IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
VALDOSTA DIVISION

KATELYN WEILBRENNER, A MINOR, AND DI ANN COURTOY, INDIVIDUALLY AND AS NATURAL MOTHER AND NEXT FRIEND OF KATELYN WEILBRENNER,	:	
Plaintiffs,	:	Civil Action No. 7:08-CV-23 (HL)
v.	:	
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	
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ORDER

This case is before the Court on Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") Motion for Summary Judgment (Doc. 37). For the following reasons, the Motion is denied.

I. FACTS

On January 16, 2006, Plaintiff Katelyn Weilbrenner was prescribed the antibiotic minocycline hydrochloride by her primary care physician, Dr. Robert Hawes, for treatment of acne. Katelyn was fifteen years old at the time. On that same day, Katelyn's mother, Plaintiff Di Ann Courtoy, had the prescription filled. The prescription was refilled on February 28, 2006. Katelyn began taking the minocycline daily on January 16, 2006, and stopped once her skin cleared up. When she experienced a new outbreak in April, Katelyn resumed taking the medication daily. On or about April 24,

2006, Katelyn began experiencing severe headaches. She presented to Dr. Hawes and his assistant for examination and treatment on May 8 and 9, 2006.

On May 11, 2006, Katelyn was seen by an optometrist, Dr. Michael Hopkins, and an ophthalmologist, Dr. Terrance Croyle. She was diagnosed with optic disc edema, papilledema, and pseudotumor cerebri ("PTC").[1] Katelyn stopped taking the minocycline for good on May 11, 2006, and by that time had ingested a total of 54 minocycline capsules.

Minocycline is the generic form of the branded drug Minocin®, and is approved by the United States Food and Drug Administration ("FDA") as an antibiotic commonly prescribed to treat bacterial infections, including acne. In 1996, Teva became the owner of abbreviated new drug application No. 63-009 for 100 milligram minocycline hydrochloride capsules. The minocycline ingested by Katelyn was manufactured by Teva.

At the time Katelyn ingested the capsules, the package insert for Teva's minocycline product contained the following information:

PRECAUTIONS

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[1]Papilledema is the "swelling and protrusion of the blind spot of the eye caused by edema." Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/medical/papilledema. Pseudotumor cerebri is "an abnormal condition that is characterized by increased intracranial pressure, headaches of varying intensity, and papilledema without any demonstrable intracranial lesion." It tends to occur in overweight women from 20 to 50 years of age. Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/medical/pseudotumor%20cerebri.

> Pseudotumor cerebri (benign intracranial hypertension) in adults has been associated with the use of tetracyclines. The usual clinical manifestations are headache and blurred vision. Bulging fontanels have been associated with the use of tetracyclines in infants. While both of these conditions and related symptoms usually resolve after discontinuation of the tetracycline, the possibility for permanent sequelae exists.
>
> **ADVERSE REACTIONS**
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> ***
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> *Central Nervous System*: Bulging fontanels in infants and benign intracranial hypertension (pseudotumor cerebri) in adults (see **PRECAUTIONS, General**) have been reported. Headache has also been reported.

It is undisputed that on the day he prescribed the minocycline for Katelyn, Dr. Hawes did not review the package insert. According to Dr. Hawes, he did not have a package insert to reference. He also did not review the Physicians' Desk Reference ("PDR"), but Teva's product was not listed in the PDR at the time. Dr. Hawes believes he reviewed information regarding minocycline at some point in his career prior to writing the prescription for Katelyn, but has no specific recollection of when or where.

Plaintiffs contend that Katelyn developed PTC and subsequent vision loss as a result of her ingestion of Teva's minocycline product. They allege that Teva's minocycline label was defective, that Teva failed to adequately communicate to physicians the potential danger of PTC and permanent visual loss in adolescents from minocycline use, and that Teva failed to provide sufficient and appropriate educational material to health care providers.

II. ANALYSIS

A. Summary Judgment Standard

Summary judgment must be granted if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material facts and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact arises only when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 2510 (1986).

When considering a motion for summary judgment, the Court must evaluate all of the evidence, together with any logical inferences, in the light most favorable to the nonmoving party. Id. at 254-55. The Court may not, however, make credibility determinations or weigh the evidence. Id. at 255; *see also* Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150, 120 S.Ct. 2097, 2110 (2000).

The moving party "always bears the initial responsibility of informing the district 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." Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 2553 (1986) (internal quotation marks omitted). If the moving party meets this burden, the burden then shifts to the nonmoving party to go beyond the pleadings and present specific evidence showing that there is a genuine issue of material fact. Id. at 324-26. This evidence must consist of more than mere conclusory allegations. *See* Avirgan v. Hull,

932 F.2d 1572, 1577 (11th Cir. 1991). Under this scheme summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

B. Conclusions of Law

1. Federal preemption

Before discussing the substance of Plaintiffs' claims, the Court must address the issue of preemption. Teva argues that Plaintiffs' state law failure-to-warn claims are preempted by the federal regulatory regime governing pharmaceuticals.

The manufacture and sale of branded and generic prescription drug products in the United States falls under the jurisdiction of the FDA. Manufacturers of a branded drug must submit a new drug application ("NDA") to the FDA. 21 U.S.C. § 355.[2] In order to obtain approval of an NDA, the applicant, also known as an innovator, must demonstrate the safety and efficacy of the drug for its intended indications to the satisfaction of the FDA, typically through extensive clinical trials in humans. The innovator must also provide labeling that accurately portrays the risks and benefits of the drug, and the label must be approved by the FDA. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).

The approval process for generic drugs is much less complicated. In 1984, Congress passed the Hatch-Waxman Amendments to the Federal Food, Drug, and

[2]The NDA regulations are codified at 21 C.F.R. Part 314.

Cosmetic Act[3], which establish the current procedure for obtaining approval from the FDA to market and sell a generic drug. 21 U.S.C. § 355(j); 35 U.S.C. §§ 156, 271, 281. Under the Hatch-Waxman Amendments, a drug company may seek permission from the FDA to market a generic version of a branded drug that has lost patent protection by submitting an abbreviated new drug application ("ANDA").[4] The ANDA requirements are set forth at 21 U.S.C. § 355(j).

With regard to conditions of use, active ingredient(s), route of administration, dosage form, and strength, an ANDA drug must be the same as the branded drug that has already been approved by the FDA. 21 U.S.C. § 355(j)(2)(A)(i)-(iii). The generic drug manufacturer must show that the new drug is bioequivalent to the branded drug, which means that the dosage formulation of the generic product has the same pharmacological action in the human body as does the branded drug. 21 U.S.C. § 355(j)(2)(A)(iv). Because it is only required to show bioequivalence, the generic drug manufacturer is relieved of the responsibility of conducting human clinical trials. Finally, the generic manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v)[5]. If the

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[3]The Federal Food, Drug, and Cosmetic Act is found at 21 U.S.C. § 301, et seq.

[4]As previously noted, Teva is the owner of ANDA No. 63-009 for 100 milligram minocycline hydrochloride capsules.

[5]The "labeling" includes the container label, package insert, and, if applicable, medication guide. *See* 21 C.F.R. § 314.94(a)(8)(iv). When the Court refers to the minocycline label, this includes the package insert as well.

information submitted in the ANDA application is insufficient to show that the labeling proposed for the drug is the same as the approved label for the branded drug, the application will not be approved. 21 U.S.C. § 355(j)(4)(G).[6]

Teva argues that Plaintiffs' state law claims create an impermissible conflict with federal law and obstruct the purposes and objectives of Congress in regulating generic drugs. The basic contention is that Teva cannot abide by federal law, which requires the generic label to be exactly like the branded counterpart, and state law, which may require a heightened or additional warning on the generic label. Teva also argues that the purpose behind the Hatch-Waxman Amendments, which is having generic drugs brought to market quickly and at less expense, would be undermined if additional state law duties were placed on generic manufacturers in connection with the labeling of their drugs, as those costs would be passed on to consumers.

In 2009, the United States Supreme Court ruled that state law failure-to-warn claims against the manufacturer of a branded drug were not preempted by federal law. Wyeth v. Levine, --- U.S. ---, 129 S.Ct. 1187 (2009). While the case before the Court deals with a generic drug, rather than a branded drug, at least two appellate courts and

[6]While some differences in labeling are permitted, those differences are irrelevant here. For instance, if the branded drug and generic drug are manufactured by different companies, the name of the manufacturer listed on the labels can be different. 21 U.S.C. § 355(j)(2)(v).

a number of district courts have examined Wyeth and how it relates to generic drugs and preemption arguments exactly like those made by Teva.[7]

One of the most recent, Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), involved metoclopramide, the generic form of Reglan. The plaintiff was prescribed metoclopramide to treat her gastroesophageal reflux. In the lawsuit, the plaintiff alleged that long-term ingestion of the drug caused her to develop tardive dyskinesia.[8] Id. at 430. She asserted state law claims for failure to warn of the risks of neurological disorder after long-term use of the drug. She specifically argued, among other things, that the defendant drug manufacturer failed to request a labeling revision from the FDA and failed to change the label itself even though no prior FDA approval was required to do so. Id.

The defendant moved to dismiss the lawsuit, arguing that the state law claims were conflict-preempted. The district court denied the motion, and the issue went up on appeal. Like Teva in this case, the defendant in Demahy argued that it was impossible to comply with both the federal regulatory requirements concerning generic drugs and the putative state-imposed duty to heighten warning labels, or in the

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[7]The Eleventh Circuit has not addressed the preemption argument as it relates to generic drugs. The Georgia Court of Appeals has held with regard to a branded drug that state common law claims are not preempted by the FDCA. Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 402, 585 S.E.2d 723 (2003).

[8]Tardive dyskinesia is "a neurological disorder characterized by involuntary uncontrollable movements especially of the mouth, tongue, trunk, and limbs. . . ." Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/medical/tardive%20dyskinesia.

alternative, that the state law obstructed the goals of the FDCA and the Hatch-Waxman Amendments. Id. at 434.

The Fifth Circuit expressed its concern about finding preemption because federal law provides no remedy for an injured consumer. "Preemption of state failure-to-warn claims would foreclose a remedy that was traditionally available and for which federal law provides no substitute." Id. at 435. The court also noted that courts in general are reluctant to find preemption without an "unambiguous signal of congressional intent." Id. It pointed to the fact that Congress has already expressly preempted state failure-to-warn claims for some products governed by the FDCA, including medical devices.[9] In the Fifth Circuit's opinion, the fact that Congress had not done the same for generic drugs militated further against a finding of preemption. Id.

The court went on to consider the defendant's claim that it could not comply with both federal and state law. The defendant argued, as Teva does here, that "federal law requires that it maintain at all times a label that is the 'same as' the name brand's, thus preventing simultaneous compliance with a state law requiring additional warnings." Id. at 436.

The Fifth Circuit acknowledged, and the plaintiff agreed, that a generic drug's label must initially conform to a branded drug's label. The plaintiff's argument, however, was that the defendant was liable for failing to take steps to change the label after approval in order to provide adequate warning once additional risks emerged. The

[9] *See, e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S.Ct. 999 (2008).

court noted that the statutory scheme was "silent as to the manufacturer's obligations after the ANDA is granted." Id. (quoting Bartlett v. Mutual Pharma. Co., Inc., 659 F.Supp.2d 279, 294 (D.N.H. 2009)). "The regulations on which Actavis relies, however, do not purport to bar generic labeling modifications following initial approval. Instead, they require only that a generic's label initially conform to the listed drug's; if the label does not, these regulations provide that an ANDA application will be denied. They do not address post-approval modifications at all." Id. at 436. The court believed the regulatory framework makes plain that brand-name and generic drug manufacturers must act to warn customers when they learn that they may be marketing an unsafe drug. Id. at 437.

Like Teva, the defendant in Demahy argued that it could not revise the label of its generic drug, because doing so would result in the FDA's withdrawal of approval of the ANDA application. *See* 21 C.F.R. § 314.150. While the Fifth Circuit agreed that drug manufacturers cannot make whatever changes they want, it noted Wyeth, where the Supreme Court said it found it "difficult to accept" that "the FDA would bring an enforcement action against a manufacturer for strengthening a warning." Demahy, 593 F.3d at 439 (quoting Wyeth, 129 S.Ct. at 1197).

Most labeling changes are pursued through a "major changes" procedure. Under this procedure, FDA approval is required before any labeling modification takes place. 21 U.S.C. § 356a(c)(1); 21 C.F.R. § 314.70(b)(2)(v). At times, however, a manufacturer may use the "changes being effected" ("CBE") procedure to make certain changes to

a label before receiving FDA approval. 21 C.F.R. § 314.70(c)(iii). The plaintiff in Demahy argued that the defendant could have complied with FDA regulations and state law by using the CBE procedure, by using the "major changes" procedure, or by sending warnings directly to health care providers. The Fifth Circuit examined these procedures in turn.

Where the labeling change would "add or strengthen a contraindication, warning, precaution, or adverse reaction," to reflect "information not previously submitted to the [FDA]" and is based on "sufficient evidence of a causal association," it qualifies for the CBE process. This means that the manufacturer may make a labeling change upon filing its supplemental application with the FDA and does not have to wait for FDA approval. Demahy, 593 F.3d at 439-40. After reviewing the regulations governing the CBE process, the court determined that because there was no explicit reference to the use of the CBE process by generic manufacturers, it would not read in a bar to its use. Id. at 444.[10]

The court next determined that nothing in the regulations explicitly barred generic manufacturers from proposing a label change through the prior approval process. Id. "While FDA regulations provide for permissive use of the CBE process for warning

[10]In support of its preemption argument, Teva, like the Demahy defendant, has relied on two amicus briefs filed by the FDA in Colacicco v. Apotex Corp., a case heard in the Eastern District of Pennsylvania, 432 F.Supp.2d 514, and then in the Third Circuit, 521 F.3d 253 (3d Cir. 2008). In light of Wyeth, however, the United States withdrew as amicus in Colacicco. The Court agrees with the Fifth Circuit that in light of the withdrawal, the FDA's amicus views should not be considered.

enhancements, and the prior approval process is required for 'major changes,' there is no indication of an agency policy, let alone congressional intent, to prevent generic manufacturers from proposing any and all labeling changes-no matter the significance of the change-through the prior approval process." Id.

Finally, the court addressed the plaintiff's contention that the defendant could have satisfied its state law duty to warn by sending a "Dear Doctor" letter to physicians containing an explanation of the risks associated with prolonged use of metoclopramide. While such a letter would be subject to FDA regulation because it falls within the definition of "labeling," when promulgating its labeling regulations, "the FDA made clear that the requirements do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." Id. (quotation marks and citation omitted). The court found that while generic drug manufacturers cannot send out "Dear Doctor" letters without FDA approval, they could always suggest that the FDA send out such letters on their behalf. Id. at 444-45.

After reviewing these avenues for complying with both state and federal law, the Fifth Circuit came to the conclusion what while the FDA is the final arbiter of labeling changes, "the manufacturer retains primary responsibility for the content of its label. The federal interest is in maintaining safe and effective labeling that is consistent across name brand and generic bioequivalent versions of the same drug. *Who* prompts the FDA to consider necessary changes to that shared label is immaterial." Id.

at 445 (emphasis in original). While there may be an argument that the CBE process is not available to an ANDA holder, the prior approval process and "Dear Doctor" letter methods of complying with both state and federal law are available to generic drug manufacturers. Id. As the state-imposed duty to warn did not render compliance with federal regulation impossible, the court found that the plaintiff's state law failure-to-warn claims were not preempted.

The court also found that a duty to warn under state law did not obstruct the goals of federal regulation, which are maintenance of safety and efficacy. To the extent the Hatch-Waxman Amendments have the goal of cheaper drugs, those drugs have to remain safe, and since drug manufacturers have superior access to information about their drugs, they bear the primary responsibility for drug labeling. Id. at 446-49.

The Eighth Circuit reached the same conclusion in Mensing v. Wyeth, Inc., 588 F.3d 603 (2009).[11] The plaintiff there also alleged that long-term ingestion of metoclopramide caused her to develop tardive dyskinesia. She sued both the manufacturer of the name-brand drug, Reglan, and the manufacturer of the generic drug that she actually ingested. The plaintiff argued that the manufacturers should have taken steps to change the label warnings to reflect a greater risk of tardive dyskensia than what was indicated on the label. Id. at 605.

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[11]The Court recognizes that the Demahy and Mensing decisions were issued after the parties completed briefing on the Motion for Summary Judgment. Nevertheless, the Court finds these cases instructive on the preemption issue, along with the cited district court cases that were issued both before and after the briefs were submitted.

The court determined that consideration of the CBE process was not required because "the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." Id. at 608 (emphasis in original).[12] Like the Demahy court, the Eighth Circuit found that the regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing a dangerous drug. Id. In response to the generic manufacturer's argument that its label matched the innovator's label, and the innovator did not do anything to strengthen the label despite evidence of a potential hazard, the court stated that generic manufacturers cannot passively "accept the inadequacy of their drug's label as they market and profit from it." Id. at 609. In addition to finding that the generic manufacturers could have proposed a label change, the court also found that they could have suggested that the FDA send out a "Dear Doctor" letter to health care professionals. Id. at 610.

The court also addressed the issue of how the FDA's response to a labeling change request affected the preemption question. In Wyeth, the Supreme Court held that "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." 129 S.Ct. at 1198. The Eighth Circuit

[12]The Court acknowledges that Plaintiffs' own expert, Dr. Christopher Rhodes, testified that the CBE process is not available for generic drugs. However, the Court need not resolve the question of whether the process is available for generic drugs in order to reach its decision.

noted that the record contained no evidence to suggest the FDA would have rejected a labeling proposal from the generic manufacturers. Id. at 611.

In finding that the state law failure-to-warn claims were not preempted, the court made what this Court finds to be a very insightful and persuasive argument:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

Id. at 611.[13]

A number of district courts have reached the same result as the Demahy and Mensing courts. For instance, in Couick v. Wyeth, Inc., No. 3:09-cv-210-RJC-DSC, 2009 WL 4644394 (W.D.N.C. Dec. 7, 2009), the Western District of North Carolina rejected the generic drug manufacturer's preemption argument, noting that the manufacturer could have proposed a label change through the prior approval process, and further that the manufacturer did not articulate why it could not have complied with state law by using means other than a label change to warn customers of the risks

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[13]The Mensing court also found that the state law claims did not obstruct the purposes and objectives of federal law, finding that failure-to-warn actions "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." Id. at 612 (quoting Wyeth, 129 S.Ct. at 1202). The court "decline[d] to assume that Congress intended to shield from tort liability the manufacturers of the majority of prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy." Id.

associated with the drug (i.e, a "Dear Doctor" letter). The court looked to Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), in support of its finding that the state law claims were not conflict-preempted, wherein the Fourth Circuit stated, "The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law." Id. at 170.

The Northern District of Ohio (Fulgenzi v. Wyeth, Inc., No. 5:09CV1767, 2010 WL 649349 (N.D. Ohio Feb. 19, 2010)), the Northern District of Florida (Munroe v. Barr Labs., Inc., --- F.Supp.2d ---, 2009 WL 4047949 (N.D. Fla. 2009)), the District of New Hampshire (Bartlett v. Mutual Pharm. Co., Inc., 659 F.Supp.2d 279 (D.N.H. 2009)), the District of Vermont (Kellogg v. Wyeth, 612 F.Supp.2d 437 (D.Vt. 2009)), the Northern District of Illinois (Stacel v. Teva Pharms., USA, 620 F.Supp.2d 899 (N.D. Ill. 2009))[14], and the Western District of Oklahoma (Schrock v. Wyeth, Inc., 601 F.Supp.2d 1262 (W.D. Okla. 2009)) have all also found that federal law does not preempt state law failure-to-warn claims.[15]

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[14] Stacel also involved minocycline manufactured by Teva. In her well-reasoned opinion, District Judge Joan B. Gottschall made a statement worth repeating: "Although it is clear that the Hatch-Waxman Amendment was devised to allow generic drug manufacturers to get their drugs to market both cheaply and quickly, the purpose was to be achieved by permitting manufacturers to forego duplicative clinical trials. It was *not* to be achieved by permitting manufacturers to engage in negligent activities." 620 F.Supp.2d at 907.

[15] *Contra* Gaeta v. Perrigo Pharmas. Co., --- F.Supp.2d ---, 2009 WL 4250690 (N.D. Cal. 2009); Morris v. Wyeth, Inc., 642 F.Supp.2d 677 (W.D. Ky. 2009).

The Court agrees with the Fifth Circuit, Eighth Circuit, and the various district courts that have rejected the preemption defense raised by generic drug manufacturers. Simply by proposing a label change or requesting that the FDA send out a "Dear Doctor" letter, generic manufacturers can comply with FDA rules and regulations and, at the same time, meet their state law duty to warn the public of any known risks. Teva's argument that there is no assurance that a requested label change would have been granted by the FDA does not alter the Court's decision, as "[what the FDA might have done once [the manufacturer] suggested these changes is immaterial to the imposition of liability." Demahy, 593 F.3d at 446. There simply is no evidence in the record that suggests that the FDA would have rejected a labeling proposal from Teva. Further, allowing state law failure-to-warn claims in no way obstructs the purposes of federal law. On the contrary, the purpose of all the FDA rules and regulations is to ensure that the public receives safe drugs. Allowing state law claims furthers consumer protection and safety. Plaintiffs' state law claims are not conflict-preempted.

2. Failure to warn

Plaintiffs allege that even though Teva knew of the association between minocycline and the potential for the development of PTC in adolescent patients, it failed warn of this danger on its label and failed to notify any physicians, including Dr. Hawes, of the risks associated with minocycline. To establish a failure-to-warn claim, Plaintiffs must show that Teva had a duty to warn, Teva breached that duty, and the

breach was the proximate cause of the injury. Powell Duffryn Terminals, Inc. v. Calgon Carbon Corp., 4 F.Supp.2d 1198 (S.D. Ga. 1998), *aff'd*, 176 F.3d 494 (11th Cir. 1999). Teva argues that Plaintiffs have failed to establish these elements, and thus, their case should be dismissed.

Teva first argues that it is entitled to summary judgment based on the learned intermediary doctrine. This doctrine provides that the manufacturer of a prescription drug does not have a duty to warn the patient of the dangers involved with the product, but instead only has a duty to warn the patient's doctor. The doctor is then to act as a learned intermediary between the patient and the drug manufacturer. McCombs v. Synthes (U.S.A.), 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003). "The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular needs and susceptibilities." Id. (internal quotation marks and citations omitted). However, the doctrine also requires that the manufacturer's warnings to the physician be adequate or reasonable under the circumstances of the case. Id. (citations omitted).

In Teva's opinion, the minocycline label in effect when Katelyn was prescribed the drug was adequate. Teva points to the package insert which states that "[p]seudotumor cerebri . . . in adults has been associated with the use of tetracyclines," that "[t]he usual clinical manifestations are headache and blurred vision," that "the

possibility for permanent sequelae exists," and that "benign intracranial hypertension . . . in adults . . . ha[s] been reported. Headache has also been reported," and argues that through these warnings it fulfilled any duty it had to warn about PTC and possible permanent sequelae, and also provided the necessary information for Dr. Hawes to consider when prescribing the drug to Katelyn.

Plaintiffs, on the other hand, argue that the label was not adequate. Plaintiffs' expert, Dr. Christopher Rhodes, identified four ways in which Teva's minocycline label was allegedly inadequate and defective: (1) it failed to warn of the association between minocycline (rather than the general category "tetracyclines") and PTC; (2) it failed to warn of the association between minocycline and PTC in adolescents; (3) it failed to warn of the association between minocycline and permanent visual loss; and (4) it failed to provide adequate directions for its use, i.e., that patients should be regularly checked for papilledema while taking the drug.

The adequacy of drug warnings is generally a question of fact, but it can "become a question of law where the warning is accurate, clear and unambiguous." Thom v. Bristol-Meyers Squibb Co., 353 F.3d 848, 853 (10th Cir. 2003) (quoting Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 105 (Fla. 1989)).

The fact that the package insert mentioned PTC does not make the warning adequate as a matter of law. *See* Id. at 853; Stahl v. Novartis Pharms. Corp., 283 F.3d 254 (5th Cir. 2002). The drug manufacturer "has discharged its duty to consumers of its prescription drugs when it has *reasonably* informed prescribing physicians of the

dangers of harm from such a drug. Thus, . . . a mere reference to an adverse effect is not necessarily an 'adequate warning.'" Stahl, 283 F.3d at 266-67 (internal quotation marks and citation omitted).

While the label makes specific reference to possible PTC, that warning was directed to adults only. The only other warning was directed to infants for a condition other than PTC. Katelyn was fifteen years old when she was prescribed the minocycline, which means she fell into the group the FDA calls "pediatric patients." This group is defined as "the pediatric age group, from birth to sixteen years, including age groups often called neonates, infants, children, and adolescents." *See* 21 C.F.R. § 201.57(c)(9)(iv). When drug labels are developed, manufacturers are required to provide separate information about pediatric use, including "specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates) [and] differences between pediatric and adults responses to the drug." 21 C.F.R. § 201.57(c)(9)(iv); 21 C.F.R. § 201.80. As the FDA requires warning information for pediatric patients separate and apart from that provided for adult patients, the Court is hard-pressed to find that a physician like Dr. Hawes could, would, or should have assumed that the minocycline PTC warning for adults also applied to adolescents or other pediatric sub-groups.

The label states that PTC in adults has been associated with use of tetracyclines in general. It does not warn of a specific association with minocycline. Teva argues that Plaintiffs' claim that the label should have warned of an association between PTC and

minocycline is illogical because the warning appeared in the label for minocycline, and that while the label provided a broader warning about tetracyclines in general, it is obvious to any physician that the minocycline label would not include warnings not applicable to minocycline itself. Unfortunately for Teva, its own expert's testimony lends at least some credence to Plaintiffs' position. Dr. Steven Lamm testified as follows:

> Q. All right, sir. And where it says, "to determine if other commonly implicated medications, such as tetracycline," do you believe that that is an accurate statement?
>
> A. I think the tetracycline is a medication that has been implicated and is mentioned with respect to PTC, yes.
>
> Q. And tetracycline use -- minocycline is a tetracycline drug?
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> A. Minocycline is a particular tetracycline drug.
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> Q. All right, sir. "These analysis revealed that" --
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> A. Excuse me, I want to expand on that.
>
> Q. Please.
>
> A. And that is, just because minocycline is a tetracycline class drug does not mean that everything that applies to tetracycline applies to minocycline; and likewise, doesn't mean that everything that applies to minocycline applies to tetracycline.

(Lamm Dep., pp. 103-04) (internal objection omitted).

If, as Dr. Lamm's testimony indicates, minocycline and tetracycline are not interchangeable, then a warning that relates to tetracyclines but not specifically to minocycline may not be appropriate, as Plaintiffs contend.

Plaintiffs have also presented expert testimony from Dr. Rhodes that the minocycline label should have contained specific information that permanent vision problems were a possibility and that patients should be closely monitored for possible vision problems. The label as it existed in 2006 warned of the possibility of "permanent sequelae," or permanent harm, but made no explicit reference to permanent vision loss. While Teva argues that Dr. Rhodes does not have a sufficient basis for his expert opinion, that is not an issue for the Court to address on summary judgment. Plaintiffs have presented expert testimony that the label was inadequate to fully warn physicians of the potential dangers of prescribing minocycline to adolescents. Plaintiffs have created an issue of fact as to whether the warnings Teva provided were sufficient under Georgia law.

That does not end the inquiry, however. The issue of proximate cause must also be addressed. Teva argues that even if its warnings were inadequate, Plaintiffs have failed to establish proximate cause between the warnings and Katelyn's injuries. It grounds this argument on two bases: (1) Dr. Hawes did not read the label prior to prescribing the minocycline; and (2) Plaintiffs have not put forth any evidence that Dr. Hawes would not have prescribed minocycline to Katelyn, even if he had read the label and that label had contained stronger warnings.

The Court will address Teva's second argument first. During his deposition, Dr. Hawes expressed his reluctance to state that had the minocycline label contained a black box warning concerning the risk of PTC and possible permanent sequelae in

adolescents, he absolutely would have shared that information with Katelyn or her mother. He also had concerns about saying with certainty what he would have done (i.e., prescribe the minocycline or not) if the labeling had been different. Prior to his deposition, he changed a statement drafted by Plaintiffs' attorneys to read that a different warning "may or may not" have changed his decision to prescribe the drug or to discuss the risks of the drug with Plaintiffs.

After his deposition, Dr. Hawes signed an affidavit in which he stated that had he been aware that PTC in adolescents had been associated with the use of minocycline, or that the possibility of permanent vision loss existed, he "most likely" would not have prescribed minocycline to Katelyn. He also averred that if he had prescribed the drug knowing of the potential problems, he would have instructed Katelyn and her mother to discontinue the medication and return to his office immediately if she began to experience headaches or visual disturbances, and he also would have insisted that Katelyn be regularly checked for papilledema while taking the medication.

While Teva has not filed a formal motion to strike, it argues that Dr. Hawes' affidavit should be disregarded since it contradicts, without explanation, his deposition testimony and statements declining to speculate as to whether or not a different label would have changed his decision to prescribe minocycline to Katelyn or to discuss the possible risks with Plaintiffs. While the Eleventh Circuit has rejected affidavits submitted by parties which contain unexplained contradictions of previously given clear answers

to unambiguous questions, Dr. Hawes is not a party.[16] As noted in Reese v. Hubert, 527 F.3d 1253, 1270 n. 28 (11th Cir. 2008), the Eleventh Circuit has "never squarely addressed whether, and in what circumstances, a district court may disregard the affidavit of a non-party that is inherently inconsistent with the deposition testimony given by the non-party previously in the same case."[17] In any event, the Court does not agree with Teva that Dr. Hawes' deposition testimony and affidavit are inherently inconsistent. Dr. Hawes testified on deposition that if the label had indicated an increased susceptibility to PTC for adolescents, he might have treated Katelyn differently (Hawes Dep., pp. 42-43), and that had a black box warning appeared on the

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[16] *See* Van T. Junkins & Assoc., Inc. v. U.S. Indus., Inc., 736 F.2d 656, 657 (11th Cir. 1984) ("When a party has given clear answers to unambiguous questions which negate the existence of any genuine issue of material fact, that party cannot thereafter create such an issue with an affidavit that merely contradicts, without explanation, previously given clear testimony.") This rule has been limited in the following manner: "[O]ur cases require a court to find some inherent inconsistency between an affidavit and a deposition before disregarding an affidavit." Rollins v. TechSouth, Inc., 833 F.2d 1525, 1530 (11th Cir. 1987).

[17] In the case of Prophecy Corp. v. Charles Rossignol, Inc., 256 Ga. 27, 28-30, 343 S.E.2d 680, 681-82 (1986), the Georgia Supreme Court held that if, on motion for summary judgment, a respondent offers unexplained self-contradictory testimony on a dispositive issue in the case, the contradictory testimony must be construed against the respondent for purposes of summary judgment. The court later held in Thompson v. Ezor, 272 Ga. 849, 536 S.E.2d 749 (2000), that the Prophecy rule does not apply to the testimony of a non-party expert witness, and provided a number of compelling reasons why the rule should not apply to experts: "Because a party to litigation is without power to prevent his or her witnesses from contradicting themselves when testifying, the party should not be held responsible under Prophecy when such contradictions inevitably rise in the testimony of expert witnesses. Furthermore, simply because an expert witness's testimony is contradicted is no cause for disregarding it under the Prophecy rule-the fact that an expert witness's testimony is contradictory has never rendered that testimony inadmissible. To the contrary, such contradictions go solely to the expert's credibility, and are to be assessed by the jury when weighing the expert's testimony." Id. at 852.

labeling, he might have done something different with respect to prescribing the drug to Katelyn (Hawes Dep., pp. 75, 80). It is not inherently inconsistent for him then to state in his affidavit that he "most likely" would not have prescribed the drug to Katelyn had he known of the risks to adolescents. To the extent there is any conflict between the statements, the conflict is a question of credibility for a jury. Teva can certainly vigorously cross-examine Dr. Hawes on his deposition testimony versus his affidavit.

The next issue, causation, is a bit more difficult to resolve. To establish a failure-to-warn claim, a plaintiff must show proximate cause, which means he must show that the product complained of caused the injury. In order to survive Teva's Motion for Summary Judgment, Plaintiffs must produce evidence that would allow a reasonable jury to find that minocycline is (1) capable of causing PTC and subsequent vision loss and (2) that minocycline did in fact cause Katelyn to develop PTC and vision loss. *See* Jack v. Glaxo Wellcome, Inc., 239 F.Supp.2d 1308, 1321 (N.D. Ga. 2002).

Plaintiffs have presented expert testimony from Dr. Edward Chaum and Dr. Nancy Newman, both of whom have opined that minocycline can cause PTC and vision loss, and that the minocycline did in fact cause Katelyn to develop PTC and vision loss.[18] But as this is a failure-to-warn case, Plaintiffs must also show that a different

[18]Teva points out that Dr. Robert Spector, another of Plaintiffs' experts, testified that he could not rule out the possibility that Katelyn's obesity and systemic hypertension were the primary cause of the PTC. One of Teva's experts, Dr. Jeffrey G. Odel, provided an expert report in which he opined that Katelyn's obesity, combined with her age and gender, is the most likely cause of the PTC. Teva argues that in light of the testimony of Drs. Spector and Odel, Plaintiffs have failed to establish the specific causation element of their failure-to-warn claim. The Court disagrees. All Teva has pointed out is that there is conflicting expert

label or warning would have avoided Katelyn's injuries. The problem for Plaintiffs, however, is that Dr. Hawes did not read the minocycline label immediately prior to prescribing the drug to Katelyn. He also did not read the PDR entry for Teva's product, but that was impossible anyway, because there was no such entry in the PDR. Teva argues that Dr. Hawes' failure to read the label or PDR breaks the causal chain,[19] and cites to a number of cases which it contends stand for the proposition that when a physician fails to read or rely on a drug manufacturer's warnings, proximate cause cannot be established, even if the warnings were inadequate.

The Court does not read Dr. Hawes' testimony as unambiguously as Teva does. Certainly, Dr. Hawes testified that on the day he prescribed the minocycline to Katelyn, he did not reference the PDR or a package insert or any other source of information. He also testified, however, as follows:

> Q. At the time that you prescribed Minocycline to Ms. Weilbrenner, had you ever read the full prescribing information for Minocycline?
>
> A. No.

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testimony about the cause of the PTC, which precludes summary judgment. *See* Lennen v. Dept. of Transp., 239 Ga. App. 729, 730, 521 S.E.2d 885 (1999). This sort of dispute is the reason jury trials exist.

[19]The Court finds Teva's argument as to the PDR to be somewhat disingenuous. On one hand, Teva argues that proximate cause cannot be established because Dr. Hawes did not look up minocycline in the PDR. It is undisputed, however, that Teva's minocycline product was not listed in the PDR at the time Dr. Hawes prescribed the medication. When Plaintiffs point this fact out, Teva argues that it has no obligation to advertise in the PDR. The Court has a problem with Teva attempting to bolster its argument with an impossibility.

Q. By full prescribing information, I'm talking about information as it appears in the PDR or as it appears in the package insert for the medication or any other source that might have been available to you for prescribing information?

A. At the time it was prescribed or prior to that?

Q. I'm talking about at that time or any time prior to that. At that time had you?

A. I don't know that I can answer that one either. I know that I did not reference the PDR or a package insert. I didn't have a package insert to reference but there's a reproduction of the information in the PDR, so that's the same thing. I didn't go and get the PDR and look at it at the time I prescribed it for her.

Had I reviewed information regarding Minocycline prior to that visit and that date of the prescription at some point in my career, I would think the answer to that is yes. Can I specifically remember that, no.

***

Q. And we've established that on January 16th, 2006 you did not review the full prescribing information for Minocycline, correct?

A. That's correct.

Q. And we've established that you have no specific recollection of reviewing the prescribing information for Minocycline at any time prior to January 16th, 2006, correct?

A. Correct in that --

Q. And I asked a specific recollection?

A. You did. However, that does not mean that I did not do it.

(Hawes Dep., pp. 64-65, 77) (internal objection omitted).

Construing Dr. Hawes' testimony in the light most favorable to Plaintiffs, the Court cannot agree with Teva's position that a finding of proximate cause is precluded. Instead, it appears that there is an issue of fact with regard to whether Dr. Hawes read the label and when he did so, if he in fact did.[20] This Court cannot resolve this question on summary judgment.

"As a general rule, issues of causation are for the jury to resolve and should not be determined by a trial court as a matter of law except in plain and undisputed cases." Ogletree v. Navistar Int'l Transp. Corp., 245 Ga. App. 1, 3-4, 535 S.E.2d 545 (2000). This is not one of those plain and undisputed cases. Summary judgment is not appropriate on the failure-to-warn claims.[21]

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[20]One of the cases relied on by Teva in support of its lack of probable cause argument is Thom v. Bristol-Meyers Squibb Co., 353 F.3d 848 (10th Cir. 2003). The district court in Thom determined that the plaintiffs were unable to establish that a different warning would have avoided the injuries, as it found that the facts were uncontroverted that the doctor did not read nor rely upon the drug package insert or the PDR prior to prescribing the drug. The Tenth Circuit disagreed, and referenced certain testimony given by the physician, including that he did not know if he read the PDR entry before prescribing the drug, and that he probably looked up the drug in the PDR, but did not have a specific recollection of doing that. Id. at 856-57. The Tenth Circuit found that there was an issue of fact with regard to whether the physician ever read the entire package insert for the drug, which precluded summary judgment for the defendant. Id. at 857-58.

[21]Teva also argues that Plaintiffs' failure-to-warn claims cannot survive summary judgment because Teva complied with all post-marketing surveillance and reporting requirements. According to Teva, no legal or regulatory authority required it to petition the FDA for a label change, and there is no evidence that even if it contacted the FDA with information about minocycline, the FDA would have made a change to the label prior to Katelyn's ingestion of the medication. This argument, however, is no different from the preemption argument, as regardless of the eventual decision by the FDA, Teva still could have proposed or requested a label change or a "Dear Doctor" letter if appropriate.

3. Plaintiffs' other claims

In addition, summary judgment is not warranted on Plaintiffs' strict liability, breach of warranty, or misrepresentation, concealment, and nondisclosure claims. Teva's only argument is that these claims fail because they are all contingent on Plaintiffs' failure-to-warn claim. As the failure-to-warn claims survive summary judgment, so do the remainder of Plaintiffs' claims.

4. Punitive damages

Finally, Teva argues that Plaintiffs have not set forth a legally adequate claim for punitive damages. O.C.G.A. § 51-12-5.1 provides that "[p]unitive damages may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." An award of punitive damages is not intended to punish conduct, but instead is intended to punish or deter a defendant. May v. Crane Bros., Inc., 276 Ga. 280, 281, 576 S.E.2d 286, 287 (2003).

Plaintiffs argue that punitive damages are warranted in this case because Teva had independent knowledge of adolescent females suffering PTC associated with the use of minocycline, as well as knowledge through medical literature and adverse event reports, well before Katelyn's injury. Plaintiffs argue that even with this knowledge, Teva intentionally did nothing to warn about the danger of PTC and vision loss.

The Court has already determined that Plaintiffs' failure-to-warn claims survive summary judgment. Whether a tort was sufficiently aggravating to warrant punitive damages is generally a jury question. Tookes v. Murray, 297 Ga. App. 765, 768, 678 S.E.2d 209, 213 (2009). If Teva did in fact know of the dangers alleged by Plaintiffs but did nothing to warn anyone about them, a jury could find that punitive damages are appropriate. Thus, summary judgment on the punitive damages claim is not warranted.

III. CONCLUSION

For the reasons set forth above, Teva's Motion for Summary Judgment (Doc. 37) is denied.

SO ORDERED, this the 10th day of March, 2010.

s/ Hugh Lawson
HUGH LAWSON, SENIOR JUDGE

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