UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LILLIAN CHASE,

Plaintiff,

v. CASE NO: 8:04-cv-885-T-26TBM

NOVARTIS PHARMACEUTICAL CORP., et al.,

Defendants.
_____/

ORDER

Before the Court is Defendant Novartis Pharmaceuticals Corporation's Motion for Summary Judgment, Statement of Undisputed Facts, and various exhibits (Dkts. S- 7, 8 & 9), and Plaintiff's Response, Statement of Undisputed Facts, and exhibits. (Dkts. S-10 & 11). After careful consideration of the submissions of the parties, the Court concludes that summary judgment should be granted.

Background

This case, based on diversity jurisdiction, was initially transferred to this Court from the Southern District of Mississippi. (Dkt. 1 & 89).[1] The Complaint sounds in products liability and seeks to recover damages for injuries suffered from taking an anti-fungal, prescriptive oral tablet known as Lamisil. Dr. Perez prescribed Lamisil for

[1] Although the Multi-District Litigation panel (MDL) entered a conditional order transferring this case to the Eastern District of Pennsylvania, see docket 101, this Court conducted a status conference and reopened the case for resolution in the Middle District of Florida.

Plaintiff Lillian Chase in August 2000, and Plaintiff continued the treatment for approximately forty days. She discontinued Lamisil because she developed dysgeusia,[2] nausea, and a black, hairy tongue. She was hospitalized in November 2000 for dehydration, weight loss, malnutrition, gastroesophageal reflux disease and dysgeusia.

All of the claims in the Complaint have either been dismissed by the Court[3] or by stipulation of the parties[4] with the exception of those asserting a theory of failure to warn of the dangerous side effects of Lamisil. As part of the failure-to-warn claims, Plaintiff asserts that Defendant Novartis Pharmaceutical Corporation (Novartis) knew of adverse incidents and events as early as 1994, and in any event no later than 1998, relating to taste distortion and detrimental weight loss and should have initiated a change to its package insert with the Food and Drug Administration (FDA). Although in June 1998 discussions began between Novartis and FDA to make changes to the package insert, Plaintiff stresses that Novartis made no mention to FDA of the associated weight loss and permanent dysgeusia and, consequently, the insert failed to adequately warn of such dangers.[5]

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[2] She experienced a loss and distortion of taste, predominantly sensing a salty taste.

[3] See Order of April 27, 2004, at docket 89.

[4] See Stipulation of Voluntary Dismissal of August 25, 2006, at docket 150.

[5] Specifically, Plaintiff's expert Dr. Ehrreich opined that the insert should have been revised by adding the following language to two different sections of the label:

[1.] Taste loss with loss of appetite and potential weight loss

Novartis now seeks summary judgment on the grounds that Plaintiff's expert testimony, either through Dr. Ehrreich or Dr. Perez, fails to satisfy the causation element, and on various other grounds relating to federal preemption of state-law failure-to-warn claims and to the lack of any duty to unilaterally revise the insert. Because the Court finds that the causation element has not been established, the remaining bases for summary judgment need not be reached.

Analysis

In this diversity case, Florida's product liability law applies. To demonstrate a prima facie case, the Plaintiff must prove by a preponderance of the evidence that "within a reasonable degree of medical probability," the failure to warn was the proximate cause of Plaintiff's weight loss and dysgeusia. See Christopher v. Cutter Labs., 53 F.3d 1184, 1191 (11th Cir. 1995) (citing Reaves v. Armstrong World Indus., Inc., 569 So.2d 1307, 1309 (Fla.Dist.Ct.App. 1990)). The Plaintiff must show that "more likely than not" the warning to the physician was inadequate and the warning did not sufficiently inform the prescribing physician about the risks involved in prescribing the drug. Id. This requirement represents the "learned intermediary doctrine" which Florida follows. See Timmons v. The Purdue Pharma Co., No. 8:04-cv-1479-T-26MAP, 2006 WL 263602, at

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> have occurred in patients taking Lamisil. [2.] [T]he effect may be long lasting and in some cases irreversible. [3.] [F]emale patients over the age of 55, who have a low body mass index, are particularly susceptible to these particular adverse events.

*4 (M.D. Fla. Feb. 2, 2006); see also Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820, 822 (Fla.Dist.Ct.App. 1981) (holding that duty to warn of dangerous commodity such as prescription drug is fulfilled by adequate warning given to physicians). Thus, the adequacy of the warning is irrelevant if the prescribing physician, as opposed to the patient, has knowledge of the risks and benefits of the drug and would have prescribed the drug anyway had the warnings been different.[6]

Dr. Perez, Plaintiff's treating physician, never testified that Lamisil was "more likely than not" the cause of her injuries. He also never stated that to a reasonable degree of medical probability, Lamisil was the cause in fact of Plaintiff's injuries. Regarding causation he testified as follows:

> Q: They [an ENT, a taste disorder specialist, a neurologist, and a GI doctor] all go back to Lamisil as the potential cause . . . of Mrs. Chase's symptoms, do you agree with that?
> . . . .
> That all of the doctors who saw her were unable— first, they were unable to come up with a definitive diagnosis of their own as to what the cause of her problems were?
> . . . .
> Not a one of them were able to come up with a definitive diagnosis of what was causing her problems, were they?
>
> A: No.

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[6] See Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254 (5th Cir. 2002). In Stahl, the Eleventh Circuit upheld the district court's grant of summary judgment for Novartis on a failure-to-warn claim involving Lamisil. Although Louisiana law applied in Stahl, the district court applied the learned intermediary doctrine to the treating physician's testimony that the warnings in Lamisil's package insert were adequate to inform him of the risk of liver damage.

> Q: And not a one of them was able to rule out Lamisil as the cause of her problem?
>
> A: According to their notes, they seem to think that that was a possibility.
>
> Q: . . . *do you consider Lamisil to be the more likely cause of her problems*?
>
> A: *It's possible*.
>
> Q: Do you have any other potential cause that's left out there that we were unable to rule out?
> . . . .
> . . . is there anything besides a reaction to Lamisil that you think may have caused Mrs. Chase's symptoms that you were treating her for in 2000, 20001?
>
> A: I have to rely basically on the documentation available. So back then, *I thought that was a possibility*. . . . I mean, besides the possibility that the Lamisil may have something to do with that, I don't have any other idea.

(Dkt. S-3, depo. of Dr. Perez at pgs. 261-264) (emphasis added).

With respect to whether a different label would have changed Dr. Perez's decision to prescribe Lamisil to Plaintiff, he testified as follows:

> Q: Before you had your experience with Mrs. Chase, your standard practice in talking to potential Lamisil patients about potential side effects was to talk about potential adverse liver effects and potential adverse GI effects, right?
>
> A: Yes.
>
> Q: Then after your experience with Mrs. Chase you added potential taste disturbance as another side effect that you talked about with patients, right?

A: Yes.

. . . .

Q: . . . this package insert . . Remember the language . . . with respect to, uncommonly, Lamisil may cause taste disturbance (including taste loss) which usually recovers within several weeks after discontinuation of the drug. And the additional language, rarely, taste disturbance is associated with oral terbinafine have been reported to be severe enough to result in decreased food intake leading to significant and unwanted weight loss.

A: Yes.

Q: *If that language had been included in the 2000 PDR that was in effect when you prescribed Lamisil to Mrs. Chase in August of 2000, would you— would that have changed your prescribing decision with respect to Mrs. Chase in any way?*

A: No, it wouldn't.

. . . .

Q: But I think you just said that the reason that you changed your approach with patients is because you had an experience with Mrs. Chase relating to taste disturbance, right?

A: Yes, I said so, but at the same time, if you see — and still the line is there stating— what is it? What is it? Uncommonly. . . . Lamisil and so forth. So, in this case when we have an addition of this paragraph, because, you know, you read that at least once to see which things you would tell the patient. *Obviously they give a more detailed information about that potential side effect. . . . But that's something that probably, and I cannot retrospectively say yes or no, but I would say, well, that's something that I probably would consider.*

. . . .

Q: But you don't know one way or the other as you sit here today, right, about what you would have done back in 2000 with respect to Mrs. Chase?

A: Retrospectively, I could not say without this information there.

(Dkt. S-3, depo of Dr. Perez at pgs. 316-17 & 319-321) (emphasis added). Plaintiff argues that this testimony is sufficient to create a question of fact for a jury as to whether the additional information presented in the revised insert would have caused Dr. Perez not to prescribe Lamisil to Plaintiff. The Court disagrees. Dr. Perez unequivocally states that he would not have changed his prescription decision for Plaintiff in 2000, even with the addition of the language now found in the package insert. At most, Dr. Perez acknowledges that he would have considered the additional language had it been there in 2000, but he never testified that he would change his decision to treat with Lamisil.

It is therefore **ORDERED AND ADJUDGED** as follows:

1) Defendants' Motion for Summary Judgment (Dkt. S-7) is **GRANTED**.

2) The Clerk is directed to enter final summary judgment in favor of Defendant and against Plaintiff on all remaining claims.

3) The Clerk is directed to close this file.

DONE AND ORDERED at Tampa, Florida, on September 28, 2006.

s/*Richard A. Lazzara*
RICHARD A. LAZZARA
UNITED STATES DISTRICT JUDGE

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Counsel of Record