

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

PAMELA BLAIN, et al.,)	
)	
Plaintiff,)	CIVIL ACTION
)	
v.)	No. 07-1157-MLB
)	
SMITHKLINE BEECHAM CORPORATION)	
d/b/a GLAXOSMITHKLINE,)	
)	
Defendant.)	
)	

MEMORANDUM AND ORDER

This case comes before the court on defendant's motion for summary judgment. (Doc. 33). Plaintiffs are the parents of Trevor Blain, an adolescent who committed suicide after being prescribed Paxil. Defendant manufactures the drug Paxil for use in patients who are diagnosed with depression and other mental illnesses. Plaintiffs' complaint states claims for wrongful death, fraud, breach of warranty and negligence. (Doc. 1). Defendant's motion has been fully briefed and is ripe for decision. (Docs. 34, 44, 50). Defendant's motion is granted for the reasons herein.

I. Motion to Strike

First, plaintiffs move to strike defendant's exhibits due to defendant's failure to authenticate the exhibits in accordance with D. Kan. R. 56.1(d). (Doc. 40).

Unauthenticated documents, once challenged, cannot be considered by a court in determining a summary judgment motion. In order for documents not yet part of the court record to be considered by a court in support of or in opposition to a summary judgment motion they must meet a two-prong test: (1) the document must be attached to and authenticated by an affidavit which conforms to rule 56(e); and (2) the affiant must be a competent witness

through whom the document can be received into evidence Documentary evidence for which a proper foundation has not been laid cannot support a summary judgment motion, even if the documents in question are highly probative of a central and essential issue in the case.

Guang Dong Light Headgear Factory Co., Ltd. v. ACI Intern., Inc., No. 03-4165, 2008 WL 53665, *3 (D. Kan. Jan. 2, 2008)(quoting In re Harris, 209 B.R. 990, 996 (B.A.P. 10th Cir. 1997); see also Bell v. City of Topeka, Kan., 496 F. Supp.2d 1182, 1185 (D. Kan. 2007); Toney v. Cuomo, 92 F. Supp.2d 1186, 1196 (D. Kan. 2000), *aff'd*, 221 F.3d 1353 (10th Cir. 2000).

Defendant responds that the exhibits are self-authenticating or that they have been authenticated through plaintiffs' affidavits. (Doc. 48). Defendant has confused the "ultimate issue of authentication during trial and the standards set forth by Rule 56(e) and D. Kan. Rule [56.1(d)]." Resolution Trust Co. v. Scaletty, No. 92-1101, 1993 WL 444303, *5 (D. Kan. Oct. 29, 1993). Defendant failed to comply with the local rules. Plaintiffs' motion to strike is granted. (Doc. 40).

II. FACTS¹

The drug Paxil belongs to a class of prescription medications generally referred to as selective serotonin reuptake inhibitors (SSRIs). In 1989 and 1991, defendant manipulated the data on its studies of Paxil in order to minimize any causal link between Paxil

¹ Even though the court struck defendant's exhibits, those facts set forth by defendant that were not controverted by plaintiffs will remain uncontroverted for the purposes of this order. The facts recited herein are viewed in the light most favorable to plaintiffs.

and suicidal behavior.² Defendant accomplished this by improperly counting suicide attempts that took place outside of the dates of the official study. When the data is not manipulated, the study results show that a patient prescribed Paxil is eight times more likely to commit suicide. In 1992, Paxil was approved as safe and effective in the treatment of adult depression. In the labeling that accompanied Paxil, the "PRECAUTIONS" section stated that the "[s]afety and effectiveness in children have not been established" and that "the possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy." In 1996, the labeling information added that the "[s]afety and effectiveness in the pediatric population have not been established." Defendant has conducted six placebo-controlled studies of Paxil for pediatric patients. The study results showed that the patients receiving Paxil had nearly four times greater risk of suicidal events than those receiving a placebo.

On May 25, 2000, eleven-year old Trevor Blain began treatment with Donna Powers, ARNP. Powers was working under the supervision of psychiatrist Dr. Ralph Bharati. Powers believed Trevor had Major

² Defendant has attempted to controvert plaintiffs' additional facts regarding defendant's behavior and past studies. Defendant's exhibits that allegedly controvert plaintiffs' facts, however, have not been authenticated pursuant to D. Kan. R. 56.1(d). Defendant has also asserted that plaintiffs' facts are controverted on the basis that their expert is unreliable under Fed. R. Evid. 702. Defendant, however, failed to file a motion to strike the expert report on that basis and has failed to provide any argument in its memorandum to counter the expert's reliability. Defendant has therefore failed to properly controvert plaintiffs' facts and they are deemed admitted.

Depressive Disorder and separation anxiety disorder. Trevor was prescribed 10 mg of Paxil on October 17, 2000, even though both Powers and Bharati knew that Paxil was not approved for pediatric use. Powers did not inform Trevor or Pamela Blain that Paxil was not approved for use in children. Powers also did not inform of the risk of suicide with Paxil. On November 10, 2000, Powers increased the dosage of Paxil to 20 mg. On November 20, Trevor attempted suicide by hanging himself. On December 7, Trevor died from his injuries. Trevor's death certificate states that the cause of death was an "Accident" and the police report states that the cause was "Home Acc. - asphyxiation."

Pamela Blain has experienced depression and anxiety since 1995. Blain's last gainful employment ended around that same time period. In 2001, after Trevor's death, Blain spoke with detectives to determine if they found any information on his computer that would indicate the reason for his suicide. Blain's effort was unsuccessful. Blain also asked Powers for Trevor's records, including the conversation that occurred during his final visit with Powers. Blain does not subscribe to a newspaper and did not see any articles on Paxil until April 2004, when she was shown an article on Paxil and its increased risk of suicide in pediatric patients. Blain herself was prescribed Paxil until she discontinued the use in 2004.

The Blains filed their complaint against defendant on March 23, 2006, more than five years after Trevor's death. Defendant asserts that plaintiffs' claims are barred by the applicable statute of limitations. Plaintiffs respond that their claims have been tolled by defendant's fraudulent concealment.

III. SUMMARY JUDGMENT STANDARD

The rules applicable to the resolution of this case, now at the summary judgment stage, are well-known and are only briefly outlined here. Federal Rule of Civil Procedure 56(c) directs the entry of summary judgment in favor of a party who "show[s] that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). An issue is "genuine" if sufficient evidence exists "so that a rational trier of fact could resolve the issue either way" and "[a]n issue is 'material' if under the substantive law it is essential to the proper disposition of the claim." Adler v. Wal-Mart Stores, Inc., 144 F.3d 664, 670 (10th Cir. 1998). When confronted with a fully briefed motion for summary judgment, the court must ultimately determine "whether there is the need for a trial-whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). If so, the court cannot grant summary judgment. Prenalta Corp. v. Colo. Interstate Gas Co., 944 F.2d 677, 684 (10th Cir. 1991).

IV. ANALYSIS

In order to determine whether the claims are barred by the applicable statute of limitations, the court must first decide which state's laws apply to plaintiffs' claims. Generally, a federal trial court sitting in diversity applies the forum state's choice of law. However, where a case is transferred from one forum to another under 28 U.S.C. § 1404(a), as occurred in this case, then the transferee

court must follow the choice of law rules of the transferor court. Trierweiler v. Croxton & Trench Holding Corp., 90 F.3d 1523, 1532 (10th Cir. 1996).

Both parties agree that the choice of law rules of the state of Pennsylvania apply in this case. (Doc. 34 at 11; Doc. 44 at 9). The parties also agree that Pennsylvania law mandates the application of its statute of limitations.³ Id. Pursuant to Pennsylvania's so-called "borrowing statute," Pennsylvania applies its own statute of limitations to causes of action that accrued in a foreign jurisdiction, unless the foreign jurisdiction's statute of limitations is shorter. 42 Pa. Cons. Stat. Ann. § 5521(b)(2005). In this case, Kansas' statute of limitations is not shorter than Pennsylvania's statute of limitations. See 42 Pa. Cons. Stat. Ann. 5524(2), (7)(2005); K.S.A. § 60-513(2006). Therefore, Pennsylvania's statute of limitations applies to this cause of action.

Pennsylvania law provides for a two-year statute of limitations for plaintiffs' claims, with the exception of a four-year statute of limitations for plaintiffs' claim of breach of express warranty⁴. 42 Pa. Cons. Stat. Ann. §§ 5524(2), (7), 5525 (2005). Under Pennsylvania law, the statute of limitations can be tolled in two different

³ The parties sharply disagree, however, regarding whether Pennsylvania would choose to apply its own law, or Kansas law, with respect to the substantive law. It is unnecessary to resolve this question since the court has determined that plaintiffs' claims are barred by the applicable statute of limitations.

⁴ Even though the court has found plaintiffs' claims barred by the statute of limitations, supra, plaintiffs' claim of breach of express warranty would not survive a motion for summary judgment on the merits. At no time have plaintiffs identified any express warranty made by defendant to them or made directly to Dr. Bharati.

scenarios. First, a party may assert that her claims are tolled due to the discovery rule. Under Pennsylvania law, an action for wrongful death and survival accrues at death and cannot be tolled. Hoppe v. SmithKline Beecham Corp., 437 F. Supp.2d 331, 336 (E. D. Pa. 2006). Therefore, the discovery rule would not apply in this case and plaintiffs have not argued that their claims are tolled by the discovery rule. Plaintiffs assert the second exception applies - the doctrine of fraudulent concealment.

The doctrine of fraudulent concealment is based on the theory of estoppel. It "provides that the defendant may not invoke the statute of limitations, if through fraud or concealment, he causes the plaintiff to relax his vigilance or deviate from his right of inquiry into the facts." Fine v. Checcio, 582 Pa. 253, 271, 870 A.2d 850, 860 (2005).

The doctrine does not require fraud in the strictest sense encompassing an intent to deceive, but rather, fraud in the broadest sense, which includes an unintentional deception. The plaintiff has the burden of proving fraudulent concealment by clear, precise, and convincing evidence. While it is for the court to determine whether an estoppel results from established facts, it is for the jury to say whether the remarks that are alleged to constitute the fraud or concealment were made.

Moreover, because the doctrine captures even unintentional conduct on a defendants part and the standard of reasonable diligence requires from a party only that knowledge which is reasonably attained under the circumstances, we do not believe that deviation from that standard to a higher threshold of knowledge is warranted. Thus, we conclude that a statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its cause.

Id. at 271-72.

The doctrine essentially requires a plaintiff to establish three elements: 1) defendant caused plaintiff to delay bringing the action; 2) by committing a fraudulent act, and; 3) plaintiff acted with reasonable diligence. Id.; Hoppe, 437 F. Supp.2d at 336. Plaintiffs argue that defendant's actions in concealing its study results from the public and the FDA, writing a positive article on a Paxil study and positively promoting Paxil in the use of children were all acts of fraudulent concealment that have tolled the statute of limitations. The court will address these acts in turn.

Plaintiffs argue that defendant has known about Paxil's increased suicide risk for more than fifteen years and has failed to inform the public. In 1989, defendant manipulated data submitted to the FDA in a study done with adult patients. The manipulated data hid the increased risk of suicide for those adults that were given Paxil during the study. Defendant also failed to properly label its medication with information that would inform the consumer that Paxil was associated with a higher risk of suicidal behavior. Defendant also conducted at least six studies with pediatric patients. Three of those studies, completed in 1998 and 2001, showed an increased risk of suicide in those patients taking Paxil. In 2004, defendant's admitted the increased risk of suicide with pediatric patients and later published the data in 2006.

Plaintiffs essentially claim that defendant's actions in hiding their study information from the public and failing to include an appropriate warning on the label amounts to fraudulent concealment. First, to toll the statute of limitations, plaintiffs must establish that defendant's actions caused them to delay bringing their action.

Fine, 582 Pa. at 271; Hoppe, 437 F. Supp.2d at 336; Wawrzynek v. Statprobe, Inc., 422 F. Supp.2d 474, 479 (E. D. Pa. 2005); Schaffer v. Larzelere, 410 Pa. 402, 406, 189 A.2d 267 (1963); Lange v. Burd, 800 A.2d 336, 339 (Pa. Super. 2002); Gambo v. Com. Dept. of Transp., No. 04-CV3318, 2005 WL 4346598, *6 at n. 2 (Pa. Com. Pl. Aug. 26, 2005). Plaintiffs painstakingly recite fact after fact to describe defendant's conduct in the years prior to Trevor beginning his medication and the years that followed. While this factual information may support a finding that defendant was attempting to conceal the effects of Paxil on adolescents, plaintiffs set forth no facts that defendant's conduct caused plaintiffs to delay in filing this action. There is no claim that defendant's actions were specifically directed towards plaintiffs. Speicher v. Dalkon Shield Claimants Trust, 943 F. Supp. 554, 559 (E. D. Pa. 1996).⁵

In Speicher, the plaintiff suffered injuries caused by an IUD manufactured by the defendant. The plaintiff asserted that the manufacturer hid its knowledge from the public that the IUD caused many infections and even death. The court held that the plaintiff could not maintain an action for fraudulent concealment since the plaintiff could not establish that her delay in discovering her injury resulted from defendant's actions. The court stated that defendant's alleged conduct was merely concealment aimed at the general public and not the plaintiff. In support of its decision, the court cited two

⁵ In Speicher, the plaintiff's claims were tolled under the discovery rule, with the exception of her tort claim for fraudulent concealment. The independent tort claim of fraudulent concealment, like the tolling doctrine of fraudulent concealment, requires a plaintiff to establish that the defendant's conduct caused the plaintiff to delay. See Speicher, 943 F. Supp. at 559.

cases which bear on the issues herein. The first case is Ciccarelli v. Carey Canadian Mines, Ltd., 757 F.2d 548 (3rd Cir. 1985). In Ciccarelli, the plaintiffs' decedents were former employees of the defendant who died as a result of asbestos-related injuries. The plaintiffs asserted that the statute of limitations should be tolled based on the conduct of defendant in concealing the harm of asbestos. The court of appeals held that the doctrine of fraudulent concealment requires that the plaintiffs establish that the defendant caused the plaintiff to "relax vigilance or to deviate from a line of inquiry" and the plaintiffs did not establish causation by merely showing that the defendant concealed information from the general public. Id. at 557.

The second case cited by the court in Speicher is Urland v. Merrell-Dow Pharmaceuticals, 822 G.2d 1268, 1270 (3rd Cir. 1987), which actually proceeded to trial on the issue of fraudulent concealment by the manufacturer defendant. In Urland, the plaintiffs' child was born with a birth defect. The plaintiffs suspected that the birth defect was caused by a medication manufactured by defendant. Within months of the child's birth, her mother made numerous inquiries, including her treating physicians, the FDA and a Congressman, regarding her suspicions. Ultimately, the mother received a letter from the manufacturer stating that the medication would not have caused her to have a child with birth defects. The court concluded that this letter was sufficient evidence to submit to the jury on the issue of fraudulent concealment. The letter was a direct act of defendant which allegedly caused the plaintiffs to delay bringing the action.

In this case, in contrast, plaintiffs undertook no investigation remotely similar to that taken in Urland. More important, there are no facts that defendant's actions caused plaintiffs to delay bringing their action. "Whatever the morality of defendant['s] actions with regard to [Paxil], the defendant[] [is] not estopped from asserting a statute of limitations defense." Ciccarelli, 757 F.2d at 557.

Next, plaintiffs assert that defendant's actions in publishing an article in 2001 which mischaracterized its study on children and promoting Paxil by lectures and posters rises to fraudulent concealment. Plaintiffs, again, have failed to identify any facts which would support the conclusion that those actions by defendant caused plaintiffs to delay filing this action. The record is completely devoid of any facts that would demonstrate that plaintiffs read the article, attended any lecture or observed the posters. Harry Miller Corp. v. Mancuso Chemicals Ltd., 469 F. Supp.2d 303, 317 (E. D. Pa. 2007)(documents cannot mislead a plaintiff if those documents were not seen by plaintiff). Plaintiffs have failed to establish any evidence, much less clear and convincing evidence, that defendant's actions caused them to delay bringing this case. Lange v. Burd, 800 A.2d 336, 339 (Pa. Super. 2002)("[D]efendant must have committed some affirmative independent act of concealment upon which the plaintiffs justifiably relied.")

Moreover, the court doubts that defendant's act of concealing the risk of suicide while taking Paxil could be characterized as fraudulent concealment. First, Pennsylvania courts have held that a mere failure to warn cannot constitute fraudulent concealment. Speicher, 943 F. Supp. at 558; Gravinese v. Johns-Manville Corp., 471

A.2d 1233, 1238 (Pa. Super. 1984). Second, under the doctrine of fraudulent concealment, silence can only constitute fraud if the defendant had "an affirmative duty to disclose because of a fiduciary relationship between the parties or a similar relationship of trust and confidence." Mest v. Cabot Corp., 449 F.3d 502, 517 (3rd Cir. 2006)(applying Pennsylvania law)(citing Chiarella v. United States, 445 U.S. 222, 227-28, 100 S. Ct. 1108, 63 L. Ed.2d 348 (1980); Sevin v. Kelshaw, 417 Pa. Super. 1, 611 A.2d 1232, 1236 (1992); Smith v. Renaut, 387 Pa. Super. 299, 564 A.2d 188, 192 (1989).

Under Pennsylvania law, a drug manufacturer does not have a duty to warn the patient who is prescribed the medication. Incollingo v. Ewing, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971). "When a drug is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." Coyle by Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1385 (Pa. 1991).⁶ In their response, plaintiffs do not directly address the issue of duty. Instead, plaintiffs cite to a nonexistent federal regulation, C.F.R. § 201.56(c)7(6)(i), to support their conclusion that defendant had an affirmative duty to the consumer. Plaintiffs then cite Gambo v. Commonwealth, 2005 WL 4346598, *6 n. 2 (Pa. Co. Pl. Aug. 26, 2005), for the proposition that a failure to warn of contamination is "tantamount to fraudulent concealment." In Gambo, the court stated in a footnote that fraudulent concealment tolls the statute of limitations if, through

⁶ Kansas law also provides that the manufacture has a duty to warn the prescribing physician and not the patient. Wright ex rel. Trust Co. of Kansas v. Abbott, 259 F.3d 1226, 1233 (10th Cir. 2001).

fraud or concealment, the defendant causes the plaintiff to relax his vigilance. Gambo does not support the conclusion that defendant had a duty to warn plaintiffs.

There is no evidence that plaintiffs relaxed their vigilance or deviated from their right of inquiry, much less that defendant caused them to do so. Since plaintiffs have failed to establish that defendant committed an affirmative act which caused plaintiffs to delay filing the action, plaintiffs' claims are barred by the statute of limitations. Defendant's motion for summary judgment is granted.

V. Conclusion

Defendant's motion for summary judgment (Doc. 33) is GRANTED for the reasons stated more fully herein. The clerk is directed to enter judgment for defendant pursuant to Rule 58.

A motion for reconsideration of this order is not encouraged. Any such motion shall not exceed 3 double-spaced pages and shall strictly comply with the standards enunciated by this court in Comeau v. Rupp, 810 F. Supp. 1172, 1174 (1992). The response to any motion for reconsideration shall not exceed 3 double-spaced pages. No reply shall be filed.

IT IS SO ORDERED.

Dated this 19th day of February 2008, at Wichita, Kansas.

s/ Monti Belot
Monti L. Belot
UNITED STATES DISTRICT JUDGE