UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased, and PAUL SCHILF and CYNTHIA SCHILF, individually,	*	CIV 07-4015
Plaintiffs,	*	MEMORANDUM OPINION AND ORDER ON PENDING MOTIONS
vs.	*	
ELI LILLY AND COMPANY and QUINTILES TRANSNATIONAL CORPORATION,	*	
Defendants.	*	

A pretrial conference was held in this case on Monday, September 20, 2010. The Court announced its ruling on some of the pending motions and heard oral argument on a number of other motions. This Order will address the following motions:

1. Docket 112: Motion for Summary Judgment on All Claims;
2. Docket 118: Motion to Strike Plaintiffs' Untimely Disclosure of Steve Timmerman as a Fact Witness;
3. Docket 120: Motion for Summary Judgment Based on Federal Preemption;
4. Docket 126: Second Motion for Partial Summary Judgment on Product Defect and Statutory Deceit Claims and on Lilly's Learned Intermediary Affirmative Defense;
5. Docket 135: Motion to Strike The Affidavit of Paul Forrest Hickman and to Prohibit Plaintiffs from Calling Mr. Hickman as a Fact or Expert Witness;
6. Docket 161: Motion to Compel (by Subpoena or Writ) Lilly to Produce Dr. Charles Beasley;
7. Docket 168: Motion to Strike Plaintiffs' Prozac-Related Designations and Evidence.

The Court is waiting to receive additional information from the parties in regard to Defendants' Motion for Summary Judgment on Plaintiffs' Failure to Warn Claims, doc. 123, and that motion will be addressed in a subsequent order. Defendants' Motion to Exclude the General Causation Opinion of Dr. Joseph Glenmullen, doc. 206, and Motion for Summary Judgment Based on the Exclusion of Dr. Joseph Glenmullen's General Causation Opinion, doc. 208, also will be addressed in the subsequent order.

DISCUSSION

1. Defendants' Motion for Summary Judgment on All Claims (Doc. 112).

In their written response to Defendants' motion for summary judgment on all claims, Plaintiffs indicated that they are not proceeding with the following claims: negligent misrepresentation, § 402B misrepresentation and warranty claims. Accordingly, those claims will be dismissed. At the pretrial conference on September 20, Plaintiffs said they are not pursuing their strict liability design defect claim. That claim also will be dismissed.

In addition to their negligent failure to warn claim, Plaintiffs assert three negligence claims against Defendants: 1) negligent failure to test; 2) negligent overpromotion; and 3) negligent infliction of emotional distress. For the following reasons, Defendants are entitled to summary judgment on these negligence claims.

First, in *Burley v. Kytec Innovative Sports Equip., Inc.* 737 N.W.2d 397 (S.D. 2007), the South Dakota Supreme Court said that there must be expert testimony on causation when it is outside the common experience and capability of a jury to determine that failure to test was the legal cause of an injury. There is no such expert testimony in the record in this case.

Secondly, there are no South Dakota cases recognizing overpromotion as a separate cause of action and, even if such a cause of action was recognized in South Dakota, the facts on the record in this case do not support a negligent overpromotion claim.

Third, bystander emotional distress claims have been recognized by the South Dakota Supreme Court if caused by contemporaneous observation of the serious injury or death of a third party with whom the bystander has a close relationship. The bystander must be within the zone of danger. The emotional distress suffered may be caused by fear for the third person and need not be caused by the bystander's fear for his own safety. The distress must be accompanied with physical manifestations. *See Nielson v. AT&T*, 597 N.W.2d 434 (S.D. 1999). Plaintiffs did not contemporaneously observe Peter's suicide and they were not in the zone of danger.

Defendants also seek summary judgment on Plaintiffs' claims for deceit and punitive damages. Viewing the evidence in the light most favorable to Plaintiffs, the Court finds that genuine issues of material fact exist regarding those claims, including what information Lilly was aware of regarding Cymbalta and increased risk of suicide, and whether Lilly purposefully chose not to disseminate information linking Cymbalta to pediatric and adolescent suicide before Dr. Briggs prescribed Cymbalta to Peter. Because there is a genuine issue of material fact whether Lilly acted with the requisite intent, Defendants are not entitled to judgment as a matter of law on the deceit and punitive damage claims. Accordingly, Defendants' motion for summary judgment on all claims, doc. 112, is granted in part and denied in part.

2. Defendants' Motion to Strike Steve Timmerman as a Fact Witness (Doc. 118)

The parties agreed as a result of their Rule 26(f) conference that all pre-discovery disclosures pursuant to F.R.Civ.P. 26(a)(1) would be made no later than September 28, 2007.[1] The discovery deadline for this case expired on September 8, 2008. In late September 2008, Plaintiffs served supplemental Rule 26 disclosures that for the first time identified Dr. Steven J. Timmerman as an individual likely to have discoverable information[2]. Plaintiffs' disclosure of Dr. Timmerman was nearly a year overdue and was as follows:

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[1]*See* Form 35 Report, doc. 34, p. 4.

[2]Defendants assert the supplemental disclosure was made on September 30, 2008. Plaintiffs represent the disclosure was made on September 23, 2008. The precise date is of no significance to this decision - the disclosure was untimely.

Steve Timmerman
300 22nd Avenue
Brookings, SD 57006
Phone: 605-696-9000

Doc. 132, p. 6. The disclosure does not give Defendants notice of the substance of Dr. Timmerman's expected testimony as required by Rule 26(a)(1)(A).

Dr. Timmerman is a doctor of pharmacy and friend of the Plaintiffs. After Peter's suicide, Dr. Timmerman visited with the Schilfs about issues relating to antidepressants, the distribution of pharmaceutical samples by physicians instead of pharmacists[3], and the FDA's mandate of black box warnings and the timing of Peter's death in relation to them. Defendants seek to have the late-filed supplemental disclosure of Dr. Timmerman stricken and request Plaintiffs be prohibited from calling Dr. Timmerman as a witness at trial. Plaintiffs counter that Defendants were made aware of Dr. Timmerman's name, credentials and views as early as June 14, 2006, during the deposition of Cynthia Schilf. Plaintiffs also provided copies of Dr. Timmerman's writings to Defendants on October 31, 2006. Plaintiffs indicate Dr. Timmerman was again discussed during Paul Schilf's deposition on September 10, 2008. Plaintiffs assert, therefore, the supplemental disclosure in late-September of 2008 was "merely a formality." Neither party has suggested Dr. Timmerman has first hand relevant knowledge of the factual matters at issue. Moreover, Plaintiffs have not disclosed Dr. Timmerman as an expert witness. In fact, by Plaintiffs' own admission their disclosure included only his name, address, and telephone number and gave no indication of the substance of his testimony.

Federal Rule of Civil Procedure 37(c)(1) states that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Significantly, "[w]hen a party fails to provide information . . . in compliance with Rule 26(a) or (e), the district court has wide discretion to fashion a remedy or

[3]Dr. Timmerman opposes pharmaceutical samples being distributed by physicians

sanction as appropriate for the particular circumstances of the case." *Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008); *see also In re Baycol Products Litigation*, 596 F.3d 884, (8th Cir. 2010). "The district court may exclude the information or testimony as a self-executing sanction unless the party's failure to comply is substantially justified or harmless." *Wegener*, 527 F.3d at 692. "When fashioning a remedy, the district court should consider, inter alia, the reason for the noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony." *Id.*

Applying the Eighth Circuit's factors, the Court concludes that the failure to disclose Dr. Timmerman as a witness is not substantially justified and exclusion of Dr. Timmerman as a witness is appropriate. A review of Dr. Timmerman's Affidavit, doc. 126, exhibit 1, coupled with the parties' assertions of his expected testimony, reveals Dr. Timmerman has no first hand knowledge of the factual matters at issue in this case. His testimony as a fact witness would constitute inadmissible hearsay. Dr. Timmerman's opinions concerning pharmaceutical samples being distributed by physicians are more prejudicial than probative.[4] Thus, Defendants' motion to strike, doc. 118, is granted.

3. Defendants' Motion for Summary Judgment Based on Federal Preemption (Doc. 120)

Defendants assert they are entitled to summary judgment on all of Plaintiffs' claims because Plaintiffs' claims are preempted by the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq., and its implementing regulations. Plaintiffs assert that, at least as of September or October, 2004, Lilly knew that the existing suicide warning on Cymbalta was inadequate for the protection of pediatric users of the drug, both because the warning was not strong enough and because the warning did not appear on the label in a manner and form sufficient to protect pediatric users. Thus, several weeks before Peter Schilf's physician gave him a sample pack of Cymbalta, Lilly knew that its drug was misbranded under federal law. Defendants argue that the FDA

[4]Defendants' practice of distributing professional pharmaceutical samples to physicians is specifically authorized under federal law. *See, generally,* 21 C.F.R. § 203, Subpart D.

specifically directed Lilly not to implement a black box warning until FDA gave Lilly notice and approval, and that such notice and approval was not given until after Peter Schilf's death. Thus, according to Defendants, any claim that Lilly did not implement those warnings sooner is preempted. Plaintiffs acknowledge that Lilly did what the FDA specifically directed it to do, but contend that Lilly could have "gotten the word" out in a number of ways to inform the public that the FDA had concluded Cymbalta's existing warnings were inadequate, that the FDA had requested a black box warning, and that discussions on the final language of that warning were ongoing.

While this motion was pending the United States Supreme Court decided *Wyeth v. Levine*, - - - U.S. - - - , 129 S.Ct. 1187 (2009). In *Wyeth*, the Supreme Court ruled that failure to warn claims against drug manufacturers are not preempted by the FDCA:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, ... Congress has not enacted such a provision for prescription drugs.... Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Wyeth, 129 S.Ct. at 1194-95. The majority rejected the legal argument that Wyeth could not unilaterally add a warning without violating federal law governing misbranding and unauthorized distribution of unapproved drugs. After rejecting Wyeth's argument that it was not legally possible to change its labeling unilaterally, the majority looked for "clear evidence" in the record that FDA would not have approved a change to Phenergan's package insert. After *Wyeth*, lower courts are left to determine what satisfies this "clear evidence" standard in each case. Plaintiffs in the present case argue that an email from the FDA indicating that Lilly should not change the Cymbalta label until it is finally approved by the FDA is not "clear evidence" that the FDA would have rejected attempts by Lilly to "get the word out" in other ways. The Court agrees. The record in this case does not contain clear evidence of preemption. *See Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009) (state failure to warn claim against a generic manufacturer not preempted by federal law requiring labeling

of a generic drug be identical to that of the name-brand product on which it is based; FDA's statement that generic manufacturers may not revise their labeling to vary from that of the name brand not clear evidence that the FDA would reject the labeling changes argued by the plaintiff); *In re Prempro Products Liability Litigation*, 586 F.3d 547 (8th Cir. 2009) (rejecting preemption argument by a name-brand drug manufacturer). *See also Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (reversing dismissal, based on preemption, of claim that Paxil's labeling failed to warn of suicide risk among young adults; defendant did not show that the FDA likely would have rejected tougher warnings on Paxil's purported suicide risks had defendant voluntarily pursued such a change when it submitted data to the FDA before the suicide). Accordingly, Defendants' motion for summary judgment based on federal preemption, doc. 120, is denied.

4. Plaintiffs' Motion for Partial Summary Judgment on Product Defect, Deceit and Learned Intermediary Defense (Doc. 126)

As stated earlier, Plaintiffs are not pursuing the strict liability design defect claim, so that portion of this motion will be denied as moot. In denying Defendants' motion for summary judgment on the deceit claim, the Court indicated that questions of material fact exist regarding Defendants' intent. Plaintiffs' motion for summary judgment on the deceit claim also will be denied for that reason. Finally, the motion for summary judgment on the learned intermediary defense will be addressed in the Court's subsequent order on the failure to warn claims.

5. Defendants' Motion to Strike Affidavit of Paul Forrest Hickman and to Preclude Plaintiffs from Calling Ms. Hickman as a Witness (Doc. 135)

The discovery deadline expired on September 8, 2008. On October 20, 2008, Plaintiffs filed their Renewed Motion for Partial Summary Judgment and in support thereof submitted the Affidavit of Paul Forrest Hickman, doc. 127, attachment 6. Hickman had not previously been disclosed as an individual likely to have discoverable information.

Hickman is the office manager for Internet Archive. Internet Archive is a website that provides access to a digital library of internet sites. Further, Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to locate an archived version of a website. The Internet Archive receives data which is donated from third parties.

Attached to the Hickman Affidavit are various printouts of the Internet Archive's records. Plaintiff asserts that the documents show the cymbalta.com website did contain the BLACK BOX warning as early as December 9, 2004. This contradicts the testimony of Lilly's Cymbalta website team leader that Lilly was unable to put language from the BLACK BOX warning or the patient medication guide on its website prior to FDA approval in February 2005.

Plaintiffs' response indicates they "had no intention of calling Hickman as a witness either via deposition or at trial." However, Plaintiffs resist the motion to strike Hickman's affidavit and assert Defendants' motion is nothing more than a poorly disguised effort to exclude authenticated and relevant documents. In their reply, Defendants clarify their motion to strike is not a motion to exclude the documents attached to the Hickman affidavit, but it is instead a motion to exclude Hickman as a fact or expert witness during the trial because of Plaintiffs' failure to disclose Hickman as a witness as required by Rule 26.

Based on the representations in the parties' briefs, the Court concludes that Defendants do not object to the documents attached to the Hickman affidavit, and those documents have been considered by the Court for purposes of Plaintiffs' motion for partial summary judgment. Plaintiffs will be precluded from calling Ms. Hickman as a witness. Accordingly, Defendants' motion to strike the Hickman Affidavit is denied, and their motion to prohibit Plaintiffs from calling Ms. Hickman as a witness is granted.

6. Plaintiffs' Motion to Compel Lilly to Produce Dr. Charles Beasley (Doc. 161)

Dr. Beasley is a Lilly employee who lives in Indiana. He has never served as an officer or director of Lilly; he has not been designated as a Rule 30(b0(6) witness or disclosed as a witness with knowledge in this case; his deposition was never taken or requested to be taken by Plaintiffs until after discovery was closed and dispositive motions had been filed. Plaintiffs now ask the Court to compel Dr. Beasley's appearance at trial. Plaintiffs admit there is no legal authority in support of their request. Plaintiffs assert that they need testimony from Dr. Beasley to support their punitive damage claim because he was Lilly's "go to guy" for Prozac-related information. The Court

concludes that it has no authority to compel Dr. Beasley's appearance or testimony in this case, and Plaintiffs' motion to compel Lilly to produce Dr. Beasley, doc. 161, will be denied.

7. Defendants' Motion to Strike Plaintiffs' Prozac-Related Designations and Evidence (Doc. 168)

In support of their punitive damage claim, Plaintiffs designated portions of Dr. Beasley's deposition taken in November of 2000, in a Prozac case in the United States District Court in Vermont. Plaintiffs also designated deposition excerpts of several other current and former Lilly employees who had some involvement with Prozac, including Gary Tollefson, Mitchell Daniels, Leigh Thompson, and Allan Weinstein. Like Dr. Beasley, these individuals were not disclosed as witnesses with knowledge or deposed in this case. The Court concludes that Plaintiffs' Prozac-related deposition designations and additional materials are irrelevant to Plaintiffs' claim for punitive damages in this case. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 401, 422 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346, 354 (2007). As stated by the Court at the pretrial conference, this ruling is limited to Plaintiffs' claim for punitive damages. If Plaintiffs seek to admit Prozac evidence during the trial for an issue other than punitive damages, the Court will rule on any objections made to the evidence at that time. For all of these reasons,

IT IS ORDERED:

1. That Defendants' Motion for Summary Judgment on All Claims, doc. 112, is granted as to the following claims: negligent misrepresentation; negligent failure to test; negligent overpromotion; negligent infliction of emotional distress; § 402B misrepresentation; warranty claims; and strict liability design defect claim. The Defendants' Motion for Summary Judgment on All Claims, doc. 112, is denied as to Plaintiffs' claims for deceit and punitive damages.

2. That Defendants' Motion to Strike Steve Timmerman as a Witness, doc. 118, is granted.

3. That Defendants' Motion for Summary Judgment Based on Federal Preemption, doc. 120, is denied.

4. That Plaintiffs' Motion for Partial Summary Judgment, doc. 126, is denied. The portion of the motion regarding the learned intermediary defense will be addressed in a subsequent order.

5. That Defendants' Motion to Strike Affidavit of Paul Forrest Hickman, doc. 135, is denied; and Defendants' Motion to Preclude Plaintiffs from Calling Ms. Hickman as a Witness, also doc. 135, is granted.

6. That Plaintiffs' Motion to Compel Lilly to Produce Dr. Charles Beasley, doc. 161, is denied.

7. That Defendants' Motion to Strike Plaintiffs' Prozac-Related Designations and Evidence, doc. 168, is granted as to Plaintiffs' punitive damage claim.

Dated this 30th day of September, 2010.

BY THE COURT:

Lawrence L. Piersol
United States District Judge

ATTEST:
JOSEPH HAAS, CLERK
BY: Colleen Schulte
DEPUTY