion

The Defendants have moved for summary judgment on all of Plaintiff's counts. Federal Rule of Civil Procedure 56 requires that summary judgment be granted "if 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 moving party bears 'the initial responsibility of informing the . . . court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the

affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.'" Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1259 (11th Cir. 2004) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (internal quotations omitted)). Where the moving party makes such a showing, the burden shifts to the non-movant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

The applicable substantive law identifies which facts are material. Id. at 248. A fact is not material if a dispute over that fact will not affect the outcome of the suit under the governing law. Id. An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the non-moving party. Id. at 249-50.

In resolving a motion for summary judgment, the court must view all evidence and draw all reasonable inferences in the light most favorable to the non-moving party. Patton v. Triad Guar. Ins. Corp., 277 F.3d 1294, 1296 (11th Cir. 2002). But, the court is bound only to draw those inferences which are reasonable. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial."

Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (internal citations omitted); see also Matsushita, 475 U.S. at 586 (once the moving party has met its burden under Rule 56(c), the nonmoving party "must do more than simply show there is some metaphysical doubt as to the material facts").

A. Abandoned Claims

As a preliminary matter, Plaintiff has abandoned many of her claims. See L.R. 7.1(B), NDGa ("Failure to file a response shall indicate that there is no opposition to the motion."). First, Plaintiff has abandoned all claims against Dollar General. Plaintiff does not mention these Defendants in any of her substantive discussion of the issues. As well, Plaintiff has abandoned her breach of express and implied warranty claims against Defendant Faria. Therefore, Defendant's Motion [48] is **GRANTED** as to all claims against Dollar General and all breach of warranties claims against Faria.

B. Product Liability

Defendants have moved for summary judgment on Plaintiff's product liability claims. Georgia law provides that manufacturers are liable for product defects which proximately cause injury to individuals. In pertinent part, O.C.G.A. § 51-1-11 provides:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

O.C.G.A. § 51-1-11(b)(1).

Based upon this language, Georgia courts recognize three theories of products liability claims: manufacturing defects, design defects, and warning defects. See Banks v. ICI Americas, Inc., 450 S.E.2d 671, 672 (Ga. 1994). Plaintiff has asserted all three and the Court will consider them in turn.

1. Design Defects

In the case of design defects, as opposed to manufacturing or warning defects, "it is not possible to ascertain whether a product is 'defective' by simply

comparing it to a properly manufactured item from the same product line." Id. A design-defect claim, in other words, alleges not that the product in question is uniquely defective, but rather that the entire product line from which it was manufactured contains a defect in design.

In Banks, the Georgia Supreme Court set out the legal standard applicable to cases alleging defective design. Id. at 674-76. After exhaustively reviewing the legal landscape of products liability, the Court adopted the risk-utility analysis, which requires the trier of fact to "balanc[e] the risks inherent in a product design against the utility of the product so designed" to determine whether a design is defective. Id. at 674. In doing so, the Court laid out a non-exhaustive list of factors for the trier of fact to consider in applying the risk-utility test. These factors include:

> the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e. , the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the user's ability to avoid danger; the state of the art at the time the product is manufactured; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product's price or by purchasing insurance. We note that a manufacturer's proof of compliance with industry-wide practices, state of the art, or federal

> regulations does not eliminate conclusively its liability for its design of allegedly defective products.
>
> Alternative safe design factors include: the feasibility of an alternative design; the availability of an effective substitute for the product which meets the same need but is safer; the financial cost of the improved design; and the adverse effects from the alternative.
>
> In regard to the benefits aspect of the balancing test, factors that could be considered include the appearance and aesthetic attractiveness of the product; its utility for multiple uses; the convenience and extent of its use, especially in light of the period of time it could be used without harm resulting from the product; and the collateral safety of a feature other than the one that harmed the plaintiff.

Id. at 675 n.6 (citations omitted).

At the "heart" of a design-defect case, however, "is the reasonableness of selecting from among alternative product designs and adopting the safest feasible one." Jones v. NordicTrack, Inc. 550 S.E.2d 101, 103 (Ga. 2001). Because O.C.G.A. § 51-1-11 incorporates the concept of "reasonableness" into the determination of whether a product is defective, the trier of fact must consider "whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk posed by the design, the usefulness of the product in that condition, and the burden on the

manufacturer to take the necessary steps to eliminate the risk." Id. at 673. Thus, in addition to adopting the risk-utility test, the Court held that evidence of alternative safer designs is admissible to prove a design defect.

The Court finds that the Rub Cream is not defectively designed. First, beyond inserting the words "and necessarily a design defect" to a quote regarding manufacturing defects in Georgia, Plaintiff does not even discuss the Rub Cream design. See Pl.'s Opp., Dkt. No. [60] at 15. Arguably, Plaintiff has abandoned any design defect claim. See L.R. 7.1(B), NDGa.

Regardless, Plaintiff has presented neither an alternative design nor any evidence of the product's inherent risks. Rather, Plaintiff relies on the open FDA Form 483 and FDA Warning Letter which–by Plaintiff's own description–deal with manufacturing processes, not this design. Id. at 16 (stating that the FDA Form 483 and Warning Letter concerned "manufacturing processes"). Here, the only evidence before the Court is that the Rub Cream's chemical composition was tested for compliance with the federal specifications, and that the FDA generally recognizes such a composition as safe and effective. Dep. Hacku, 109:23-110:25; 21 C.F.R. § 348.1 *et seq*. As such, Defendants motion is **GRANTED** on the design defect claim.

2. Manufacturing Defect

For manufacturing defect claims, the trier of fact must ask whether the product would have been safe for consumer use had it been manufactured in accordance with the design. S K Hand Tool Corp. v. Lowman, 479 S.E.2d 103, 108 (Ga. Ct. App. 1996). As one court noted,

> [T]he plaintiff is not required to show negligence by the manufacturer, but must show that the product, when sold, was not merchantable and reasonably suited to the use intended and its condition when sold is the proximate cause of the injury sustained. It is not necessary for the plaintiff to specify precisely the nature of the defect. He must show that the device did not operate as intended and this was the proximate cause of his injuries.

Owens v. General Motors Corp. , 613 S.E.2d 651, 654 (Ga. Ct. App. 2005) (citing Williams v. Am. Med. Sys., 548 S.E.2d 371 (2001)).

Plaintiff maintains that there is a genuine issue of material fact on this claim because during the time period that the at-issue creme was being manufactured, Faria was under an open FDA Form 483 and Warning Letter. Upon reviewing these documents, the Court is only able to discern one observation which expressly relates to the Rub Cream–Observation 9. That observation noted that

> "[r]eports from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validatior of the supplier's test results at appropriate intervals . . .
>
> (b)The firm did not complete full testing to establish the reliability of the vendors' Certificates of Analysis for urea, chlorophyllin copper complex sodium, inositol, cysteine, methionine, oleoresin capsicum, lidocaine HCl, [redacted] raw materials used to manufacture Papain-Urea-Copper complex ointment, Amino Cervical cream, Thermal Rub cream, and Lidocaine Hydrocotisone cream (respectively).

FDA Form 483, Dkt. No. [66-1] at 5 (emphasis added). The inspection which created this observation occurred October 15-17, 2005. Id. at 1. However, the Rub Cream which allegedly caused Plaintiff's injury was manufactured between August 14-20, 2007. Dep. Hacku, Dkt. No. [66] at 97:23-98:9.

Plaintiff claims that the FDA' s observation that Faria was not rechecking the supplied components–outside of the suppliers' own analysis–creates a genuine issue of fact on the manufacturing defect issue. First, it should be noted that the inspection which led to this observation occurred approximately two years prior to the at-issue Rub Cream's manufacture. And, Kathleen Hacku–Faria's Quality Assurance Manager–testified that once Faria receives observations from the FDA, it "always respond." Id. at 139:13-141:12. And, all

of the observations–including this one–on the Form 483 were not deemed critical by the FDA. Id. In fact, pharmaceutical manufacturers are not even obligated to correct minor Form 483 Observations; that decision is at the individual manufacturer's discretion. Id. at 133:20-134:14. Only when the FDA pursues routes outside of the Form 483 is the manufacturer required to respond. Id. at 135:12-136:6.

Additionally, the Court notes that Plaintiff does not allege that the components of the Rub Cream were either too strong or too weak and thus Plaintiff's injuries were caused. See Pl.'s Opp., Dkt. No. [60]. In fact, Plaintiff did not even have the at-issue Rub Cream tested to mount such a claim. Rather, the Plaintiff wants Faria's minor failure to double check the supplier's previous analysis to create a genuine issue of material fact. The Court does not find any genuine issue here. Therefore, Faria's Motion for Summary Judgment is **GRANTED** on the manufacturing defect claim.

3. Failure to Warn

Faria also moves for summary judgment based upon the Plaintiff's alleged failure to present evidence in support of her failure to warn claim. To maintain a claim for breach of a duty to warn, a plaintiff must show that (1) the

defendant knew, or had reason to know, that the product is likely to be dangerous for the intended use; (2) the defendant had no reason to believe that the person affected would realize the danger; and (3) the defendant failed to exercise reasonable care in informing the user about the danger. Carmical v. Bell Helicopter Textron, Inc., 117 F.3d 490, 495-96 (11th Cir. 1997) (applying Georgia law); see also Chrysler Corp. v. Batten, 450 S.E.2d 208, 211 (Ga. 1994). In determining whether such a duty exists, the court should consider the foreseeability of the use in question, the type of danger involved, and the foreseeability of the user's knowledge of the danger. Zeigler v. CloWhite Co., 507 S.E.2d 182, 184 (Ga. Ct. App. 1998). "Such matters generally are not susceptible of summary adjudication and should be resolved by a trial in the ordinary manner." Exxon Corp. v. Jones, 433 S.E.2d 350, 352 (Ga. 1993).

Plaintiff alleges that Faria "knew or certainly had reason to know that the subject Muscle Rub was likely to be dangerous for the intended use of irritating the skin, dilating blood vessels and increasing local blood flow in high-risk diabetic persons." Pl.'s Opp., Dkt. No. [60] at 19. However, Plaintiff bases this view on the deposition testimony of Dr. Goodhart and Dr. Plunkett who, in the Plaintiff's own words, only state that Faria "should know that the muscle rub

cream would irritate [or be absorbed by] the skin"–not that this reaction would be injurious to diabetics. See Pl.'s SMF, Dkt. No. [62] at ¶¶ 15-16.

Additionally, Faria notes that Plaintiff's own expert, Dr. Plunkett, states that she isn't aware of a single complaint, allegation, article, or study regarding Rub-Cream-induced injuries to diabetics. Dep. Plunkett, Dkt. No. [54] at 151:16-152:14, 160:10-23, 167:1-20, 182:13-21. Even more to the point, Faria itself had not received any reports of injury, much less to a diabetic, prior to Plaintiff's complaint–and Faria has manufactured over 8,000,000 tubes of Rub Cream. Aff. Haku, Dkt. No. [57] at ¶ 7-8. Further, the FDA has categorized the Rub Cream as a product "generally recognized as safe and effective." Def.'s SMF, Dkt. No. [48-3] at ¶ 22; 21 C.F.R. § 348, *et seq*. Faria's lack of knowledge is telling, and Defendant's Motion for Summary Judgement is **GRANTED**.[1]

[1]The Court also notes a strong proximate causation problem for the Plaintiff. The Plaintiff is a diabetic who incurred diabetic-related foot injuries both before and after use of the cream. Def.'s SMF, Dkt. No. [48-3] at ¶¶ 37-38. Moreover, Plaintiff used the Defendants' product without incident for approximately a year prior to the injury. Id. at ¶ 40. The injury only occurred after the Plaintiff applied the product and then put on socks and shoes, which in the Court's opinion, is inconsistent with the Defendants' warning not to "bandage" the applied area. See id. at ¶¶ 29, 31.

III. Conclusion

Based on the foregoing, Defendants' Motion for Summary Judgment [48] is **GRANTED**. The Clerk is directed to close this case.

SO ORDERED this 3rd day of May, 2011.

RICHARD W. STORY
UNITED STATES DISTRICT JUDGE