IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

PETRINA BRASLEY-THRASH,	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO.: 10-00031-KD-N**
	)	
TEVA PHARMACEUTICALS	)	
USA, INC., *et al.*,	)	
Defendants.	)	

ORDER

This matter is before the Court on Plaintiff's Motion for Leave to Amend the Complaint (as amended) (Docs. 69, 70, 71), Defendants' Response (Doc. 73, 74), Plaintiff's Reply (Doc. 77), and Defendants' Sur-Reply (Doc. 80).

Plaintiff initiated this failure to warn action against the Defendants (manufacturers of generic metoclopramide) asserting claims under the *Alabama Extended Manufacturers Liability Doctrine* ("AEMLD"), and for negligence and wantonness under Alabama law. Specifically, plaintiff alleges that she suffered severe drug-induced neurological injury, tardive dyskinesia, due to toxic cumulative overexposure to metoclopramide from ingesting generic drug products made by the defendants; namely, generic versions of the brand name drug known as Reglan.® Plaintiff alleged that the defendants failed to provide adequate warnings regarding the dangers of their product.

After filing her complaint, the Supreme Court issued its opinion in Pliva, Inc. v. Mensing, 131 S.Ct. 2567 (2011). The Court in Pliva, Inc. v. Mensing addressed the issue of whether state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide were pre-empted by federal law. Id. at 2571. The Court held that federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-

empted, the plaintiff's state-law claims of failure to provide an adequate warning label. Id.

Pursuant to Rule 15 of the Federal Rules of Civil Procedure and based on decision in Pliva, Inc. v. Mensing, Plaintiff seeks leave of Court to amend her complaint to: 1) reflect that Defendant Morton Grove Pharmaceuticals, Inc., has been dismissed; 2) to delete claims against the remaining defendants that are preempted by Mensing; and 3) to plead that the remaining defendants are liable for their failure to send a "Dear Doctor" letter (or other permissible communication) to her treating physicians in a timely manner on or after July 26, 2004 (the date the FDA approved a labeling change for brand-name Reglan® which stated that "[t]herapy should not exceed 12 weeks in duration[]"), advising of the new, stronger warning for the drug Reglan® and its generic equivalents.

Rule 15(a) provides that courts "should freely give leave [to amend] when justice so requires." FED.R.CIV.P. 15(a)(2). However, courts may deny leave when such amendment would be "futile." See, e.g., Foman v. Davis, 371 U.S. 178, 182 (1962); Brewer v. Commissioner, Internal Revenue, 435 F. Supp. 2d 1174, 1176 (S.D. Ala. 2006). An amendment is futile, for example, when the complaint is subject to dismissal, or when the proposed amendment introduces state-law claims that are preempted by federal law. See, e.g., Fetterhoff v. Liberty Life Assur. Co., 282 Fed. Appx. 740, 743 (11th Cir. Jun. 17, 2008) (unpublished); Burger King Corp. v. Weaver, 169 F.3d 1310, 1320 (11th Cir. 1999).

I. FEDERAL PREEMPTION

Defendants contend that plaintiff's effort to amend is futile because her state law claim that the defendants' failed to adequately disseminate the approved strengthened label, via a dear health care provider ("DHCP") letter, is pre-empted. Specifically defendants argue that under the

principles of Pliva v. Mensing, if a party cannot act on its own under federal law, state law requiring that action is preempted. In that regard, Defendants contend that FDA regulations prohibit a generic manufacturer from issuing a DHCP letter without the approval of the FDA.

Plaintiff asserts that:

> [t]he implied-conflict preemption announced in the *Pliva* decision does not preempt all Alabama tort law pertaining to generic-prescription-drug products. *Pliva* only preempts Alabama law that would impose liability for a failure to convey information that was not contained in the FDA-approved brand-name labeling. The Alabama tort-law duty to convey adequate warnings imposes a duty on a generic-drug manufacturer to, at a minimum, convey the warnings contained in the FDA-approved labeling for the brand-name version of the drug. This duty does not conflict with federal law, because federal law requires the warnings labels of a brand-name drug and its generic copy to always be the same…

(Doc. 70 at 2). Thus, plaintiff contends that her state law claim, that the defendants failed to adequately disseminate through a DHCP letter information regarding the updated label for Reglan, is not pre-empted.

In Pliva, Inc. v. Mensing, the Supreme Court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." Mensing, 131 S.Ct. at 2581. Thus if the FDA requires defendants to seek approval to send a DHCP letter that provides updated label information, then plaintiff's state law claim is pre-empted.[1]

Defendants point to 21 U.S.C. § 355-1(i) for support of their position that the FDA would have required approval for the DHCP letters that plaintiff contends were needed to properly

1 The Pliva, Inc. v. Mensing decision did not directly address the issue at hand. Rather, on the subject of letters to doctors the court stated that "federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters." Id. at 2576 (emphasis added). The plaintiff's proposed claim does not implicate "additional" warnings.

disseminate the updated label. As to generic drugs ("ANDA") this section provides as follows:

> A drug that is the subject of an abbreviated new drug application under section 355(j) of this title is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) of this section for the applicable listed drug:
>
> * * *
>
> For an applicable listed drug for which a drug is approved under section 355(j) of this title, the Secretary--
> **(A)** shall undertake any communication plan to health care providers required under subsection (e)(3) of this section for the applicable listed drug; and
> **(B)** shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

Assuming that this provision is applicable to the DHCP letters proposed by the plaintiff, this provision directing that any communication must go through the Secretary of the FDA was not, as noted by the defendants, effective until March 2008. Plaintiff alleges that she consumed the drug from February 2006 through August 2008, such that at the time she was prescribed the drug there was not a statutory directive to the generic manufacturers regarding communications.

However, the defendants contend that the Court can infer that such FDA approval was required based on statements made by the FDA in their amicus brief in Pliva, Inc. v. Mensing. Specifically, defendants point to the FDA's statement that the FDA "mediates the channels available to an ANDA holder under federal law for disseminating strengthened warnings[.]" (Doc. 73-1 at 25). Defendants take this statement out of context; the strengthened warnings referenced are not strengthened warnings included in the approved label. Moreover, although in the context of explaining an ANDA's ability to send out warnings not included in the approved label, the FDA states also that "[c]ontrary to the court of appeals' view, nothing in the FDCA or FDA's regulations categorically forbids an ANDA holder from unilaterally sending such correspondence." (Doc. 73-1

at p. 24). Rather such letters, after they are sent, are subject to review by the FDA to determine whether they are misleading and if they are the generic manufacturer risks losing its ANDA approval.[2] Id. Thus, generic manufacturers "do not customarily send DHCP letters without coordinating with FDA." Id. However, the only specific FDA requirement in effect at the relevant time was that the "letters must be 'consistent with and not contrary to [the drug's] approved ... labeling.' 21 CFR § 201.100(d)(1)." Pliva, Inc. v. Mensing, 131 S.Ct. at 2576. Accordingly, at this time, the defendants have not convinced this Court that generic drug manufacturers must seek out the FDA's approval when sending a DHCP letter that simply reiterates warnings contained in the approved label. Thus, the plaintiff's claim is not pre-empted.

II. STATE LAW CLAIMS

Defendants argue that plaintiff fails to state a claim under AEMLD. The Court agrees. "[T]he adequacy of the warning issued by a drug manufacturer bears on whether a plaintiff has proved a prima facie case under the Alabama Extended Manufacturer's Liability Doctrine." Stone v. Smith, Kline & French Laboratories, 447 So.2d 1301, 1304 (Ala. 1984). Because the plaintiff is pre-empted from disputing the "adequacy" of the warning, an AEMLD claim is not available to the plaintiff.

Defendants also argue that plaintiff's claim of negligent failure to warn fails because there is no duty under state law to provide a warning to the doctor that prescribes the drug. Rather, defendants' duty to warn is satisfied upon including the approved label with the product. However, the existence of a duty to warn is a question of fact for the jury. Toole v. McClintock 999 F.2d

2 As to the proposed DHCP letters in Pliva v. Mensing, FDA took the position that a letter sent solely from the generic manufacturers listing additional warnings would be misleading because it would inaccurately imply a therapeutic difference between the brand and generic drugs.

1430, 1433 (11th Cir. 1993). Moreover, there appears to be a duty to warn the physician under the "learned intermediary doctrine." Id. (providing that "[u]nder the 'learned intermediary doctrine,' the adequacy of Baxter's warning is measured by its effect on the *physician*, Dr. McClintock, to whom it owed a duty to warn, and not by its effect on Ms. Toole.") (emphasis added).

As such, it is **ORDERED** that the Plaintiff's Motion for Leave to Amend the Complaint (Docs. 69, 70, 71) is **GRANTED in part** and **DENIED in part.**

DONE and **ORDERED** this the **12th** day of **September 2011.**

/s/ Kristi K. DuBose
KRISTI K. DuBOSE
UNITED STATES DISTRICT JUDGE