Levine v. Wyeth Inc. et al Doc. 107

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JASON LEVINE,

Plaintiff,

v. CASE NO. 8:09-cv-854-T-33AEP

WYETH, INC., et al.,

Defendants.
_____/

ORDER

This cause comes before the Court on Defendants Actavis Inc. and Actavis-Elizabeth, LLC's (collectively referred to as "Actavis") Motion for Summary Judgment. (Doc. # 97). Plaintiff opposes the motion. (Doc. # 98). Actavis filed a reply brief. (Doc. # 101). For the reasons explained below, the motion is denied.

I. Standard of Review

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The Court must draw all inferences from the evidence in the light most favorable to the non-movant and resolve all reasonable doubts in that party's favor. See Porter v. Ray, 461 F.3d 1315, 1320 (11th Cir. 2006). The moving party bears the initial burden of showing the Court, by reference to

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materials on file, that there are no genuine issues of material fact that should be decided at trial. See id. When a moving party has discharged its burden, the non-moving party must then go beyond the pleadings, and by its own affidavits, or by depositions, answers to interrogatories, and admissions on file, designate specific facts showing there is a genuine issue for trial. See id.

II. Background

Plaintiff filed suit against Actavis and others for his injuries resulting from his use of a prescription drug, Reglan (the generic form of metoclopramide), to treat his acid reflux. Actavis manufactured the Reglan pills that Plaintiff ingested. Plaintiff contends that the drug caused him to develop tardive dyskinesia, a neurological movement disorder. At issue in the instant motion is whether Actavis adequately warned of the risk of developing tardive dyskinesia from using Reglan at the time that Plaintiff took Reglan.

Dr. Shawkat Kero prescribed the drug to Plaintiff. During Kero's deposition, he testified to the following (Doc. # 97, Ex. A): Kero is a gastroenterologist, who has been in private practice for twenty-seven years. (p. 5). He has been prescribing metoclopramide for twenty years, and he has been doing so despite knowing that there was a risk that the patient could develop tardive dyskinesia. (p. 6-8). Plaintiff is the

first patient of Kero's that has developed tardive dyskinesia after using Reglan. (p. 34, 51-52). Kero continues to prescribe the drug today. (p. 10).

Kero treated Plaintiff for acid reflux on two occasions. On Plaintiff's first visit on February 9, 2006, Kero gave Plaintiff a one-month prescription for metoclopramide (consisting of 2 tablets per day), with three refills. (p. 13, 15, 16). Kero did not see Plaintiff again until his next visit on January 18, 2007, when Kero gave Plaintiff a prescription for six months worth of metoclopramide (consisting of 3 tablets per day). (p. 16, 25, 31).

At the time that Kero was treating Plaintiff, Kero believed that long-term use of the drug was within the standard of care as long as the patient was not experiencing any side effects and the medication was alleviating the gastroenterological symptoms. (p. 31-34). Additionally, at the time that he was treating Plaintiff, Kero believed that tardive dyskinesia was a very rare side effect and that older women were the ones most at risk. (p. 34).

At the time that Plaintiff was taking Reglan, Actavis' warning stated that "[t]herapy should not exceed 12 weeks in duration," that the drug is "indicated as short-term (4 to 12 weeks) therapy," and that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." (Doc. # 97, Ex. B,

p. 3, 10). Regarding the risk of developing tardive dyskinesia, the warning provided the following:

> Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.
>
> * * *
>
> There is no known treatment for established cases of tardive dyskinesia although the syndrome may remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn. Metoclopramide itself, however, may suppress (or partially suppress) the signs of tardive dyskinesia, thereby masking the underlying disease process.

(Doc. # 97, Ex. B, p. 5).

In February of 2009, the FDA put a black box warning on Reglan,[1] which specifically states the following:

> WARNING: TARDIVE DYSKINESIA
>
> Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.
>
> Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.
>
> Treatment with metoclopramide for longer than 12 weeks

[1](Doc. # 97, Ex. A, p. 38).

should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.

(Doc. # 97, Ex. C, p. 1). Also, Actavis provides an additional warning that points out that a study reported a 20% risk in developing tardive dyskinesia after using Reglan and further states the following:

> Tardive Dyskinesia (see Boxed Warnings)
>
> Treatment with metoclopramide can cause tardive dyskinesia (TD), a potentially irreversible and disfiguring disorder characterized by involuntary movements of the face, tongue, or extremities. Although the risk of TD with metoclopramide has not been extensively studied, one published study reported a TD prevalence of 20% among patients treated for at least 12 weeks. Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing TD.
>
> Although the risk of developing TD in the general population may be increased among the elderly, women, and diabetics, it is not possible to predict which patients will develop metoclopramide-induced TD. Both the risk of developing TD and the likelihood that TD will become irreversible increase with duration of treatment and total cumulative dose.
>
> Metoclopramide should be discontinued in patients who develop signs or symptoms of TD. There is no known effective treatment for established cases of TD, although in some patients, TD may remit, partially or completely, within several weeks to months after metoclopramide is withdrawn.
>
> Metoclopramide itself may suppress, or partially suppress, the signs of TD, thereby masking the underlying disease process.

(Doc. # 97, Ex. C, p. 5).

When Kero was deposed regarding the differences between

Actavis' warning that was in place when he treated Plaintiff and the warning that accompanied the drug in 2009, Kero testified to the following (Doc. # 97, Ex. A):

> Q Okay. Now, the FDA revised label also includes a statement that a recent study has found a 20 percent prevalence. I assume that would be very, I don't want to say shocking information, but surprising information that there might be a 20 percent risk of tardive dyskinesia with Reglan, would that be correct, long-term use of Reglan.
>
> * * *
>
> A That's correct.
>
> * * *
>
> Q That would have been information different from what you previously believed in 2006?
>
> * * *
>
> A Again, it's a rare side effect. Although the number seems high, 20 percent, it's still a rare side effect of Reglan.
>
> * * *
>
> Q Okay. But the 20 percent number would have been an attention-grabbing figure, would it not?
>
> * * *
>
> A Right.
>
> * * *
>
> Q And it would have been markedly different than what your perception was in 2006?
>
> * * *
>
> A Yes. Yes.
>
> * * *
>
> Q Okay. Is it fair to say that the FDA label, with the information that it included, has reduced the prescribing of Reglan, from what it was prior to the advent of the label?
>
> * * *
>
> A Under what you're saying, sounds true. There are conditions where we have no recourse, but to use Reglan. And once we explain the side effects to the patients, and the benefits that they get from that, they will still continue to use on a short-term basis, Reglan, for the right reasons.
>
> * * *
>
> Q I understand that there's still going to be those, as the FDA label says, those rare circumstances where a benefit exceeds risk.

A Right.
Q But is it true that the FDA label has altered the risk benefit analysis to some degree, such that the use of Reglan is probably less common than it used to be?
A Correct.
Q And the citation of a potential 20 percent risk and the mention of a restriction to use less than 90 days for other than the rare patient would be something that would enter into the risk benefit analysis of a doctor such as yourself prescribing Reglan?
A Correct.

(p. 39-41).

When asked what effect the changed warning had on his prescribing practice, Kero testified to the following:

Q [Regarding the] . . . 2009 FDA label change[,] . . . if that had occurred at any time prior, or if similar information or change had been made aware to you, it would have changed the risk benefit analysis at that time as well?

* * *

A It would have -- I would have still prescribed . . . [it to Plaintiff], with the warning, that to be more wary of this particular situation, and use it with caution.

* * *

Q Did -- if I understood your last answer, correctly, . . . you just said that if -- if you had been making a prescribing decision in 2006, based upon information you now know, you still would have prescribed the drug? You just would have given maybe a different warning?
A Correct. Correct.
Q Okay. Have you ever read the 2009 black box warning . . . ?
A I think I have, yes.
Q I take it, from your testimony, that even given that warning, you are still prescribing metoclopramide to patients; correct?
A Correct.
Q So the black box warning, that new black box warning has not deterred you from prescribing it in some patients?

A It doesn't deter me from prescribing, other than reiterating the side effects, in particular, tardive dyskinesia, and similar ones a little bit more emphatically.

(p. 47-49).

III. Motion for Summary Judgment

Defendant moves for summary judgment on Plaintiff's claim that Actavis failed to adequately warn of the risk of developing tardive dyskinesia from using Reglan at the time that Kero prescribed the drug to Plaintiff. In order for Plaintiff to prevail on his failure to warn claim, Plaintiff must "prove that the warning label was inadequate, that the inadequacy of the warning proximately caused his injury, and that he suffered an injury from using" Reglan. Hoffmann-LaRoche Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 1st DCA 2009)(citation omitted).

However, a prescription drug manufacturer's duty to warn about its drug's dangerous side effects extends only to physicians; the manufacturer's duty to warn generally does not extend to the patient. See Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989). This is because the ultimate consumer of a prescription drug cannot obtain the drug without a prescription from a physician, and as such, the prescribing physician acts as a learned intermediary between the manufacturer of the drug and the ultimate consumer. See Buckner v. Allergan Pharm., Inc., 400 So. 2d 820, 823 (Fla. 5th DCA 1981); Felix, 540 So. 2d at 104 ; Beale v. Biomet, Inc., 492 F. Supp.2d 1360, 1368

(S.D. Fla. 2007). Accordingly, because the physician "weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs," the focus of a failure to warn claim involving a prescription drug focuses on the warning given to the physician and the effect the warning has on the physician's decision to prescribe the drug. Felix, 540 So. 2d at 104. If an adequate warning exists, the manufacturer of the drug will not be held liable in those situations where the physician does not convey the warning to the patient. See id. at 105; Beale, 492 F. Supp.2d at 1370 ; Baker v. Danek Medical, 35 F. Supp.2d 875, 881 (N.D. Fla. 1998).

In order to show that the allegedly inadequate warning caused Plaintiff's injury, Plaintiff must show that Actavis' warning of the risk of developing tardive dyskinesia at the time that he took Reglan caused his injuries. This means that in order to succeed on this claim, Plaintiff must "prove by a preponderance of the evidence, with reasonable medical probability, that [Actavis'] alleged . . . failure to warn was the proximate cause of his injury." Mason, 27 So. 3d at 77 (citation omitted).

Under the facts of this case, this means that Plaintiff must show that if the 2009 version of Reglan's warning had existed at the time when he sought treatment from Kero, Kero would not have made the same prescribing decision. See Edgar v. Danek Medical,

Inc., 1999 WL 1054864, at *6 (M.D. Fla. Mar. 31, 1999). Thus, Plaintiff must show that Actavis' inadequate warning regarding the risk of developing tardive dyskinesia affected Kero's decision to use Reglan to treat Plaintiff, which caused injury to Plaintiff. See Baker, 35 F. Supp.2d at 881.

However, Plaintiff's failure to warn claim will fail for lack of causation if the evidence shows either that (1) Kero would have made the same prescribing decision if the 2009 version of Reglan's warning had existed at the time when he treated Plaintiff, or (2) Kero was, in fact, independently aware of substantially the same information regarding the risk of developing tardive dyskinesia as set forth in the 2009 version of Reglan's warning when he treated Plaintiff. See id.; Beale, 492 F. Supp.2d at 1365. Actavis now moves for summary judgment, arguing that Kero would have made the same prescribing decision if the 2009 version of Reglan's warning had existed at the time when he treated Plaintiff.

In support of its position, Actavis points to Kero's deposition testimony, in which the following exchange occurred:

> Q [Regarding the] . . . 2009 FDA label change[,] . . . if that had occurred at any time prior, or if similar information or change had been made aware to you, it would have changed the risk benefit analysis at that time as well?
>
> * * *
>
> A It would have -- I would have still prescribed . . . [it to Plaintiff], with the warning, that to be more wary of this particular situation, and use it with caution.

* * *

Q Did -- if I understood your last answer, correctly, . . . you just said that if -- if you had been making a prescribing decision in 2006, based upon information you now know, you still would have prescribed the drug? You just would have given maybe a different warning?

A Correct. Correct.

* * *

Q So the black box warning, that new black box warning has not deterred you from prescribing it in some patients?

A It doesn't deter me from prescribing, other than reiterating the side effects, in particular, tardive dyskinesia, and similar ones a little bit more emphatically.

(Doc. # 97, Ex. A, p. 47-49).

Plaintiff responds by arguing that Kero did not state that he would have prescribed Reglan to treat Plaintiff for the same duration that he did in 2006 and 2007. Plaintiff points out that Kero had given Plaintiff a prescription for a four-month supply of Reglan in 2006 and another prescription for a six-month supply of Reglan in 2007. However, Kero testified that after the 2009 version of the warning came out, doctors continue to prescribe Reglan "on a short-term basis." (Doc. # 97, Ex. A, p. 40). Therefore, Plaintiff argues that a jury could find that Kero would not have given Plaintiff a ten-month supply of Reglan if Actavis had adequately warned of the risk of developing tardive dyskinesia.

Furthermore, Plaintiff points out that Kero also testified that after the 2009 version of the warning came out, he now warns of the risk of developing tardive dyskinesia "more emphatically."

(Doc. # 97, Ex. A, p. 49). Additionally, Kero stated that had he known of the risk of developing tardive dyskinesia set forth in the 2009 version of the warning, he would have warned Plaintiff to be more cognizant of the possibility of developing tardive dyskinesia and to use Reglan with caution. (Doc. # 97, Ex. A, p. 48). Thus, Plaintiff argues that this shows that Actavis' inadequate warning affected Kero's decision regarding the substance and strength of the warning he conveyed to his patients in general, and to Plaintiff specifically, about the risk of developing tardive dyskinesia from Reglan. Therefore, Plaintiff concludes, a reasonable jury could find that had Actavis initially provided the stronger warning about the risk of developing tardive dyskinesia, Kero would have conveyed such risk more emphatically to Plaintiff, and Plaintiff would not have taken Reglan.

In support of his argument that summary judgment should be denied, Plaintiff cites Munroe v. Barr Laboratories, Inc., 670 F. Supp.2d 1299 (N.D. Fla. 2009). In Munroe, the personal representative of the decedent's estate brought a wrongful death and failure to warn claims against the manufacturer of the generic version of the prescription drug Adderall. See id. at 1301. The court denied the manufacturer's motion for summary judgment on the issue of whether the allegedly inadequate warning caused the decedent's death. See id. at 1306. The court found

that genuine issues of material fact existed as to: (1) whether a better warning from the manufacturer about the risk of death from taking Adderall in combination with pseudoephedrine (found in the over-the-counter medication, Sudafed) would have caused the decedent's doctor to warn her about such risk, and (2) whether the decedent would have heeded such a warning (and not taken Sudafed) and lived. See id.

Similarly, in Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993), the plaintiff sued the manufacturer of her silicone breast implants to recover for injuries she sustained when the implants ruptured.[2] The appellate court affirmed the lower court's denial of the manufacturer's motion for a directed verdict on the plaintiff's failure to warn claim. See id. at 1433. The appellate court stated that the denial was proper because there was evidence from which the jury could have reasonably concluded that a different warning about the risk of implant rupture would have caused the plaintiff's doctor to warn her of such risk

[2]While Toole is based on Alabama law, this Court finds Toole to be persuasive since both Florida and Alabama apply the learned intermediary doctrine when analyzing a failure to warn claim against a manufacturer of a prescription drug or device. See Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301, 1304-05 (Ala. 1984)(finding that the duty to warn of the risk of side effects extends to the physician, not to the ultimate consumer)(citing Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974)). Both the Florida Supreme Court and the Alabama Supreme Court rely on the Fifth Circuit case of Reyes v. Wyeth Laboratories when explaining the learned intermediary doctrine. See Felix, 540 So. 2d at 104; Stone, 447 So. 2d at 1304-05; see also Buckner, 400 So. 2d at 822.

before her augmentation surgery. See id.

This Court is persuaded by Munroe and Toole that genuine issues of material fact exist that preclude summary judgment in this case. As such, the Court must deny Actavis' motion.

IV. Conclusion

Accordingly, it is

ORDERED, ADJUDGED, and **DECREED:**

Actavis' Motion for Summary Judgment (Doc. # 97) is **DENIED**.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 10th day of December, 2010.

Virginia M. Hernandez Covington

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE

Copies:

All Counsel of Record