UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA

KATELYN WEILBRENNER, A MINOR AND DIANN COURTOY, INDIVIDUALLY AND AS NATURAL MOTHER AND NEXT FRIEND OF KATELYN WEILBRENNER, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Case No. 7:08-cv-23

TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

In the instant action, Teva is entitled to summary judgment. Plaintiffs Katelyn Weilbrenner and DiAnn Courtoy ("Plaintiffs") contend that Ms. Weilbrenner developed the condition pseudotumor cerebri ("PTC") and subsequent vision loss as an adverse reaction to Teva's pharmaceutical product minocycline hydrochloride ("minocycline"). 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. Plaintiffs allege that Teva should be held liable for failing to adequately warn of the risks of PTC and subsequent vision loss in patients of all ages, including adolescents, associated with minocycline. Teva herewith moves for summary judgment on several grounds.[1]

Plaintiffs have failed to establish the requisite failure to warn elements of duty, breach of duty, and causation. Under Georgia's learned intermediary doctrine, a pharmaceutical manufacturer's duty to warn of potential adverse effects of a drug extends only to the prescribing physician, not to the patient. Teva's minocycline package insert provided a clear and adequate warning of a possible PTC reaction and possible permanent sequelae to Ms. Weilbrenner's prescribing physician, Dr. Robert Hawes, thus satisfying any duty to warn that Teva may have had under Georgia law. Indeed, Plaintiffs' designated regulatory expert, Dr. Christopher Rhodes, could not identify any regulations, legal authority, or specific legal duty to support Plaintiffs' claim that Teva's minocycline label was deficient in any way. Furthermore, even if

[1] While Plaintiffs' Complaint is not partitioned into separate claims for relief on different legal theories, it appears that Plaintiffs seek to hold Teva liable on one or more claims purporting to sound in: strict liability in tort or negligence, breach of express or implied warranty, negligent or innocent failure to warn, and negligent or innocent misrepresentation, concealment, or nondisclosure. (Compl. ¶ 14.) Although Plaintiffs allege these various theories of recovery, the substance of the Complaint is that Teva's minocycline labeling did not provide adequate warnings, and all of Plaintiffs' claims are contingent on this issue. (*Id*. at ¶¶ 10-11.) Plaintiffs' claim for punitive damages (Compl. ¶ 17) fails for all the reasons set forth in this brief. Plaintiffs have put forth no evidence, much less clear and convincing evidence, that Teva's conduct warrants the imposition of punitive damages.

Teva's warnings were found to be inadequate, Plaintiffs would not be able to meet their proximate cause burden of proving that a stronger or different warning would have affected Dr. Hawes's decision to prescribe minocycline to Ms. Weilbrenner. Dr. Hawes testified unambiguously that he did not read Teva's minocycline label prior to prescribing minocycline to Ms. Weilbrenner. As such, regardless of the content of the label, since Dr. Hawes did not read it, the warning could not have affected his prescribing decision. Indeed, Dr. Hawes's failure to read Teva's label decidedly precludes Plaintiffs from establishing proximate cause. That the proximate causation link is broken is also plainly demonstrated in Dr. Hawes's deposition testimony and communications with Plaintiffs' counsel, wherein Dr. Hawes repeatedly refused to acknowledge, or to sign any statements attesting, that he would have changed his prescribing decision if the minocycline label had contained stronger warnings.

Plaintiffs' failure to warn claims also fail to the extent that they are grounded in Teva's alleged failure to report new information about minocycline to the FDA or to healthcare providers. Teva has complied with all of its post-marketing surveillance and reporting requirements, and has produced documents to Plaintiffs evidencing its full compliance. Plaintiffs, including their designated regulatory expert[2], can point to no regulatory or legal authority requiring Teva to petition for a label change from the FDA, or even *permitting* Teva to circulate safety information to healthcare providers. Finally, Plaintiffs present no evidence that the FDA would have acted on a petition for a label change submitted by Teva, or that Dr. Hawes would not have prescribed minocycline to Ms. Weilbrenner, if Teva had filed such a petition with the FDA or sent such a "Dear Healthcare Provider" letter to practitioners.

[2] Teva reserves the right to submit *Daubert* motions, at the appropriate time, challenging the ability of Plaintiffs' designated experts – including the regulatory expert Dr. Christopher Rhodes – to testify at trial.

Lastly, all of Plaintiffs' state law claims fail insofar as they attempt to hold Teva liable under state law for failing to provide warnings different from or stronger than the FDA-approved warnings. Federal regulations require that the product labeling for Teva's generic drug minocycline be identical in all material respects to that of its reference-listed drug Minocin®, thus dictating the precise warning language that had to accompany the product that Ms. Weilbrenner allegedly ingested. Federal regulations prohibit Teva from making any changes to the labeling that would cause it to diverge from the FDA-approved Minocin® labeling, under threat of removal of Teva's product from the market. Further, the imposition of state law duties on Teva, above and beyond Teva's existing duties under federal law, would obstruct the purposes and objectives of Congress in regulating generic drugs. As such, Teva cannot be held liable under state law for complying with mandatory federal statutory and regulatory law. The recent Supreme Court decision in *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (U.S. Mar. 4, 2009) is not dispositive herein, because the issue of preemption here relates to *generic drugs*, and this issue was not before the Supreme Court and was not decided by the Supreme Court.

For these reasons, Teva is entitled to summary judgment on all of Plaintiffs' claims.

STATEMENT OF FACTS

All facts are described in a light most favorable to Plaintiffs[3] and, even in that light, do not give rise to any genuine issue of material fact on any of Plaintiffs' claims.

A. Alleged Ingestion and Injuries

Plaintiffs allege that on January 16, 2006, Katelyn Weilbrenner was prescribed minocycline by her primary care physician, Dr. Robert Hawes, for treatment of acne. (Compl. ¶ 4; Ex. A, Pl.'s Resp. Interrogs. 5.) For purposes of this Motion only, Teva does not dispute

[3] Teva has construed the evidence in a light most favorable to Plaintiffs for purposes of this Motion only, as required for a motion for summary judgment. Nevertheless, Teva reserves its right to contest at trial any allegations of fact

that Plaintiffs filled this prescription on the same day with Teva's 100 mg minocycline hydrochloride capsules, or that Plaintiffs refilled the prescription once more on February 28, 2006 with the same minocycline product. (*Id.*) It is alleged that Ms. Weilbrenner began taking minocycline on January 16, 2006, took it regularly for approximately thirty days and then sporadically until May 11, 2006, and ingested a total of about 54 capsules. (Ex. B, Courtoy Dep. 102:2-9; 106:5-110:15.) It is further alleged that Ms. Weilbrenner ceased taking minocycline no later than May 11, 2006. (*Id.* at 104:19-105:2; Compl. ¶ 5.)

Plaintiffs claim that on or about April 24, 2006, Ms. Weilbrenner began experiencing severe headaches. (Compl. ¶ 5.) When the headaches persisted, Ms. Weilbrenner presented to her primary care physician and his assistant on May 8 and May 9, 2006. (*Id.*) On May 11, 2006, Ms. Weilbrenner was seen by an optometrist, Dr. Michael Hopkins, and an ophthalmologist, Dr. Terrance Croyle, and was diagnosed with optic disc edema, papilledema, and pseudotumor cerebri. (*Id.*; Ex. C, Croyle Dep. 43:15-44:22, 51:15-52:17.) Plaintiffs allege that, to date, Ms. Weilbrenner continues to suffer from vision loss resulting from these conditions. (Compl. ¶ 5.)

B. Federal Regulation of Generic Drugs

The manufacture and sale of prescription drug products in the United States is a highly regulated industry, under the jurisdiction of the FDA. The FDA draws its statutory authority as to the approval of such manufacture and sale of drugs primarily from its enabling statute, the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., as amended by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Amendments") (collectively, the "Food and Drug Act"), and has promulgated regulations implementing such statutes, which may be found in pertinent part at 21 C.F.R. Part 314.

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stated herein.

Broadly speaking, under the United States' regulatory scheme, prescription drugs fall into two categories, branded drugs and generic drugs. A branded drug is one that has not yet been established or generally recognized by persons with relevant scientific training as safe and effective for the purposes or medical indications for which its use is intended. 21 U.S.C. § 312(p). The right to manufacture and market such a drug in the United States is secured through the filing of a New Drug Application ("NDA"). In order to obtain approval of an NDA, the applicant (innovator) must demonstrate the safety and efficacy of the drug for its intended indications to the satisfaction of the FDA, typically through the conduct of extensive clinical trials in humans. The research and development of such drugs and the conduct of the requisite clinical trials is often a costly process, which takes years to complete. The large, research-driven pharmaceutical companies who bring such drugs to market are most often accorded patent protection and a period of exclusivity in marketing their drugs, which are sold under proprietary brand names and are often very expensive.

In the public policy interest of providing more affordable prescription drugs for consumers and lowering medical costs, as well as fostering competition, Congress and the FDA enacted statutory provisions and regulations to encourage the manufacture and marketing of the other category of drugs, known as generic drugs. Specifically, the Hatch-Waxman Amendments (codified at 21 U.S.C. § 355(j); 35 U.S.C. §§ 156, 271, 281), established the current procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). The ANDA applicant need only demonstrate that its generic drug product will be bioequivalent to its branded counterpart (*i.e.*, its "reference-

listed drug") and that its proposed labeling, including warning language, is identical to that of the branded drug. 21 U.S.C. § 355(j)(2)(A).[4]

The requirements that a generic manufacturer must meet under the ANDA process are set forth in Section 505(j) of the Food and Drug Act, 21 U.S.C. § 355(j). Specifically, the process begins with a requirement that the information not be new or innovative, but wholly derivative of information already provided by the innovator manufacturer. *See* 21 U.S.C. § 321(aa) (ANDA must "rel[y] on the approved application of another drug with the same active ingredient to establish safety and efficacy.") The 1984 House Report on the Hatch-Waxman Act, 21 U.S.C. § 355 (j), explains that "the focus of [§ 505(j)] is to provide [FDA] with sufficient information to assure that the generic drug is the same as the listed drug," thereby obviating any need for duplicate testing for safety or effectiveness of the generic drug. H.R. Rep. No. 98-857, at 21 (Ex. D.) Thus:

> the manufacturer of a pioneer drug must conduct tests on humans that show the product to be safe and effective and submit the results in a new drug application (NDA). A manufacturer of a generic drug must conduct tests that show the generic drug is the same as the pioneer drug and that it will be properly manufactured and labeled.

Id. at 16. As such, an ANDA applicant is not required or expected to conduct clinical trials to establish the safety and efficacy of its drug. The Food and Drug Act and FDA's regulatory scheme contemplates that safety and efficacy will have been established by the pharmaceutical company who originally submitted the NDA for the drug. In contrast, the generic manufacturer

[4] The elements that the generic drug manufacturer must establish are explained in H.R. Rep. No. 98-857 at 21-22. The ANDA must show that:

- the conditions of use on the proposed labeling for the generic drug are the same as those approved for the listed drug [§ 505(j)(2)(A)(i)], excepting only indications covered by a patent or subject to exclusivity protection under FDCA § 505(j)(5)(D). *See* 21 C.F.R. § 314.94(a)(8)(iv); *see also* 57 Fed. Reg. at 17,961.
- the active ingredient is the same as that of the listed drug [§ 505G)(2)(A)(ii)].
- the route of administration, dosage form, and strength are the same as those of the listed drug [§ 505(j)(2)(A)(iii)].
- the generic drug is bioequivalent to (i.e., can be expected to have the same therapeutic effect as the listed drug) [§ 505(j)(2)(A)(iv)].

is obliged only to conduct so-called "bioequivalency" studies, to establish that its dosage formulation of the generic product has the same pharmacological action in the human body as does the relevant reference-listed drug. In that case, that is, if the generic version of the drug is shown to be "bioequivalent" to its reference-listed drug, it is assumed to have the same safety and efficacy profile. By avoiding time-consuming and costly clinical trials, generic drug manufacturers are able to bring generic drugs to market quickly and at less expense.

The flip side of this regulatory framework is that the labeling – that is, the prescribing information or package insert – of the generic drug may not deviate in any material respect from that of its reference-listed drug. But for differences relating to the fact of the product being manufactured by a different company, chiefly physical description, inactive ingredients and, perhaps, listing fewer indications for use, the generic manufacturer's labeling, including all statements as to Warnings, Precautions, Contraindications, Adverse Reactions, must adhere letter for letter to the corresponding provisions of the labeling of the relevant reference-listed drug.

C. Teva's Minocycline Product and Labeling

In 1992, Teva's predecessor, Biocraft Laboratories, Inc. ("Biocraft"), first received approval of ANDA No. 63-009 for its 100 mg minocycline hydrochloride capsules. (Ex. E.) In 1996, Biocraft (together with Lemmon Company) formed the corporate entity Teva Pharmaceuticals USA, Inc., and Teva became owner of this ANDA for minocycline. (Ex. F.)

In accordance with the above-described regulatory framework, in securing approval of its minocycline ANDA, Biocraft did not conduct safety and efficacy testing *per se*, but only bioequivalency tests to establish that its generic minocycline product would be bioequivalent to its reference-listed drug Minocin®. (*See generally* Ex. G, Zwicker Dep. 28:17-31:2.) As required, Biocraft, at the time of approval, conformed its FDA-approved minocycline labeling in all material respects, including the Warnings, Precautions, and Adverse Reactions sections, to

that of Minocin®. Not to have done so would have meant that the minocycline product was misbranded and unapprovable.

It is undisputed that Teva's package insert for its generic minocycline product, in effect when Plaintiffs allege ingestion, warns in two separate sections of PTC as a potential adverse reaction and of the possibility of permanent sequelae (Ex. H):

> **PRECAUTIONS**
> * * *
> 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**
> * * *
> *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.

ARGUMENT

I. SUMMARY JUDGMENT STANDARD

A defendant is entitled to summary judgment 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). If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the nonmovant, 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). If there is a failure of proof on an essential element, there is no genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

It is well-established that "unsupported speculation . . . does not meet a party's burden of producing some defense to a summary judgment motion. Speculation does not create a *genuine* issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment." *Cordoba v. Dillard's Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005); *Lil' Joe Wien Music v. Jackson*, 2007 WL 2274519, at *2 (11th Cir. 2007) (holding that "evidence that is merely colorable or not significantly probative is not enough" to survive summary judgment).

II. PLAINTIFFS' FAILURE TO WARN CLAIMS FAIL UNDER GEORGIA'S LEARNED INTERMEDIARY DOCTRINE

Under Georgia law, a plaintiff has the burden of proving three elements for recovery under a failure to warn theory: (1) the defendant had a duty to warn; (2) the defendant breached that duty; and (3) the breach was the proximate cause of the plaintiff's injuries. *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) (citation omitted); *see also Wheat v. Sofamor, S.N.C.,* 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). If a plaintiff fails to make a sufficient showing to sustain any of these elements, summary judgment is appropriate. *See Hoffman v. AC&S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001) (*quoting Clark v. Joiner*, 530 S.E.2d 45, 46 (Ga. Ct. App. 2000)) ("To win summary judgment, 'a defendant . . . must only point to an absence of evidence supporting at least one essential element of the plaintiff's claim.'"). In this case, Plaintiffs' failure to warn claims should be dismissed because Plaintiffs have failed to establish the necessary elements.

A. Under the Learned Intermediary Doctrine, Teva's Duty to Warn Was Owed Only to the Prescribing Physician

Under Georgia law, Teva's duty to warn extended solely to Plaintiff Katelyn Weilbrenner's prescribing physician. Georgia courts have adopted the learned intermediary doctrine as a defense against tort liability for pharmaceutical manufacturers. *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003); *Presto v. Sandoz Pharmaceuticals Corp.*, 487

S.E.2d 70, 73 (Ga. Ct. App. 1997); *Hawkins v. Richardson-Merrell, Inc.*, 249 S.E.2d 286, 288 (Ga. Ct. App. 1978). Referring to prescription drugs, the *McCombs* court held that manufacturers have a duty to warn only the prescribing physician, who "acts as a learned intermediary between the patient and the manufacturer," because:

> 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 need and susceptibilities.'

587 S.E.2d at 595 (internal citations omitted). Thus, the information supplied by the drug manufacturer is only one source a physician must consult, and the physician is expected to make an independent medical judgment in determining whether a drug is appropriate for a particular patient. Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform the prescribing physician of facts which may make the product likely to be dangerous. *See Presto*, 487 S.E.2d at 73. Thus, a failure to warn claim cannot survive against a manufacturer of a prescription drug where the manufacturer specifically and adequately warns the prescribing physician of a potential adverse reaction to a drug.

B. As a Matter of Law, Teva Satisfied Its Duty to Warn Because Its Minocycline Labeling Provided Adequate Warnings to the Learned Intermediary

It is undisputed that Teva's minocycline label in effect at the time Ms. Weilbrenner was prescribed the drug specifically warned of the possibility of serious side effects, including PTC. (S*ee* Ex. H.) Moreover, the insert specifically informed physicians that, with respect to PTC, the "usual clinical manifestations are headache and blurred vision," and advised physicians that "the possibility for permanent sequelae exists." (*Id.*) As Ms. Weilbrenner's prescribing physician, it was the role, duty, and obligation of Dr. Robert Hawes – and only Dr. Hawes – to select the appropriate drug to treat Ms. Weilbrenner and to inform Ms. Weilbrenner of any associated risks he thought, in his medical judgment, she should be aware of, including PTC. Teva fulfilled any

duty to warn that it may have had under Georgia law by placing a warning regarding PTC and possible permanent sequelae in its minocycline package insert and, hence, providing the necessary information for Dr. Hawes to apply his own independent medical judgment in prescribing minocycline and in informing Ms. Weilbrenner of the associated risks.

Plaintiffs have put forth no contrary evidence to show that Teva breached its legal duty to warn. Dr. Christopher Rhodes, Plaintiffs' sole expert on the issue of warnings, does not and cannot support Plaintiffs' contentions regarding the alleged inadequacy of Teva's labeling, because Dr. Rhodes is not an expert in the area of FDA regulation of pharmaceutical drugs. (*See* Ex. I, Rhodes Dep. 40:18-20, 70:10-13.) In fact, Dr. Rhodes repeatedly testified that he could cite to no regulations, legal authority, or specific legal duty to support his opinions with respect to Teva's minocycline labeling. (*Id*. at 145:13-17, 146:9-11, 117:2-7, 120:25 – 121:7.)

Plaintiffs also have put forth no evidence that a change in the minocycline labeling with respect to PTC was warranted. In fact, Plaintiffs' own expert witness, Dr. Robert Spector, testified at deposition that he has treated over six thousand cases of PTC over his thirty years of medical practice, and that he has seen less than ten cases "in which Minocin was expressed as a possible causal agent." (Ex. J, Spector Dep. 77:13-79:9.) Also, a review of the world-wide scientific literature uncovered only sixty case reports of PTC associated with minocycline (Ex. K, Lamm Affidavit and Report at 12), despite the fact that there have been millions of minocycline prescriptions worldwide in the nearly forty years that minocycline has been on the market. (*See* Ex. L, Lamm Dep. 137:16-138:18.)

Thus, Plaintiffs have failed to show the existence of any genuine issue of material fact as to whether Teva fulfilled its duty to warn with respect to its minocycline product, and Plaintiffs' failure to warn claims should be dismissed.

C. Even if Teva's Warnings Were Inadequate, Plaintiffs Have Failed to Establish Proximate Causation Between Teva's Warnings and Plaintiff Katelyn Weilbrenner's Injuries

Georgia law requires a plaintiff in a products liability suit to prove the proximate cause of the injury. *Powell*, 4 F. Supp. 2d at 1203. In a case involving prescription drugs, a plaintiff must prove that, but for the alleged inadequate warning, the prescribing physician would not have prescribed the drug. *Porter v. Eli Lilly & Co.*, 2008 WL 4138115 (11th Cir. Sept. 9, 2008) (applying Georgia law and affirming the district court's grant of defendant's summary judgment motion where plaintiff failed to prove proximate causation). In the instant case, regardless of the adequacy of Teva's minocycline labeling, Plaintiffs cannot establish proximate cause for at least two reasons. First, the prescribing physician, Dr. Hawes, did not read the labeling prior to prescribing minocycline to Ms. Weilbrenner. This fact alone categorically precludes Plaintiffs from being able to establish proximate causation or make out their failure to warn claims. Second, Plaintiffs have put forth no persuasive evidence that Dr. Hawes would *not* have prescribed minocycline to Ms. Weilbrenner, even if Dr. Hawes *had* read the minocycline labeling, and that labeling *had* contained stronger warnings as Plaintiffs propose. In fact, the evidence is to the contrary.

Dr. Hawes's failure to read the minocycline labeling prior to prescribing the drug to Ms. Weilbrenner clearly breaks the causal chain. Indeed, "[t]he majority of the courts that have examined the issue have held that when a physician fails to read or rely on a drug manufacturer's warnings," proximate cause cannot be established, even where the warning was inadequate. *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir 2003). *See also Latiolais v. Merck*, 2008 WL 5157705 (9th Cir. Dec. 9, 2008); *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004); *Conte v. Wyeth, et al.*, 168 Cal. App. 4th 89 (Cal. Ct. App. Nov. 7, 2008), *review denied* (Cal. Jan 21, 2009); *Formella v. CIBA-GEIGY Corp.*, 300 N.W.2d 356, 358-59 (Mich. Ct.

App. 1980); *Douglas v. Bussabarger*, 438 P.2d 829, 831 (Wash. 1968).[5] Thus, Plaintiffs cannot establish proximate causation, in light of Dr. Hawes's unambiguous testimony that he did not read or rely on Teva's minocycline warnings in making his prescribing decision:

> Q. So, do you have a specific recollection that you did not reference the prescribing information at the time that you prescribed the Minocycline to Ms. Weilbrenner?
> A. I do have a recollection and I did not.
> ***
> Q. At the time that you prescribed Minocycline for Ms. Weilbrenner, January 16th of 2006, you said you did not read the Minocycline prescribing information, correct?
> A. Correct.
> Q. So is it fair to say that had a black box warning or any other warning been in the labeling in the prescribing information at that time, you would not have seen it on that date; is that correct?
> A. I would not have reviewed it in the PDR; that is correct.

(Ex. M, Hawes Dep. 66:11-15, 68:3-14.) Dr. Hawes also testified that he did not review any other sources, including the PDR, at the time that he prescribed minocycline to Ms. Weilbrenner. (*Id.* at 68:18-22.) In point of fact, the content of Teva's label is completely irrelevant in this context since Dr. Hawes expressly has acknowledged that he did not review the label prior to prescribing minocycline to Ms. Weilbrenner. Even if the warnings on Teva's minocycline label were stronger or contained in a black box, as Plaintiffs propose, Dr. Hawes's decision to prescribe minocycline to Ms. Weilbrenner would not have been affected, because Dr. Hawes did not read the label. Accordingly, Dr. Hawes's failure to read the label precludes a finding of proximate causation.[6]

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[5] While Georgia law is silent on this issue in the context of the learned intermediary doctrine, Georgia courts have held that a *consumer's* failure to read instructions or printed warnings on a product prevents that consumer from recovering on a failure to warn claim. *Camden Oil Co. v. Jackson*, 609 S.E.2d 356, 359 (Ga. Ct. App. 2004); *see also Walker v. Merck & Co.*, 648 F. Supp. 931, 935-36 (M.D. Ga. 1986) ("Manufacturers are not insurers, and a manufacturer cannot be held liable for a consumer's failure to read or to listen to understandable warnings.") There is every reason to believe that Georgia would extend this ruling to treating physicians in the context of the learned intermediary doctrine.

[6] A Georgia district court recently suggested that under Georgia law a rebuttable presumption may exist with respect to a plaintiff's initial burden of proving proximate causation. *Porter v. Eli Lilly & Co.*, 2008 WL 544739, at *9-11

In addition, Plaintiffs cannot point to any persuasive evidence in the record to establish that Dr. Hawes would have acted differently even if he *had* read the minocycline label prior to prescribing the drug to Ms. Weilbrenner, and the warnings therein *had* been altered as Plaintiffs propose. On the contrary, Dr. Hawes's deposition testimony and communications with Plaintiffs' counsel suggest otherwise. On several occasions, Dr. Hawes refused to sign a memorandum drafted by Plaintiffs' attorneys, containing language to the effect that Dr. Hawes "most likely would not have prescribed Katelyn Weilbrenner Minocycline had the drug insert contained a 'black box' warning concerning the risk of papilledema and visual loss with the use of Minocycline in adolescents." (*See* Ex. N, Hawes Dep. Ex. 13.) Instead, Dr. Hawes corrected this statement to read that a different warning "may or may not" have changed his decision to prescribe minocycline to Ms. Weilbrenner or to discuss the risks of minocycline with Plaintiffs. (*Id.*) Dr. Hawes reiterated his concerns about the proposed statement in several subsequent emails with Plaintiffs' counsel: "I still have reservations about the language of the certainty of what I 'would have' done. I think trying to look back and say for certain what I would have done is wrought with speculation and question." (Ex. O, Hawes Dep. Ex. 11). During his deposition, Dr. Hawes confirmed that he "had concerns about the certainty of what [he] would have done with a different set of labeling circumstances to deal with." (Ex. M, Hawes Dep.

(N.D. Ga. Feb. 25, 2008). Specifically, if a plaintiff produces sufficient evidence that a warning is inadequate, a rebuttable presumption arises that the learned intermediary would have heeded an adequate warning; the defendant must then rebut this presumption. *Id.* In affirming the district court's decision, the Eleventh Circuit did not discuss the existence of a rebuttable presumption under Georgia law, but rather simply stated that: "[u]nder Georgia law, [plaintiff] was required to prove that, but for the alleged inadequate warning, [the learned intermediary] would not have prescribed Prozac to decedent." *Porter*, 2008 WL 4138115, at *2. Even if a rebuttable presumption were applied in this case, it would nevertheless be rebutted by Dr. Hawes's testimony that he did not read Teva's minocycline package insert. *See e.g. Harris v. McNeil Pharm.*, 2000 WL 33339657, at *3 n.3 (D.N.D. Sept. 5, 2000) ("The presumption that had an adequate warning been given it would have been read and heeded is rebutted by [the physician's] testimony that he did not read the warning.") Therefore, regardless of any presumption, Plaintiffs would still bear the burden of establishing proximate causation in this case, a burden they cannot meet.

55:10 – 56:1.)[7] Remarkably, four months after this deposition, Plaintiffs provided Teva with a signed affidavit from Dr. Hawes, wherein he appears to agree with the exact statements that he had previously rejected as inaccurate and speculative. (Ex. Q.) One can only wonder what motivated Dr. Hawes to revise his testimony to be more favorable to Plaintiffs, after repeatedly declining to provide such testimony. Indeed, this affidavit should be disregarded as after-created "evidence" since it contradicts – without explanation – Dr. Hawes's clear deposition testimony and his repeated statements expressly declining to speculate as to whether or not an altered label would have changed his decision to prescribe minocycline to Ms. Weilbrenner or to discuss associated risks with Plaintiffs. *See Van T. Junkins and 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"); *Mercado v. Rogers*, No. 7:06-cv-64, 2008 WL 553074, *5 (M.D. Ga. Feb. 27, 2008) (Lawson, J.) (disregarding an affidavit of a party "which is in conflict with the party's deposition testimony and which does not offer any valid explanation for the conflict"); *Sermons v. Fleetwood Homes of Georgia*, 227 F. Supp. 2d 1368, 1382-83 (S.D. Ga. 2002) (disregarding an affidavit of a *non-party witness* that contradicted the witness's prior deposition testimony and did not provide any explanation for the contradiction).[8]

[7] Plaintiffs clearly recognized this flaw in their proximate cause argument. In an e-mail to Dr. Hawes, Plaintiffs' counsel explained: "my concern is that allowing the defense to argue that you 'might not' have shared the black box warning with Ms. Courtoy gives rise to a 'so what' defense; that is to say, if the black box warning is not used to counsel the patient (and allow the patient to choose between minocycline or another medication), then you get the same result." (Ex. P, Hawes Dep. Ex. 9). However, at that time, Dr. Hawes still declined to change his position on the issue.

[8] Plaintiffs resorted to similar measures when faced with damaging and "unexpected" deposition testimony from Dr. Robert Spector, their own expert witness on the issue of causation. Indeed, because Dr. Spector conceded certain critical points at his deposition, Plaintiffs moved to designate two new causation experts four months after Plaintiffs' expert disclosure deadline. However, Dr. Spector's testimony and the circumstances of Plaintiffs' retention of two new causation experts are significant. Similarly significant are Dr. Hawes's testimony and prior statements, as well

Plaintiffs cannot prove that a different warning would have changed Dr. Hawes's prescribing decision and, thus, cannot carry their burden as to proximate cause.

III. PLAINTIFFS' FAILURE TO WARN CLAIMS FAIL BECAUSE TEVA COMPLIED WITH ALL POST-MARKETING SURVEILLANCE AND REPORTING REQUIREMENTS

Plaintiffs' failure to warn claims also fail to the extent that they are grounded in Teva's alleged failure to report safety information regarding minocycline to the FDA or to provide informational literature regarding minocycline to healthcare providers. Plaintiffs do not support these allegations with specific facts in admissible form, and rely solely on the single-page expert report and vague deposition testimony of Dr. Christopher Rhodes, who similarly points to no evidence in the record or regulatory or legal authority to support his opinions.

To assist the FDA in its oversight and continuing regulation of approved drugs, all drug manufacturers are subject to extensive requirements for post-marketing reporting of adverse drug experiences, including the submission of an annual report summarizing "significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product." 21 C.F.R. §§ 314.80, 314.81(b)(2)(i). Teva has provided to Plaintiffs abundant evidence of Teva's compliance with its post-marketing surveillance and reporting requirements, in the form of Teva's entire file containing minocycline-related adverse event reports, as well as Teva's minocycline periodic adverse event reports submitted to the FDA. Remarkably, Dr. Rhodes, Plaintiffs' designated expert on the issue of labeling, testified that he arrived at his opinions without reviewing any of these documents evidencing Teva's full compliance with its post-marketing surveillance and reporting requirements. (Ex. I, Rhodes Dep. 140:7-9). Teva also produced for deposition Dr. Dennis Miley, Teva's Director of North American Drug Safety

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as the circumstances of Plaintiffs' submission of an affidavit containing contradicting opinions. Plaintiffs cannot completely run away from prior negative testimony by key fact and expert witnesses in this case.

and Pharmacovigilance, who provided extensive testimony concerning Teva's Pharmacovigilance Department and concerning Teva's compliance with post-marketing surveillance and reporting requirements, both in general and with respect to Teva's minocycline product.

Dr. Rhodes opines that Teva failed to contact the FDA with new information about minocycline allegedly available to Teva by at least 2004, which purportedly would have caused the FDA to require the NDA holder and all ANDA holders to change their minocycline labeling prior to Ms. Weilbrenner's ingestion of the drug in January 2006. (*See* Ex. R, Rhodes Rep.; Ex. I, Rhodes Dep. 117:20-118:16.) This argument is clearly flawed. To begin with, Teva has demonstrated that it complied with all FDA safety information reporting requirements concerning its minocycline drug, and there is no evidence to the contrary. Dr. Rhodes does not identify any specific information (*i.e.*, case reports or literature) that Teva allegedly failed to provide to the FDA. Moreover, while asserting conclusorily that Teva had "the right, the duty, to contact FDA to try to get a change to the label" (Ex. I, Rhodes Dep. 118:14-16), Dr. Rhodes can point to no regulatory or legal authority requiring Teva to petition FDA for a label change. (*Id.* 138:2-139:18.)[9] Finally, Dr. Rhodes could only hypothesize as to whether, even if Teva *had* contacted the FDA with particular information about minocycline, this information would have been sufficiently significant to cause the FDA to direct a change to the minocycline label, and much less to have effectuated such changes prior to January 2006. (*Id.* at 138:1-139:18.)[10]

[9] Indeed, Dr. Rhodes testified that he is not aware "in the history of the FDA as to whether any labeling change has ever been made by a generic company contacting the Office of Generic Drugs and suggesting a change to the NDA labeling." (*Id.* at 119:19-24.)

[10] This issue is also critical to the question of proximate cause. Even assuming that there was new evidence about minocycline that Teva had a duty to report to the FDA, that Teva had a duty to petition for a warnings change on the basis of such evidence, and that Teva breached these duties, such breach is still not actionable unless it proximately caused the claimed injuries. In this context, proof of proximate cause would mean proof that the FDA would have acted on Teva's petition and adopted the proposed enhanced warnings, and that Dr. Hawes would have acted on

Dr. Rhodes also opines that Teva failed to provide "sufficient and appropriate educational material" regarding minocycline to healthcare providers. (Ex. R, Rhodes Rep.) This argument is equally flawed. Once again, Dr. Rhodes does not identify any specific information (*i.e.*, case reports or literature) significant enough to warrant a Dear Healthcare Provider letter to the prescribing community and, once again, Dr. Rhodes neither does nor can cite any regulatory or legal duty requiring, *or even permitting*, Teva to send such a letter, as he suggests. (Ex. I, Rhodes Dep. 144:12-145:12.) In fact, any Dear Healthcare Provider letter proposed by Teva would have required FDA approval, and *could not make any representations inconsistent with the approved labeling*. Finally, there is still no evidence, from Dr. Rhodes, Dr. Hawes, or otherwise, to establish how a Dear Healthcare Provider letter might have affected Dr. Hawes's prescribing decision with respect to Ms. Weilbrenner in January 2006.

In short, the record is devoid of any legal or evidentiary support for Plaintiffs' claim that Teva withheld safety information about minocycline from the FDA or the medical community.

IV. ALL OF PLAINTIFFS' STATE LAW CLAIMS ARE PREEMPTED BY THE SUPREMACY CLAUSE OF THE CONSTITUTION AND FEDERAL LAW

In securing and preserving the right to sell minocycline for the indications approved by the FDA, Teva was subject to the dictates of the Food, Drug and Cosmetic Act, as amended by the Hatch-Waxman Amendments, and to pervasive regulation by the FDA, including as to the content of its product labeling. Such statutory law and regulations included an obligation to maintain the content of its labeling, including warnings, indications and directions for use, in the form prescribed to it by the FDA. Any finding by a jury applying state tort law that Teva should have provided warnings or other product information inconsistent with this obligation is

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such revised warnings so as not to prescribe minocycline to Ms. Weilbrenner. There is simply no evidence in the record allowing Plaintiffs to sustain their burden on this issue, nor is it clear what form such evidence would take.

impermissible under the doctrine of federal preemption pursuant to the Supremacy Clause of the United States Constitution. The recent Supreme Court decision in *Wyeth v. Levine* is not adversely dispositive of Teva's preemption argument herein, because the issue of preemption as it applies to state law claims brought against *generic* manufacturers, such as Teva, was not before the Supreme Court and, thus, the Supreme Court did not address the issue. As such, all of Plaintiffs' state law claims must be dismissed.[11]

A. Plaintiffs' State Law Claims Create an Impermissible Conflict with Federal Law

The Supremacy Clause of the United States Constitution, article VI, clause 2, preempts any state law that conflicts with the exercise of federal power. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 102 S. Ct. 3014 (1982). "Pre-emption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Matter of Cajun Elec. Power Co-op., Inc*., 109 F.3d 248, 254 (5th Cir. 1997) (*citing Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

Without explicit pre-emptive language in the relevant statute, congressional intent to displace state law may be inferred because "[t]he scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," because "the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the

[11] In January 2009, a federal court, in finding that state law claims against a medical device manufacturer were preempted by the Medical Device Amendments to the FDCA, began its analysis by acknowledging that "federal courts are frequently confronted with sympathetic plaintiffs who are, nevertheless, without remedy by operation of law. . . . [T]he doctrine of federal preemption []leaves some plaintiffs without judicial recourse to pursue claims for damages." *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 2009 WL 35467, at *1 (D. Minn. Jan. 5, 2009). Similarly, in the instant case, even if the Court were to find that Plaintiffs were injured by Teva's product, their claims necessarily run afoul of the Supremacy Clause of the United States Constitution, and are barred.

same subject," or because "the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose." *Id.* (*quoting Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). This so-called "conflict preemption," where "a state common-law claim directly conflict[s] with a federal regulation . . ., or if it [is] impossible to comply with any such regulation without incurring liability under state common law," *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65, 123 S. Ct. 518 (2002), is applicable to the instant case. Specifically, Plaintiffs' state law claims alleging that Teva failed to provide adequate warnings in the marketing of its minocycline product create an impermissible conflict because the addition of unapproved language is in direct contravention of federal law.

1. Federal Law and Regulations Require Generic Manufacturers to Conform the Labeling of Their Drugs to That of the Counterpart Branded Drug Products

21 C.F.R. § 314.94 prescribes the procedures for filing and content of an ANDA, implementing Section 505(j) of the Food and Drug Act, 21 U.S.C. § 335(j)(2)(A)(v), which requires an ANDA applicant to submit to the FDA:

> information to show that *the labeling proposed for the new drug is the same as the labeling approved for the listed drug* referred to in clause (i) except for changes required because . . . the new drug and the listed drug are produced or distributed by different manufacturers.

(emphasis added.) *See also* 21 C.F.R. § 314.94(a)(8)(i) (generic drug manufacturer must provide a copy of currently approved labeling for the reference-listed drug); 21 C.F.R. § 314.94(a)(8)(iv) (generic manufacturer must submit side-by-side comparison of its proposed labeling with the approved labeling for the reference-listed drug, with all differences annotated and explained; no differences permitted, except as enumerated therein); 21 C.F.R. § 314.127(a)(7) (FDA will refuse to approve an ANDA if information submitted is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug").

The FDA also controls the content of the generic label post approval of the ANDA, with the content of the approved label for the relevant reference-listed drug remaining the lodestar for the generic label. Indeed, at all times throughout the life of the product, the generic label should be maintained in conformity with that of the relevant reference-listed drug, and any addition could result in the withdrawal of approval of the ANDA. *See* 21 C.F.R. § 314.150(b)(10).

2. The "Changes Being Effected" Regulation Does Not Provide an Exception to the Rule Mandating Conformation of Generic Drug Labeling to that of the Relevant Reference-Listed Drug

While it has sometimes been argued that an ANDA holder has a right to enhance warnings through the mechanism of 21 C.F.R. § 314.70(c)(6)(iii)(A), the so-called "Changes Being Effected" ("CBE") provision, this is not a proper interpretation of the regulations.

Indeed, Plaintiffs' own expert witness designated on the issue of warnings, Dr. Rhodes, testified that CBE changes are not available to ANDA holders:

> Q: CBE's, or changes being effected, are not available to ANDA holders, right?
> A: That's what I just said.

(Ex. I, Rhodes Dep. 137:22-25) (objection to form omitted).

This has always been FDA's own position – that under 21 C.F.R. § 314.70(c), *no labeling changes can be made unilaterally by a generic manufacturer*.[12] On the occasion of the publication of the Final Rulemaking on ANDA Regulations in 1992, FDA clearly rejected any notion that the

[12] The FDA's interpretation of its own regulations is entitled to significant deference. *See, e.g.*, *Auer v. Robbins*, 519 U.S. 452, 461 (1997). The Supreme Court's discussion in *Levine* of the level of deference due to the FDA's pronouncements regarding preemption in the preamble of the 2006 federal register notice is not applicable here. The preemption analysis relevant to generic manufacturers does not rely or depend on the 2006 preamble, but rather on the enactment of the Hatch-Waxman Amendments and implementing regulations. Congress's and the FDA's position on the inability of generic manufacturers to make unilateral label changes has never changed. From the time the Hatch-Waxman Amendments were enacted to permit the approval of generic drugs, generic manufacturers were required to maintain their labeling in conformity to the FDA-approved branded drug's labeling. Accordingly, the analysis of the deference due the FDA with regard to its interpretation of its own regulations that preclude generic manufacturers from relying on the CBE provision to make unilateral label changes – the analysis relevant to this case – differs dramatically from the deference analysis the Supreme Court employed in *Levine*.

CBE regulation applies to generic drug manufacturers: "[a]fter approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." *Abbreviated New Drug Application Regulations, Final Rule,* 57 Fed. Reg. 17950, 17961 comm. 40 (April 28, 1992) (Ex. S.) FDA also expressly rejected public requests that ANDA applicants be allowed unilaterally to deviate from the labeling of the innovator drug to add contraindications, warnings, precautions, adverse reactions, and other safety related information:

> Two comments said the labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information.
> * * *
> *FDA disagrees with the comments. Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the [Food and Drug Act], the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval.*

Id. (emphasis added).

This long-held position was made even more abundantly clear by the admonishment in the November 1999 FDA Guidance and the April 2004 Revision I to that Guidance that "[a]ll labeling changes for ANDA products must be consistent with § 505(j) of the Act," ("FDA Guidances") (Ex. T at 24), *i.e.*, must conform to the labeling of the relevant reference-listed drug. Further, the FDA, in a December 1996 letter, cautioned ANDA holders that they cannot adopt innovator labeling that has been unilaterally revised by the innovator through the mechanism of 21 C.F.R. § 314.70(c), unless and until such revised innovator drug labeling has been affirmatively approved by the agency. The letter stated that "[t]he FDA must still review, possibly recommend changes and approve the [revised innovator drug] labeling before it is acceptable for use as model labeling for an [ANDA] product." Letter from Douglas L. Sporn, Director, Office of Generic Drugs, Center

for Drug Evaluation and Review, at 8. (Ex. U.) *See also* 57 Fed. Reg. at 17,957, 17,961, and FDA Guidances at 24.

The FDA recently reasserted this long-standing position in its Final Rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics and Medical Devices, 73 Fed. Reg. 49603, 49605 (August 22, 2008) ("Final Rule") (Ex. V). This Final Rule sets out express guidelines for label changes through CBE supplements pursuant to 21 C.F.R. § 314.70(c)(6)(iii). Notably, with respect to the argument about the right of an ANDA holder to avail itself of this regulatory provision, as regards to pharmaceutical products, the Final Rule is directed *exclusively* to NDA holders. By implication, this is yet more evidence, if any was needed, that warnings enhancement through CBE supplementation is *not* available to ANDA holders in this context.

In addition to rulemakings and guidances, the FDA has also clearly explained its position in *amicus curiae* briefs. See Brief for United States as *Amicus Curiae*, *Colacicco v. Apotex, Inc., et al.*, No. 06-3107, at 7-8 (3d Cir. Dec. 4, 2006) (Ex. W), in which FDA squarely addressed the issue:

> For a generic drug manufacturer, there is no statutory or regulatory provision permitting a labeling change to be made without prior FDA approval. To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. See 21 C.F.R. § 314.150(b)(10); see also 57 Fed. Reg. 17,950, 17953, 17,961 (1992). If a generic drug manufacturer believes that new safety information should be added to the label for its drug, it is directed to contact FDA with "adequate supporting information."
> * * *
> The plaintiff asserts that 21 C.F.R. § 314.70(c) empowers a generic drug manufacturer to add a new warning to the label for its drug without prior FDA approval. That regulatory provision, however – like the other provisions of Title 21, Part 314, subpart B of the Code of Federal Regulations – applies to applications involving drug products for which a full application has been submitted, i. e., innovator drug products. Drug manufacturers that submit abbreviated applications to market generic drugs are subject to the requirements set forth in Title 21, Part 3314, Subpart C. Although Subpart C contains a

> provision requiring applicants to "comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application, 21 C.F.R. § 314.97, that provision does not modify the requirement that the drug label for a generic drug must be the same as the label for the approved innovator drug (with limited exceptions not relevant here). Any ambiguity in the regulatory text has been clarified by FDA, which explained at the time of promulgation that the regulations do not authorize generic drug manufacturers to add new warnings to the approved labeling for the innovator drug. *See* 57 Fed. Reg. at 17,961, 17,953, 17,955.[13]

This inability of an ANDA holder to make unilateral label changes under the CBE provision is at the heart of the argument in favor of generic preemption, and also distinguishes the recent ruling by the Supreme Court in *Levine*. In that case, the Supreme Court held that conflict preemption did not apply to shield a branded manufacturer from liability, because the CBE provision permitted the branded manufacturer to strengthen the warnings in its product labeling without obtaining prior approval from the FDA. As such, the Supreme Court found that it was not impossible for the branded manufacturer to have complied with both federal and state law with respect to the labeling of its branded drug. However, since the CBE provision does not similarly authorize generic manufacturers to make changes to their labeling without prior FDA approval, it is, in fact, *impossible* for a generic manufacturer, such as Teva, to comply with both federal and state law. Thus, whereas the *Levine* Court explained how a branded manufacturer can comply with both federal and state law, the *Levine* Court provided absolutely no guidance

[13] The FDA has recently withdrawn this amicus brief in order to conduct an analysis of its position on preemption issues in light of *Levine*. Letter from Sharon Swingle, U.S. Dep't of Justice, to Marcia M. Waldron, U.S. Court of Appeals for the Third Circuit (Apr. 28, 2009), No. 06-3107, Doc. 00319577893. However, there is no indication that the FDA intends to reexamine its clear and consistent position on the proper interpretation of § 314.70, which it had set forth in this *amicus* brief. See *supra* n.12, noting the deference due the FDA's interpretation of its own regulations. See also the FDA's discussion of the proper interpretation of § 314.70 contained in its *amicus* brief filed in the trial court, Brief for United States as *Amicus Curiae, Colacicco v. Apotex, Inc.*, Civ. Action No. 05-CV-05500, at 16-17 (E.D. Pa. May 10, 2006) (Ex. X), which had proved persuasive to the District Court. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 514 (E.D. Pa. 2006), *aff'd,* 521 F.3d 253 (3d Cir. 2008), *cert. granted and vacated and remanded to* 521 F.3d 253, 129 S.Ct. 1578 (Mar. 9, 2009), *remanded to* 432 F. Supp. 514 (3d Cir. Apr. 28, 2009).

for how a generic manufacturer, such as Teva, can possibly comply with its conflicting federal and state law duties. [14]

Accordingly, any imposition of state tort liability on Teva for not including warnings differing from those approved by the FDA is clearly an impermissible violation of the Supremacy Clause of the United States Constitution, and should not be countenanced by this Court.

B. State Law Claims Against Generic Manufacturers Obstruct the Purposes and Objectives of Congress in Regulating Generic Drugs

Furthermore, to impose state law duties on Teva with respect to the labeling of its minocycline product, above and beyond Teva's existing labeling duties under federal law, would create an impermissible "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), with respect to the regulation of generic drugs.

Congress's stated purpose behind enacting the Hatch-Waxman Amendments was to foster competition and promote the availability of affordable prescription drugs. The Hatch-Waxman Amendments purposely do not impose certain obligations on generic manufacturers – such as the requirements to conduct time-consuming and costly safety and efficacy clinical trials – so as to permit generic drugs to be brought to market quickly and at less expense. This express purpose would undoubtedly be undermined if additional state law duties were imposed on

[14] Permitting generic manufacturers to make unilateral changes to their drug labels is also impossible for many practical reasons. For example, if a generic manufacturer were to file a safety-related CBE amendment with the FDA Office of Generic Drugs – the department dedicated to generic drugs – the Office of Generic Drugs would not have the scientific and technical resources necessary to evaluate this CBE amendment, since the Office is not designed to handle safety-related issues. For another example, if a generic manufacturer were to unilaterally strengthen warnings on its drug label, resulting in different warning language from the FDA-approved branded label and from other generic labels for the same drug, a prescribing physician would need to be aware of the warning language in each manufacturer's label for the same drug, and would have to determine which warning language is preferable and which generic version of the same drug to prescribe. Such a result is clearly illogical and fundamentally contrary to the way generic drugs are prescribed, dispensed, and used in this country.

generic manufacturers in connection with the labeling and marketing of their drugs, resulting in extra expenses that will be passed on to consumers.[15]

For this further reason, the imposition of state tort liability on Teva violates the Supremacy Clause of the U.S. Constitution, and should not be countenanced by this Court.

C. The Recent Trend of Federal Case Law Supports Dismissal of Plaintiffs' Claims on Preemption Grounds

Within the last year, federal courts in at least four different jurisdictions have ruled in favor of generic preemption. In June 2008, the District Court for the District of Minnesota reached this result in *Mensing v. Wyeth,* 562 F. Supp. 2d 1056 (D. Minn. June 17, 2008). *Mensing* is a products liability case, in which plaintiff alleged injuries as a result of ingesting a generic pharmaceutical drug. After reviewing all of the FDA authority discussed above, the court accepted the generic manufacturer defendants' arguments completely in language that, while lengthy, is worth quoting in full here:

> The Court concludes that under the federal statutory scheme, the labeling for generic drugs must always remain the "same as" that of the name brand drug and that *a generic drug manufacturer cannot unilaterally change its label without prior FDA approval*. Here, it is undisputed that at all relevant times, Actavis's and Pliva's MCP drug labels were the same as that of the listed drug Reglan. Plaintiff's failure to warn claims against Actavis and Pliva rely on state law imposing a duty on the generic drug manufacturers to provide adequate warnings that Actavis and Pliva allegedly did not provide. *Any such duty to unilaterally heighten their warning labels, however, would directly conflict with the federal law requiring that their labels be the "same as" those of the listed drug, Reglan. Indeed, under these circumstances, it would be impossible for Actavis and Pliva to abide by both state and federal laws.* If Plaintiff's claims were not preempted, Actavis and Pliva would be forced to choose between complying with the federal law while being exposed to state tort liability, or unilaterally adding a heightened warning to their labels at the risk of exposing themselves to federal liability. *This conflict would stand as an obstacle to the accomplishment and full purposes and*

[15] The Supreme Court's analysis of the "purposes and objectives" issue in *Levine* is inapposite, since the Court examined only the purposes and objectives behind regulations governing branded drugs and branded manufacturers. *Levine*, 2009 WL 529172 at *6, 9-13. The *Levine* Court's opinion does not make a single mention of the Hatch-Waxman Amendments, and does not consider or opine on whether state law claims undermine the distinct and well-established purposes and objectives of the Hatch-Waxman Amendments.

> *objectives of the Hatch-Waxman Act, a key purpose of which is to increase the availability of low-cost generic drugs and to relax the generic approval and labeling process.*

(*Id.* at 1064-65) (emphasis added.) Subsequent to the decision as to generic manufacturers Pliva and Actavis, Teva, a co-defendant in *Mensing*, moved for the same relief. Treating the plaintiff's opposition to Teva's motion essentially as a petition for reconsideration of its earlier ruling, the *Mensing* court reviewed its federal preemption position and declined to change its mind, thereby extending its summary judgment ruling to Teva. *Mensing v. Wyeth*, 2008 WL 4724286 (D. Minn. Oct. 27, 2008, as amended Oct. 30, 2008).

A few days prior to the *Mensing* decision, the District Court for the Northern District of California applied the same reasoning to dismiss the plaintiffs' state law claims against a generic drug manufacturer on the grounds of federal preemption in *Gaeta v. Perrigo Pharmaceutical Company*, 562 F. Supp. 2d 1091 (N.D. Cal. June 13, 2008), holding:

> Plaintiffs' causes of action seek to hold Perrigo liable for, in part, failing to warn of risks on the labeling for its drug. Since including these warnings would put Perrigo's ANDA in jeopardy for failing to conform with the FDA's approved labeling for the listed drug, Plaintiffs' state law causes of action conflict with Perrigo's obligations under federal law.
> * * *
> The Court finds that Plaintiffs' causes of action are preempted to the extent that they allow for liability based on a lack of adequate warning.

562 F. Supp. 2d at 1098.

In August 2008, the District Court for the Southern District of Florida, in deciding three separate cases, reached the same conclusion on federal preemption of products liability claims against a generic drug manufacturer in *Bolin v. SmithKline Beecham Corp.,* 2008 WL 3286973 (S.D. Fla. Aug. 7, 2008); *Masterson v. Apotex Corp.,* 2008 WL 3262690 (S.D. Fla. Aug. 7, 2008); *Valerio v. SmithKline Beecham Corp.,* 2008 WL 3286976 (S.D. Fla. Aug. 7, 2008).

And this past October, the District Court for the Western District of Kentucky agreed with the Minnesota, California, and Florida federal courts, and similarly held that a plaintiff's state law claims against an ANDA holder were preempted. *Morris v. Wyeth,* 2008 WL 4696924 (W.D. Ky., Oct. 24, 2008); *see also Wilson v. Wyeth, Inc*., 2008 WL 4696995 (W.D. Ky. Oct. 24, 2008); *Smith v. Wyeth, Inc*., 2008 WL 4697002 (W.D. Ky. Oct. 24, 2008).[16]

The cogent, well-reasoned decision of the *Mensing* court, as well as the other generic decisions discussed above, provides clear direction. Inescapably, Teva was disabled by federal law and regulation from adding any language to the FDA-mandated minocycline labeling, and cannot be held liable under state law for not doing so. This is true whether such claims are clothed in the guise of failure to warn, negligence, breach of warranty, misrepresentation, or strict products liability. Therefore, Plaintiffs' claims are preempted and should be dismissed.

V. PLAINTIFFS HAVE NOT SET FORTH A LEGALLY ADEQUATE CLAIM FOR PUNITIVE DAMAGES

Plaintiffs' claim for punitive damages fails as a matter of law. In order to recover punitive damages under Georgia law, a plaintiff must show "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." O.C.G.A. § 51-12-5.1. In the instant case, Plaintiffs' claim for punitive

[16] This recent trend of federal case law finding in favor of generic preemption should be unaffected by the *Levine* decision. In each of these cases, the district court found that it was impossible for the generic manufacturer to comply with its state law duties commanding stronger labeling, while also complying with federal requirements of the Hatch-Waxman Amendments and § 314.70 precluding unilateral strengthening of the generic labeling. For the same reasons that the *Levine* decision does not apply to the generic preemption argument this case, it does not affect the recent trend of federal case law finding in favor of generic preemption. In fact, one of these courts has already confirmed that "[t]he holding of the *Levine* decision does not alter the Court's analysis" or its prior ruling in favor of generic preemption. *Morris v. Wyeth*, *et al.*, No. 1:07-cv-00176, 2009 WL 736200 (W. D. Ky. March 4, 2009). Thus, these federal decisions continue to hold true after *Levine*, and to provide support for Teva's Motion for Summary Judgment on generic preemption grounds. *But see Schrock v. Wyeth*, No. CIV-08-453-M, 2009 WL 635415 (W.D. Okla. March 11, 2009); *Stacel v. Teva Pharmaceuticals USA, Inc.*, No. 08-C-1143, 2009 WL 703274 (N.D. Ill. March 16, 2009).

damages is premised entirely on the bald and sweeping statement in Plaintiffs' Complaint that Teva acted with willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences. (Compl. ¶ 17.) However, Plaintiffs have neither elicited nor proffered any evidence whatsoever to support their claim of punitive damages, much less sufficient evidence to meet the strict clear and convincing standard. Therefore, Plaintiffs' punitive damages claim fails.

VI. PLAINTIFFS' REMAINING CLAIMS FAIL BECAUSE THEY ARE ENTIRELY CONTINGENT ON A FAILURE TO WARN ARGUMENT

Plaintiffs' Complaint seeks to hold Teva liable on claims sounding in: strict liability in tort or negligence, breach of express or implied warranty, negligent or innocent failure to warn, and negligent or innocent misrepresentation, concealment, and nondisclosure. (Compl. ¶ 14.) Georgia courts have recognized that "the elements of plaintiffs' strict liability theory are essentially the same as the elements of their theory of negligent failure to warn." *Wells by Maihafer v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 296 (N.D. Ga. 1985), *aff'd* in part and modified in part on other grounds, 788 F.2d 741 (11th Cir.1986); *Chrysler Corp. v. Batten*, 264 Ga. 723, 728 (Ga. 1994). Thus, for the reasons discussed *supra* with respect to Plaintiffs' failure to warn claims, Plaintiffs' strict liability claim fails. Further, Georgia courts follow the principles of Restatement (Second) of Torts (1965) § 402A, comment k, which holds that prescription drugs are deemed to be inherently dangerous, that is, "incapable of being made safe for their intended and ordinary use." *See Porter v. Eli Lilly & Co.*, 2008 WL 544739 (N.D. Ga. Feb 25, 2009). Thus, in the pharmaceutical products liability context, there is no content to an implied warranty of merchantability claim, above and beyond the negligent failure to warn

claim.[17] Finally, Plaintiffs' allegations of misrepresentation, concealment, and nondisclosure all relate to the adequacy of Teva's minocycline labeling and the warnings contained therein. Accordingly, as each of these claims is entirely contingent on the failure to warn argument, all must fail for the reasons set forth in this brief.

CONCLUSION

For all the foregoing reasons, Teva respectfully requests that its Motion for Summary Judgment be granted.

Respectfully submitted this 5th day of May, 2009.

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[17] Patently, there can be no actionable claim for breach of express warranty, since Teva's minocycline label, far from warranting against PTC, expressly identifies this condition as a potential adverse reaction to the use of the drug.