IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

DEBRA VANDERWERF, Individually and as Next Friend for Riley and Tanner Vanderwerf, Minors, and ESTATE OF WILLIAM K. VANDERWERF,	)	
Plaintiffs,	)	**CIVIL ACTION**
v.	)	**No. 05-2271-KHV**
SMITHKLINEBEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, and ELI LILLY AND COMPANY,	)	
Defendants.	)	

MEMORANDUM AND ORDER

Debra Vanderwerf, Riley and Tanner Vandwerf and the Estate of William K. Vanderwerf bring this products liability suit against SmithKlineBeecham Corporation d/b/a GlaxoSmithKline ("GSK"). Plaintiffs, the surviving wife and children of William Vanderwerf, allege that Mr. Vanderwerf committed suicide after taking Paxil, a prescription drug which GSK manufactured.[1] This matter is before the Court on Defendant's Motion For Summary Judgment (Doc. #163) filed August 31, 2007 and Defendant's Motion To Exclude The Testimony Of Peter R. Breggin (Doc. #150) filed August 10, 2007.[2] For reasons stated below, the Court sustains both motions.

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[1] In their original complaint, plaintiffs also alleged that Mr. Vanderwerf committed suicide because he took Zyprexa, a prescription drug which Eli Lilly and Company manufactured. On December 8, 2006, the Court approved a settlement between plaintiff and Eli Lilly. See Order (Doc. #118). Plaintiffs now maintain that Mr. Vanderwerf did not take Zyprexa in the few days before he committed suicide.

[2] Plaintiffs also filed a motion for leave to file a surreply in opposition to defendant's motion to exclude the testimony of Dr. Breggin. See Doc. #181. A nonmoving party should be given an opportunity to respond to new material raised for the first time in a reply brief. Green v.

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Summary Judgment Standards

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. See Fed. R. Civ. P. 56(c); accord Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986); Vitkus v. Beatrice Co., 11 F.3d 1535, 1538-39 (10th Cir. 1993). A factual dispute is "material" only if it "might affect the outcome of the suit under the governing law." Anderson, 477 U.S. at 248. A "genuine" factual dispute requires more than a mere scintilla of evidence. Id. at 252.

The moving party bears the initial burden of showing the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Hicks v. City of Watonga, 942 F.2d 737, 743 (10th Cir. 1991). Once the moving party meets its burden, the burden shifts to the nonmoving parties to demonstrate that genuine issues remain for trial as to those dispositive matters for which they carry the burden of proof. Applied Genetics Int'l, Inc. v. First Affiliated Sec., Inc.,

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[2](...continued)
New Mexico, 420 F.3d 1189, 1196 (10th Cir. 2005). Here, plaintiffs seek leave to file a surreply because GSK cites new case law in its reply memorandum. See Plaintiffs' Motion (Doc. #181) at 1. The only new case which plaintiffs identify, however, is In re Breast Implant Litigation, 11 F. Supp.2d 1217 (D. Colo. 1998) – which plaintiffs themselves cited in their opposition brief. See Plaintiffs' Memorandum in Opposition To Defendant's Motion To Strike The Testimony Of Peter Breggin, M.D. (Doc. #162) filed August 31, 2007 at 10. Furthermore, GSK cited In re Breast Implant Litigation for one additional point in its reply brief, but it had presented a similar argument in its original memorandum.

In the reply brief in support of their motion to file a surreply, plaintiffs actually raise a new argument themselves. They argue that GSK cites Smith v. Pfizer, No. 98-4156-CM, 2001 WL 968369 (D. Kan. Aug. 14, 2001) for the first time in its reply brief. The proposed surreply does not distinguish Smith v. Pfizer, however, and the GSK reply arguments regarding Smith v. Pfizer are reasonably encompassed in its original memorandum. The Court therefore overrules plaintiffs' motion to file a surreply. In any event, the arguments in plaintiffs' proposed surreply would not alter the Court's ruling on GSK's motion to exclude Dr. Breggin.

912 F.2d 1238, 1241 (10th Cir. 1990); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986); Bacchus Indus., Inc. v. Arvin Indus., Inc., 939 F.2d 887, 891 (10th Cir. 1991). The nonmoving parties may not rest on their pleadings but must set forth specific facts. Applied Genetics, 912 F.2d at 1241.

"[W]e must view the record in a light most favorable to the parties opposing the motion for summary judgment." Deepwater Invs., Ltd. v. Jackson Hole Ski Corp., 938 F.2d 1105, 1110 (10th Cir. 1991). Summary judgment may be granted if the nonmoving parties' evidence is merely colorable or is not significantly probative. Anderson, 477 U.S. at 250-51. "In a response to a motion for summary judgment, a party cannot rely on ignorance of facts, on speculation, or on suspicion, and may not escape summary judgment in the mere hope that something will turn up at trial." Conaway v. Smith, 853 F.2d 789, 794 (10th Cir. 1988). Essentially, the inquiry is "whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson, 477 U.S. at 251-52.

Factual Background

For purposes of this motion, the following facts are uncontroverted, deemed admitted or, where disputed, viewed in the light most favorable to plaintiffs.

I. Regulatory Approval Of Paxil And Its Labeling

Prescription Paxil (paroxetine hydrochloride) is one of a class of drugs known as selective serotonin reuptake inhibitors ("SSRIs"). On November 20, 1989, pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b), GSK filed a New Drug Application ("NDA") which asked the Food and Drug Administration ("FDA") to approve Paxil for treatment of depression in adults.

In connection with the Paxil NDA, because of a debate over a possible association between Prozac and suicide, the FDA asked GSK to report any relationship between Paxil and "violence-ideation and suicide-ideation."[3] On May 10, 1991, GSK submitted an analysis of its worldwide clinical database which showed that patients randomized to Paxil therapy were at no greater risk for suicidal ideation or behavior than patients who were randomized to placebo or other active medication.[4] See Exhibit 2 to Declaration Of Barbara E. Arning, M.D., attached to

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[3] In 1990, the press reported a possible relationship between suicidality and Prozac, another SSRI, based on an article which hypothesized that antidepressants might induce suicidal ideation in some patients. See M.H. Teicher et al., Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment, 147 Am. J. Psychiatry 207 (1990). In 1991 and 1992, the FDA denied citizen petitions which asked that Prozac approval be withdrawn or that Prozac labeling include a warning that it increased the risk of suicide. After analyzing case reports, clinical trials, conclusions of a Psychopharmacological Drugs Advisory Committee ("PDAC") and other evidence, the FDA rejected the request to withdraw Prozac approval, found no reasonable evidence of an association between Prozac and suicidality and concluded that no label change was warranted. See Letter from FDA to Citizen Group dated June 3, 1992 at 15; Letter from FDA to Citizen Commission dated July 26, 1991, Exhibits K & L to Defendant's Memorandum Of Law in Support Of Its Motion For Summary Judgment (Federal Preemption) (Doc. #171) filed August 31, 2007 ("Defendant's Preemption Memorandum").

[4] Plaintiffs claim that the 1991 analysis was flawed because GSK included suicides and suicide attempts in the "run-in" phase as part of its placebo data – when in fact the patients had not yet been randomized to placebo – and that this flaw skewed the statistics in favor of Paxil. See Plaintiffs' Memorandum In Opposition To Defendant's Motion For Summary Judgment (Doc. #180) filed September 24, 2007 at 7-8. The period of time when patients first come into a trial (before they are randomized to Paxil or placebo) is referred to as the "run-in" phase. See Kraus Depo. at 42. In support of their claim, plaintiffs cite the deposition of Michael Tydeman, GSK vice president of clinical data management. Tydeman admitted that GSK made a mistake in labeling the suicides on placebo which were unrandomized, but not labeling the suicide *attempts* on placebo which were unrandomized. See Tydeman Depo. at 167-70. Tydeman testified, however, that even if GSK had properly labeled the run-in suicide attempts, he did not think that it would have changed the overall conclusion. See id. at 171, 174. In addition, Tydeman explained that GSK also included some non-randomized events for the Paxil group including those on open label paroxetine. See id. at 169; see also id. at 168-69 (1991 report was accounting of all events on all patients for all phases of the trial); Mason v. Smithkline Beecham Corp., No. 05-CV-1252, 2007 WL 781758, at *9 (C.D. Ill. Mar. 12, 2007) (GSK stated not scientifically legitimate to remove placebo run-in events from calculation (continued...)

Defendant's Preemption Memorandum (Doc. #171).

On December 29, 1992, having concluded that Paxil was safe and effective in the treatment of depression in adults, FDA issued an approval letter for Paxil.[5] See Exhibit 5 to Arning Declaration. The original FDA-approved labeling did not include any warning or other statement that Paxil increased the risk of suicide or suicidality. The only references to "suicide" or "suicide attempt" appeared in the description of "a major depressive episode" and a precaution that suicide is an inherent risk for depressed patients.

On May 2, 2002 and February 6, 2003, GSK gave the FDA additional analyses of data which it had originally submitted on May 10, 1991, with regard to the original Paxil NDA. See Exhibits 15-16 to Arning Declaration. After reviewing that data, the FDA found neither an increased risk of suicidality from Paxil in adults nor a causal relationship between Paxil and suicidal thinking and behavior in adults.

On June 19, 2003, some four months after Mr. Vanderwerf's death, the FDA stated that it found "no evidence that Paxil is associated with an increased risk of suicidal thinking in adults." Extensive analyses of data from Paxil studies in adults and from postmarketing adverse event reports have revealed no increase in suicidal thoughts or suicide attempts compared to placebo. Exhibit 21 to Arning Declaration at 1; Exhibit 22 to Arning Declaration at 2.

In 2004, the year following Mr. Vanderwerf's death, the FDA asked GSK to re-analyze its

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[4](...continued)
while leaving in Paxil events from other non-randomized phases such as uncontrolled trials and open label extensions).

[5] The FDA later approved Paxil as safe and effective in the treatment of generalized anxiety disorder, social anxiety disorder, panic disorder, obsessive compulsive disorder, pre-menstrual dysphoric disorder and post-traumatic stress disorder in adult patients.

adult Paxil data for suicidal behavior because of a 2004 finding of increased risk of suicidal behavior with antidepressant use by children.[6] In March and April of 2006, GSK submitted to the FDA the results of its meta-analysis of Paxil placebo-controlled studies in adult patients with major depressive disorder ("MDD") and a similar meta-analysis of Paxil placebo-controlled studies in adult patients with non-MDD disorders.[7] See Exhibit 36 to Arning Declaration. These analyses prompted GSK to consult with the FDA and to propose specific changes to Paxil labeling and warnings with respect to the risk of suicide.

On April 27, 2006, GSK submitted a labeling supplement which proposed to include in the Paxil prescribing information the following statement in the warnings section on Clinical Worsening and Suicide Risk:

> Young adults, especially those with MDD, may be at increased risk for suicidal behavior during treatment with paroxetine. An analysis of placebo-controlled trials of adults with psychiatric disorders showed a higher frequency of suicidal behavior in young adults (prospectively defined as aged 18-24 years) treated with paroxetine compared with placebo (17/776 [2.19%] versus 5/542 [0.92%]), although this difference was not statistically significant. In the older age groups (aged 25-64 years and R65 years), no such increase was observed. In adults with MDD (all ages), there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo (11/3,455 [0.32%] versus 1/1,978 [0.05%]); all of the events were suicide attempts. However, the majority of these attempts for paroxetine (8 of 11) were in younger adults aged 18-30 years. These MDD data suggest that the higher frequency observed in the younger adult

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[6] In August of 2005, independent researchers reported their analysis of unpublished adult Paxil data from 1989 and found an increased risk of adult suicidal behavior for Paxil users as compared to placebo patients. See Ivar Aursnes et al., Suicide Attempts in Clinical Trials With Paroxetine Randomized Against Placebo, BMC Medicine 2005 3:14 (Aug. 22, 2005). The article concluded that the FDA should extend to adult use its statements about the use of paroxetine for children and adolescents. See id.

[7] A meta-analysis is a quantitative statistical analysis of separate but similar experiments or studies in order to test the pooled data for statistical significance. See Merriam Webster Online, available at http://www.m-w.com/dictionary/meta-analysis.

population across psychiatric disorders may extend beyond the age of 24.

Exhibit 38 to Arning Declaration.[8]

In May of 2006, GSK implemented these changes to Paxil prescribing information and issued a "Dear Healthcare Professional" ("DHCP") letter to inform prescribers of new data on Paxil. The letter disclosed a "possible increase in risk of suicidal behavior" in adults of all ages who took Paxil for major depressive disorder. In its entirety, the letter stated as follows:

> GlaxoSmithKline (GSK) would like to advise you of important changes to the **Clinical Worsening and Suicide Risk** subsection of the WARNINGS section in the labels for PAXIL® (paroxetine HCl) and PAXIL CR® (paroxetine HCl Controlled-Release Tablets). These labeling changes relate to your adult patients, particularly those who are younger adults. . . .
>
> Current prescribing information for paroxetine – and for all other antidepressants – contains information in the **WARNINGS** section (**Clinical Worsening and Suicide Risk** subsection) stating that "patients with MDD, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs."
>
> GSK has recently conducted a new meta-analysis (an addition to numerous prior analyses) of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders (e.g., dysthymia, panic disorder, generalized anxiety disorder, obsessive compulsive disorder). These trials included 8958 patients treated with paroxetine and 5953 with placebo.
>
> Results of this analysis showed a higher frequency of suicidal behavior in young adults (prospectively defined as aged 18-24 years) treated with paroxetine compared with placebo (17/776 [2.19%] versus 5/542 [0.92%]). In the older age groups

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[8] Eight out of the 11 suicide attempts were in the FDA pre-defined 25 to 64 year-old age group. Dr. John Kraus, a GSK employee, testified that GSK could not definitively state that any increased risk would end at a particular age, but that most of the cases were before age 30. See Kraus Depo. at 102. Dr. Kraus testified that even though the 11 events classified as suicide attempts occurred before March of 2003, the methodology for assessing that data did not exist until later, in 2004, when the FDA developed it in conjunction with experts in suicidology at Columbia University to analyze pediatric clinical trial data. See Kraus Depo. at 56-61.

(25-64 years and ≥ 65 years), no such increase was observed. This finding in young adults was not statistically significant; however, the difference was observed in paroxetine-treated patients with both depressive and non-depressive conditions.

Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo (11/3455 [0.32%] versus 1/1978 [0.05%]). This difference was statistically significant;[9] however as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

The possible increase in risk of suicidal behavior in the MDD studies was observed despite substantial evidence for efficacy in the paroxetine-treated patients (compared with placebo) as determined by standardized disease-specific instruments (e.g., Hamilton Depression Rating Scale and Montgomery-Asberg Depression rating Scale for depression). Most patients had an identified social stressor at the time of the event.

It is therefore important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated.

It is difficult to conclude a casual relationship between paroxetine and suicidality due to the small incidence and absolute number of events, the retrospective nature of the meta-analysis, and potential for confounding by the fact that the events of interest are a symptom of the psychiatric illnesses themselves. However, GSK believes it is important to draw your attention to these findings and is voluntarily amending the paroxetine labeling to reflect this new information and to emphasize the importance of careful monitoring of all patients during paroxetine therapy. . . .

Exhibit 3 to Defendant's Supplement (Exhibits) To Its Memorandum Of Law In Support Of Its Motion For Summary Judgment (Doc. #166). As noted, the letter disclosed a "possible increase in

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[9] The letter characterized the difference as statistically significant even though the "P value" was 0.058. As explained below, see infra note 10, ordinarily a P value above 0.05 is not considered statistically significant. See Coates v. Johnson & Johnson, 756 F.2d 524, 537 n.13 (7th Cir. 1985); Federal Judicial Center, Reference Manual on Scientific Evidence 124 (2d ed. 2000) ("Manual On Scientific Evidence") (0.05 level is most common in social science); id. at 357-58 (0.05 level is most common in science).

risk of suicidal behavior" in adults of all ages who took Paxil for major depressive disorder. GSK issued the DHCP letter while the FDA was reviewing its proposed labeling change.

In November of 2006, the FDA published the results of a meta-analysis which looked at 11 antidepressant drugs including Paxil. The FDA evaluated 372 placebo-controlled antidepressant clinical trials involving almost 100,000 patients. As to suicidal behavior defined as suicidal ideation or worse (the study's primary endpoint), the FDA did not find an increased risk for Paxil patients compared to placebo. See FDA, Clinical Review: Relationship Between Antidepressant Drugs And Suicidality In Adults (Nov. 17, 2006) ("FDA 2006 Clinical Review") at 26, attached as Exhibit I to Plaintiffs' Memorandum (Doc. #180) (relative risk ratio of 0.93; 95 per cent confidence interval of 0.62 to 1.42; P value of 0.75).[10] As to suicidal behavior defined as preparatory acts or worse (the

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[10] The relative risk is the ratio of the incident rate of suicidal behavior in the group exposed to Paxil divided by the rate in the placebo group. See Manual On Scientific Evidence 348-49. The "odds ratio" is similar to relative risk and is usually marginally greater than the relative risk. When the outcome – suicide or suicidal behavior – is relatively rare, the relative risk and the odds ratio are virtually the same. See Stevens v. Sec'y of Dep't of Health & Human Servs., No. 99-594V, 2006 WL 659525, at *16 (Fed. Cl. Feb. 24, 2006); see also Manual On Scientific Evidence 351 (odds ratio good approximation of relative risk; odds ratio usually marginally greater than relative risk). For ease of reference, the Court refers only to relative risk even though several studies actually use odds ratios. A relative risk of 1.00 signifies no difference between the rate of suicidal behavior in each group (i.e. the "null hypothesis" or no association). A relative risk of 2.00 means that the event (here, suicidal behavior) occurs among the population exposed to Paxil with twice the frequency as it occurs among the unexposed population. See Wade-Greaux v. Whitehall Lab., Inc., 874 F. Supp. 1441, 1452 (D.V.I.), aff'd, 46 F.3d 1120 (3d Cir. 1994). In other words, in the exposed population, a relative risk of 2.00 means that a particular event of suicidal behavior has a 50 per cent chance that it is associated with the exposure to Paxil and a 50 per cent chance that it is not associated with the exposure. See id.

A relative risk greater than 1.00 suggests that Paxil *may* cause suicidal behavior, but one must determine whether the report is statistically significant. The concept of statistical significance is used to protect against the appearance of one agent appearing better or worse than another by chance. Id. In addition to quantitative magnitude of the relative risk, several other factors determine statistical significance including confidence intervals and probability (P) values. Miller v. Pfizer, Inc., 196 F. Supp.2d 1062, 1079 (D. Kan. 2002), aff'd, 356 F.3d 1326 (10th Cir.), cert. denied, 543 (continued...)

study's secondary endpoint), the FDA found a statistically significant increased risk for adult Paxil patients with all psychiatric disorders versus placebo (relative risk of 2.76; 95 per cent confidence interval of 1.16 to 6.60; P value of 0.02). See id. at 26. The FDA noted that "[a]lthough the values for some individual drugs are statistically significant at 0.05 level, the significance of those findings must be discounted for the large number of comparisons being made." Id. at 23.

On May 1, 2007, the FDA notified GSK that it had completed its review of the labeling supplement of April 27, 2006, and that it was approvable. See Exhibit 40 to Arning Declaration. The FDA emphasized, however, that GSK needed to revise its labeling to ensure standardized labeling with all drugs that treat MDD. The letter specifically provided recommended class-wide language for all anti-depressants used to treat MDD and other psychiatric disorders.[11]

On May 2, 2007, four years after Mr. Vanderwerf's death, the FDA issued a press release

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[10](...continued)
U.S. 917 (2004).

A confidence interval has two components: a percentage and an interval or range. See Turpin v. Merrell Dow Pharms., Inc., 959 F.2d 1349, 1353 n.1 (6th Cir.), cert. denied, 506 U.S. 826 (1992). Many researchers establish the percentage at 95 per cent. At a 95 per cent confidence interval, the true relative risk value will be between the high and low ends of the confidence interval 95 per cent of the time. See id. (citing Neil Cohen, Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge, 60 N.Y.U.L. Rev. 385, 398-400 (1985)). If the confidence interval includes 1.00, the null value, the results are not considered statistically significant.

A P value is recorded on a continuous or relative scale ranging from 0 to 1.00. See Coates, 756 F.2d at 537 n.13. The level of statistical significance rises as the P value declines. See id. A P value of 0.05 indicates a five per cent probability of the disparity occurring by chance alone, even if the agents being compared are actually identical. See id. A P value below 0.05 is generally considered to be statistically significant. See id.

[11] On two occasions in May and June of 2007, GSK contacted the FDA and inquired whether the Paxil-specific language added in May of 2006 should remain in the drug's labeling. In response to both inquiries, FDA instructed GSK to delete the Paxil-specific language in favor of the class-wide labeling for anti-depressants.

which addressed all anti-depressants. See FDA Proposes New Warnings About Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medications, Exhibit 41 to Arning Declaration. It asked manufacturers of antidepressant medications to include warnings about increased risks of suicidal thinking and behavior, known as suicidality, in young adults aged 18 to 24 during initial treatment. The FDA noted that "scientific data did not show this increased risk in adults older than 24," and that adults aged 65 and older taking antidepressants had a *decreased* risk of suicidality. The FDA emphasized that depression and serious psychiatric disorders are themselves the strongest predictors of suicide.

On August 2, 2007, the FDA approved GSK's revised labeling which included a statement that "[s]hort term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." Exhibit 46 to Arning Declaration at 1. The revised labeling did not include the Paxil-specific language which GSK proposed on April 27, 2006.

II. Mr. Vanderwerf's Use Of Paxil

Before he took Paxil, Mr. Vanderwerf had a history of depression and anxiety. Without success, he had tried numerous medications, including BuSpar (an antianxiety agent), Depakote (a mood stabilizer) and Serzone (an antidepressant). On December 8, 2000, Dr. Alan Creek, Mr. Vanderwerf's primary care provider, prescribed him 20 milligrams of Paxil a day. Dr. Creek chose Paxil because he believed that it was safe and effective. When Dr. Creek prescribed Paxil, the warning label stated as follows:

> PRECAUTIONS . . . Suicide: The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Paxil should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Exhibit 17 to Arning Declaration at 10, attached as Exhibit A to defendant's Motion To File Exhibits Under Seal (Doc. #158); Pretrial Order (Doc. #160) at 7. The label contained no information that Paxil increased the risk of suicide. Dr. Creek was familiar with Paxil warnings, precautions, dosages and side effects. As part of his routine practice in treating patients with depression and anxiety, Dr. Creek instructed Mr. Vanderwerf how to take Paxil and warned him what to expect while taking it. Dr. Creek planned to closely monitor Mr. Vanderwerf on Paxil, instructing him to call at any time if he ever felt that his depression had worsened. Dr. Creek did not warn Mr. Vanderwerf that Paxil increased the risk of suicidality because when he last treated Mr. Vanderwerf (in April of 2001), Dr. Creek himself had not received any such warning. See Preliminary Report of Dr. Peter R. Breggin, M.D., attached as Exhibit 2 to Defendant's Motion To File Under Seal Certain Exhibits To Its Motions To Exclude The Testimony Of Drs. Breggin And Edlavitch (Doc. #149) at 10; Creek Depo. at 105-06.[12]

On December 21, 2001, Mr. Vanderwerf began seeing Dr. John Crane, who continued him on 20 milligrams of Paxil a day because it had been working fine for him. Beginning in January of 2002, shortly after Dr. Crane first prescribed Paxil for Mr. Vanderwerf, its label contained the following additional language under the heading of "PRECAUTIONS:"

> Because of the well-established comorbidity between major depressive disorder and other psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric disorders.

[12] Each month through December 4, 2001, Mr. Vanderwerf received Paxil which was prescribed by Dr. Creek. See Preliminary Report of Dr. Breggin at 10.

Exhibit 17 to Arning Declaration at 10; Pretrial Order (Doc. #160) at 7.[13] On March 1, 2002, Dr. Crane observed that Mr. Vanderwerf's anxiety had apparently increased. Dr. Crane therefore increased his Paxil to 40 milligrams a day and recommended that Mr. Vanderwerf consult a psychologist. Dr. Crane was familiar with Paxil warnings, precautions, dosages and side effects. As part of his standard protocol, Dr. Crane explained the risks and benefits of Paxil and instructed Mr. Vanderwerf to return if he felt that his condition had worsened. Dr. Crane did not warn Mr. Vanderwerf that Paxil increased the risk of suicidality because at that time, he had not received any such warning.

On February 7, 2003, Mr. Vanderwerf went to Dr. Crane and reported sleep problems and a decrease in concentration and interest in usual activities. Mr. Vanderwerf told Dr. Crane that he had been off Paxil for some time. Dr. Crane instructed Mr. Vanderwerf to continue 40 milligrams of Paxil daily. At that time, Paxil labeling did not inform doctors of any increased risk of suicidal behavior. In addition to Paxil, Dr. Crane prescribed 5 milligrams of Zyprexa, an antipsychotic medication, and gave Mr. Vanderwerf 14 sample tablets. Dr. Crane also referred Mr. Vanderwerf to a psychologist and instructed him to return in two weeks. In the ensuing two weeks, Mr. Vanderwerf complained of nervousness, anxiety, feelings of hopelessness at times, depressed mood and problems at work. He was very agitated and disoriented and would travel from place to place. He was fidgety, nervous and unable to sleep, and had at least one crying spell. On February 20, 2003, Mr. Vanderwerf could not sit still and was in a manic state. On February 21, 2003, at the age of 36, he committed suicide. Mr. Vanderwerf had no family history of suicide or suicidal ideation.

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[13] From January of 2002 until April of 2004, Paxil warnings regarding suicide remained unchanged. See Arning Declaration ¶ 41.

Paxil was in Mr. Vandwerf's system at the time of his death.[14]

As explained above, in May of 2006, GSK issued a DHCP letter which disclosed a "possible increase in risk of suicidal behavior" in adults of all ages who were treated with Paxil for major depressive disorder. Drs. Creek and Crane both testified that even if the information in the DHCP letter had been available when they prescribed Paxil to Mr. Vanderwerf, it would not have changed their decisions to prescribe it. See Creek Depo. at 104-05 (even today, decision to prescribe Paxil was excellent choice); id. at 100-02 (DHCP letter did not tell Creek to do anything differently); Crane Depo. at 46 (even today, agrees with decision to prescribe Paxil for Mr. Vanderwerf's adjustment disorder at that time); id. at 46-47 (if Mr. Vanderwerf presented today based on history that he related earlier, most likely would still prescribe Paxil; any uncertainty is because of success with other newer drugs, but he still relies on Paxil a lot); see also id. at 15-16 (found Paxil to be safe and effective). Dr. Creek testified that if Paxil labeling had stated that the drug increased the risk of suicide or had included the information from the DHCP letter, he would have passed along the additional information to Mr. Vanderwerf and watched him considerably more closely. See Creek Depo. at 97-98; see also id. at 95-96 (if warning in 2001 stated that Paxil increased risk of suicide, would have passed information on to patient and watched patient considerably more closely; in fact with that type of warning may not have used Paxil for certain individuals). Dr. Crane also testified that if he had the information from the DHCP letter, he would have passed along the warning information to Mr. Vanderwerf. See Crane Depo. at 70-73 (if had warnings in letter back in 2003, would have passed them on to Mr. Vanderwerf).

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[14] In 2006, based on an analysis of Mr. Vanderwerf's liver, Dr. Christopher Long determined that no Zyprexa was in Mr. Vanderwerf's system at the time of his death.

The family and Estate of William Vanderwerf filed this products liability suit against GSK, asserting claims for failure to warn and/or instruct about the risks of Paxil.[15] See Pretrial Order (Doc. #160) at 9-10. Plaintiffs allege that GSK did not adequately warn Mr. Vanderwerf's prescribing physicians that Paxil increases the risk of suicidal behavior and/or suicide precursors (such as activation, over-stimulation, anxiety, insomnia and agitation) across all psychiatric disorders for adults of all ages. See id. at 4. Plaintiffs claim that if the doctors had received such warnings, they would have acted differently by (1) not prescribing Paxil, (2) monitoring Mr. Vanderwerf more closely and/or (3) warning Mr. Vanderwerf and his family of the increased risk. Id. Plaintiffs claim that Mr. Vanderwerf would not have committed suicide if he had not received Paxil, if he had been monitored more closely or if he or his family had received proper warnings. Id.

GSK seeks summary judgment on all claims.

Analysis

GSK argues that it is entitled to summary judgment on all claims because (1) Dr. Breggin's testimony is inadmissible and plaintiffs therefore cannot show general or specific causation; and (2) plaintiffs cannot show proximate causation because GSK provided adequate warnings to Mr.

[15] Plaintiffs' third claim is labeled not as a failure to warn claim, but as a claim that GSK negligently failed to test Paxil data. Plaintiffs allege that if GSK had re-analyzed its data earlier, it would have discovered the link between Paxil and suicidality and warned consumers. See Plaintiffs' Memorandum (Doc. #180) at 16-17 (GSK ignored scientific evidence on Prozac and Paxil and accordingly never warned about link between Paxil and suicidality in February of 2003); id. at 17 (re-analysis of data at earlier date would have led to conclusions cited in GSK disclosure in April of 2004 and in letter in May of 2006); id. at 19 (additional testing and analysis would have led to proper warning prior to February of 2003). In this case, plaintiffs' testing claims are subsumed in plaintiffs' warning claims because their theory is that proper testing would have resulted in more adequate warnings. For purposes of this order, the Court assumes that the warnings were inadequate. Therefore it need not address the failure to test claim as a separate basis for liability.

Vanderwerf's physicians and additional warnings would not have changed their course of treatment.

I. General And Specific Causation

Under Kansas law, proof that a product defect caused the injury is a prerequisite to recovery in a products liability case. See Wilcheck v. Doonan Truck & Equip., Inc., 220 Kan. 230, 235, 552 P.2d 938, 942 (1976); Samarah v. Danek Med., Inc., 70 F. Supp.2d 1196, 1202 (D. Kan. 1999). In the case of failure to warn, plaintiffs must produce evidence that Paxil causes the behavior of which they complain, at least in some people. See Miller v. Pfizer, 196 F. Supp.2d 1095, 1125 (D. Kan. 2002), aff'd, 356 F.3d 1326 (10th Cir.), cert. denied, 543 U.S. 917 (2004). Unfortunately, suicidality (including ideation, attempts and completed suicides) is a leading public health problem. See Washington v. Glucksberg, 521 U.S. 702, 730 (1997). It occurs in many people who are not exposed to Paxil or any other medicine. On the other hand, many people who are exposed to Paxil do not become suicidal. Therefore plaintiffs cannot meet their burden of proving medical causation without expert testimony that Paxil can cause suicide (general causation) and that Paxil more likely than not caused Mr. Vanderwerf's suicide (specific causation). See Dodge v. Cotter Corp., 203 F.3d 1190, 1200 n.12 (10th Cir.) (given novelty of medical causation theory linking exposure to molybdenum with osteoarthritis and bony extoses, essential that expert testimony is relevant and reliable and particular opinion based on valid reasoning and methodology), cert. denied, 531 U.S. 825 (2000); Coburn v. Smithkline Beecham Corp., 174 F. Supp.2d 1235, 1239 (D. Utah 2001) (recognizing need for expert testimony that Paxil can cause some people to commit suicide and that Paxil was cause of decedent's suicide); Smith v. Pfizer, 2001 WL 968369, at *11 (expert testimony necessary to establish general causation between Zoloft and akathisia or suicidality); In re Breast Implant Litig., 11 F. Supp.2d 1217, 1225-26 (D. Colo. 1998) (because plaintiffs' injuries occur

commonly in women without breast implants, plaintiffs must present expert testimony that exposure to breast implants more than doubled risk of alleged injuries); Bacon v. Mercy Hosp., 243 Kan. 303, 307, 756 P.2d 416, 420 (1988) (unless lack of reasonable care or existence of proximate cause is apparent to average layman from common knowledge or experience, expert testimony required to establish causation).

A. General Causation

To support their claim of general causation, plaintiffs rely primarily on the testimony of Dr. Breggin. For substantially the reasons stated in Defendant's Memorandum Of Law In Support Of Its Motion To Exclude The Testimony Of Peter R. Breggin (Doc. #151) filed August 10, 2007 and Defendant's Reply In Support Of Its Motion To Exclude the Testimony Of Peter R. Breggin (Doc. #176) filed September 14, 2007, the Court excludes the testimony of Dr. Breggin under Rule 702, Fed. R. Evid., and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). In particular, as to general causation, Dr. Breggin (1) has not identified a methodology for determining general causation which has been accepted in the scientific community, (2) has failed to account for a substantial body of evidence which has found no causal link between Paxil and suicide or suicidal behavior in adults, particularly in adults beyond the age of 30 and (3) had not adequately distinguished statistical "association" from causation.

Plaintiffs argue that even without Dr. Breggin's testimony, GSK has admitted general causation through its corporate representative, Dr. John Kraus. Plaintiffs note that based on the DHCP letter in May of 2006, Dr. Kraus testified that (1) in adults of all ages with MDD, GSK found a statistically significant increase in the frequency of suicidal behavior (including preparing for suicide, suicide attempts and completed suicides) in patients treated with Paxil compared to placebo,

see Kraus Depo. at 100 (reading from DHCP letter in May of 2006); (2) in GSK's analysis of adult Paxil data, eight of the 11 suicide attempts were in the 25 to 64 year-old age group, and this data was in GSK's clinical database before 2003; and (3) GSK itself believes that the pre-2003 data suggests that the suicidal behavior risk for Paxil extends beyond age 24, see id. at 104-05, 113-17, 148-49.

Plaintiffs, however, have misrepresented Dr. Kraus' testimony. First, the DHCP letter does not say that Paxil increases the risk of suicidal behavior, let alone suicide and suicide precursors, across all psychiatric disorders for adults of all ages with major depressive disorder. It discloses a "possible" risk in adult patients, states that the risk is likely limited to younger adults between the ages of 18 and 30, and emphasizes that it is difficult to conclude a causal relationship because of (1) the small incidence and absolute number of events, (2) the retrospective nature of the meta-analysis and (3) the fact that the risk of suicidal behavior is a symptom of the underlying psychiatric illnesses. Second, while Dr. Kraus testified that GSK could not definitively state any increased risk would end at a particular age, most cases of suicide attempts (eight of 11) were before age 30. See Kraus Depo. at 75, 102; id. at 75-76 (majority of suicide attempts in younger adults between 18 and 30); id. at 77 (prior analysis indicated no difference between Paxil and placebo in 30 to 40 year old range); id. at 101 (looking at adults past age 30, difficult to find any correlation between Paxil and suicide attempts); id. at 103 (no statistically significant difference between Paxil and placebo for suicidal ideation in adults older than 30). It is therefore misleading to lump individuals aged 18 to 30 years in the 25-to-64 age group. Finally, Dr. Kraus testified that even though the 11 suicide attempts occurred before March of 2003, the methodology for assessing that data did not exist until later, in 2004, when the FDA developed it to analyze pediatric clinical trial data in conjunction with experts in suicidology at Columbia University. See id. at 56-61. Therefore, even giving plaintiffs

the benefit of all favorable inferences, GSK has at most admitted that Paxil *may* increase the risk of suicidal behavior and suicide in adult patients between the ages of 18 and 30. Dr. Kraus' testimony, viewed in its entirety, does not create a genuine issue of material fact whether Paxil causes suicidal behavior and/or suicide in adult patients beyond the age of 30, let alone constitute an "admission" that Paxil does so. Even if Paxil increases the risk of suicide below age 30 and decreases the risk of suicide above age 65, plaintiffs have presented no evidence which would assist a jury in determining whether Paxil more likely than not caused suicide in 36-year-old individuals in general or in Mr. Vanderwerf, in particular. On this record, even given Dr. Kraus' testimony, such a conclusion would be sheer speculation.

Plaintiffs also argue that the FDA has found a statistically significant increase in risk for suicidal behavior in adult Paxil patients with all psychiatric disorders compared to placebo. Again, plaintiffs have taken a single FDA finding out of context. As noted above, as to suicidal behavior defined as suicidal ideation or worse (the study's primary endpoint), the FDA did not find an increased risk for Paxil patients compared to placebo. See FDA 2006 Clinical Review at 26 (relative risk ratio of 0.93; 95% confidence interval of 0.62 to 1.42; P value of 0.75). The primary analysis therefore showed no association between Paxil and suicidal thinking (or worse) in adults. As to suicidal behavior defined as preparatory acts or worse (the study's secondary endpoint), the FDA found a statistically significant increased risk for adult Paxil patients with all psychiatric disorders versus placebo (relative risk of 2.76; 95 % confidence interval of 1.16 to 6.60; P value of 0.02). See id. at 26. The FDA, however, cautioned that "[a]lthough the values for some individual drugs are statistically significant at 0.05 level, the significance of those findings must be discounted for the large number of comparisons being made." Id. at 23; see also Manual On Scientific Evidence

127-28 (repeated testing complicates interpretation of significance levels; if enough comparisons are made, random error almost guarantees that some will yield significant findings, even when no real effect). In addition, the FDA specifically rejected any association between suicidality or suicidal behavior in adults age 25 or older. See FDA 2006 Clinical Review at 27, 29. Even now, the FDA rejects the notion of a causal link between Paxil and suicide or suicidal behavior in adults beyond the age of 24.[16] See Tucker v. SmithKline Beecham Corp., No. 04-cv-1748-DFH-WTL, 2007 WL 2726259, at *9 (S.D. Ind. Sept. 19, 2007) (FDA revised warning in May of 2007 confirms risk of suicidality with antidepressants in pediatric patients, but affirmatively rejects hypothesis of such an association in adults). As with the testimony of Dr. Kraus, the FDA limited statistical finding on Paxil in its 2006 Clinical Review does not create a genuine issue of material fact on the issue of general causation.

For the above reasons, the Court sustains defendant's motion for summary judgment on the issue of general causation.

B. Specific Causation

Absent a basis to testify on general causation, Dr. Breggin cannot offer testimony on specific

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[16] In May of 2007, the FDA proposed labeling on Paxil as follows:

> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Paxil] or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. *Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24*; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 or older.

Exhibit 40 to Arning Declaration (emphasis added).

causation. See Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (if silicone breast implants incapable of causing systemic injuries in anyone, it follows a fortiori that silicone breast implants could not have caused systemic injuries in plaintiff). As with general causation, for reasons which GSK has well articulated, the Court excludes Dr. Breggin's testimony on specific causation under Rule 702, Fed. R. Evid., and Daubert. In particular, Dr. Breggin (1) has not identified a methodology for determining specific causation which has been accepted in the scientific community, (2) has failed to account for a substantial body of evidence which has found no causal link between Paxil and suicide or suicidal behavior in adults, particularly adults beyond the age of 30 and (3) had not adequately distinguished statistical "association" from causation. Aside from the testimony of Dr. Breggin, plaintiffs offer no evidence of specific causation. Accordingly, the Court sustains defendant's motion for summary judgment on this alternative ground.

II. Proximate Causation

Even if plaintiffs could offer sufficient evidence of general and specific causation, GSK would be entitled to summary judgment on the issue of proximate causation. Under the learned intermediary doctrine, the physician acts as a learned intermediary between the drug manufacturer and the patient. Humes v. Clinton, 246 Kan. 590, 600, 792 P.2d 1032, 1039 (1990). Because "prescription drugs are available only to a physician, it is the physician's duty to inform himself or herself of the characteristics of the drugs prescribed and to exercise his or her judgment of which drug to administer in light of the drug's propensities and the patient's susceptibilities." Id. The learned intermediary doctrine allows the manufacturer to "assume a patient places reliance on the physician's judgment and relieves the manufacturer of a duty to assist the physician in communicating with patients." Id. at 601, 792 P.2d at 1039.

To survive summary judgment, plaintiffs must provide evidence that a failure to warn proximately caused Mr. Vanderwerf's death. See Wooderson v. Ortho Pharm. Corp., 235 Kan. 387, 409, 681 P.2d 1038, 1057 (1984), cert. denied, 469 U.S. 965 (1984); see also Eck v. Parke, Davis & Co., 256 F.3d 1013, 1018 (10th Cir. 2001) (citing Mazur v. Merck & Co., 742 F. Supp. 239, 262 (E.D. Pa. 1990)). Kansas law allows a rebuttable presumption of causation once plaintiffs have established that a warning is inadequate. If plaintiffs prove that GSK failed to provide a proper warning, Kansas law presumes that a doctor would have heeded a proper warning. See Wooderson, 235 Kan. at 407, 681 P.2d at 1057. Defendant may rebut this presumption by establishing that although the prescribing physician would have read and heeded the warning or additional information, it would not have changed the course of treatment. See Eck, 256 F.3d at 1019. If GSK provides credible evidence to rebut the presumption, the presumption disappears and the burden shifts back to plaintiffs to affirmatively prove causation. See id.; Woulfe v. Eli Lilly & Co., 965 F. Supp. 1478, 1483 (E.D. Okla. 1997).

Preliminarily, it is important to address the specific nature of plaintiffs' claim. In the pretrial order, plaintiffs allege that Paxil labeling should have stated that Paxil increases the risk of suicidal behavior and suicide precursors across all psychiatric disorders for adults of all ages. See Pretrial Order (Doc. #160) at 4. In their opposition to GSK's motion for summary judgment and elsewhere, plaintiffs characterize the DHCP letter – which GSK sent in May of 2006, based on pre-2003 data – as an admission that "Paxil increases the risk of suicidal behavior." See, e.g., Plaintiffs' Memorandum (Doc. #180) at 6; Pretrial Order (Doc. #160) at 4; Breggin Report at 23 (in May 2006, GSK admitted that Paxil increases risk of suicidal behavior in adults of all ages with MDD). As explained above, however, the DHCP letter actually discloses a "possible" risk in adult patients,

states that the risk is likely limited to younger adults between the ages of 18 and 30, and emphasizes that it is difficult to conclude a causal relationship. The pretrial order does not specifically allege that GSK is liable because as of February of 2003, it had failed to make the disclosures which are contained in the DHCP letter in May of 2006. Nonetheless, because the parties' discovery and briefs focus on this issue, the Court liberally construes the pretrial order to assert such a claim. See Fisherman Surgical Instruments, LLC v. Tri-anim Health Servs., Inc., 502 F. Supp.2d 1170, 1176 n.2 (D. Kan. 2007) (arguments reasonably encompassed by pretrial order permitted); Theno v. Tonganoxie Unified Sch. Dist. No. 464, 394 F. Supp.2d 1299, 1303 (D. Kan. 2005) (pretrial order liberally construed to cover all legal or factual theories embraced by language or inherent in issues defined therein); Van Enters., Inc. v. Avemco Ins. Co., 231 F. Supp.2d 1071, 1081 (D. Kan. 2002) (pretrial order liberally construed to cover any legal or factual theories that might be embraced by its language); see also Fed. R. Civ. P. 8(f) (pleadings construed to do substantial justice). Accordingly, the Court reads the pretrial order as asserting that in February of 2003, Paxil labeling should have included (1) information that Paxil increases the risk of suicidal behavior; (2) information that Paxil increases the risk of suicide precursors such as activation, over-stimulation, anxiety, insomnia and agitation; and (3) information that GSK disclosed in its DHCP letter in May of 2006.[17]

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[17] Aside from the DHCP letter in May of 2006, Dr. Breggin opines that if Paxil labeling before February of 2003 had included warnings similar to those in a DHCP letter in *May of 2004*, Mr. Vanderwerf would be alive today. See Breggin Report at 38. In May of 2004, GSK issued a DHCP letter which stated as follows:

> Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation,

(continued...)

For purposes of this analysis, the Court assumes without deciding that plaintiffs are entitled to the benefit of a presumption of causation. To rebut the presumption of causation as to all three failure-to-warn claims, GSK notes that Drs. Creek and Crane both testified that even with the information which they have today (such as the DHCP letter in May of 2006), they would have prescribed Paxil to Mr. Vanderwerf. Such testimony, which is summarized above, is sufficient to rebut the presumption of causation as to all three theories of what the Paxil labeling should have included.[18] Eck, 256 F.3d at 1019 (defendant may rebut presumption by showing that additional

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[17](...continued)
irritability, and other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers.

Breggin Report at 19. The pretrial order does not claim that in 2003, Paxil labeling was inadequate because it omitted information which was included in this letter. Plaintiffs did not address this theory in their briefing on defendant's motion for summary judgment. Thus, in addition to being inadmissible under Daubert, Dr. Breggin's opinion about the DHCP letter from May of 2004 is irrelevant to plaintiffs' claims.

[18] The pretrial order claims that GSK should have warned physicians that Paxil increases the risk of suicidal precursors. Dr. Breggin opines that by February of 2003, GSK should have included the information which was added to antidepressant labeling beginning January 25, 2005. See Dr. Breggin's Report at 20. In particular, the information which concerned possible precursors of suicide was as follows:

> The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorders as well as for other indications, both psychiatric and non-psychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Id. Drs. Creek and Crane generally testified that even today, they would prescribe Paxil for Mr. Vanderwerf. Even though they did not specifically address the issue, their testimony is sufficient to rebut the presumption of causation regarding failure to warn about suicide precursors, as well as (continued...)

warning would not have changed physician's course of treatment).[19]

GSK has not raised the issue, but plaintiffs have not explained how Dr. Creek's decision to prescribe Paxil, or his failure to monitor or warn Mr. Vanderwerf and his family through December of 2001, could be the proximate cause of Mr. Vanderwerf's suicide in February of 2003. Proximate cause is defined as that cause which in natural and continuous sequence, unbroken by an efficient intervening cause, produces the injury and without which the injury would not have occurred, the injury being the natural and probable consequence of the wrongful act. Wilcheck, 220 Kan. at 235, 552 P.2d at 942-43. Plaintiffs' claims target Paxil labeling in February of 2003, when Mr. Vanderwerf re-started the drug and committed suicide. See Pretrial Order (Doc. #160) at 4 (data available to GSK prior to 2003, but not included in Paxil labeling at time of Mr. Vanderwerf's death). Therefore, the fact that Dr. Creek may have received inadequate warnings in 2001 appears to be immaterial. Mr. Vanderwerf did well on Paxil under Dr. Creek's supervision through 2001. Even if Dr. Creek had received all of plaintiffs' proposed warnings between 2001 and 2003, he was not treating Mr. Vanderwerf during the last 14 months of his life and plaintiffs do not claim that he had an ongoing duty or opportunity to monitor or warn Mr. Vanderwerf.

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[18](...continued)
failure to warn about an increased risk of suicidality.

[19] See, e.g., Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003-04 (4th Cir. 1992) (summary judgment appropriate where physician testified that different warning would not have changed decision); Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 812 (5th Cir. 1992) (under Mississippi law, plaintiff must show reasonable likelihood that adequate warning would have prevented plaintiff from receiving drug); Stafford v. Wyeth, 411 F. Supp.2d 1318, 1321 (W.D. Okla. 2006) (presumption rebutted where prescribing physician testified that different warning would not have mattered); Miller, 196 F. Supp.2d at 1128 (same); Dyer v. Danek Med., Inc., 115 F. Supp.2d 732, 741-42 (N.D. Tex. 2000) (granting summary judgment where trier of fact would reasonably infer that physician's decision would have been unchanged).

Once the presumption is rebutted, plaintiffs must further establish proximate causation by (1) discrediting the testimony of the prescribing physicians or calling into question the substance of their testimony or (2) showing that had GSK issued a proper warning to the prescribing physicians, they would have altered their behavior and the injury would have been avoided. Miller, 196 F. Supp.2d at 1128 (D. Kan. 2002); see Eck, 256 F.3d at 1018; Mazur, 742 F. Supp. at 262.[20]

A. Discrediting Testimony Of Prescribing Physicians

Nothing in the record discredits any testimony of the prescribing physicians that they still would have prescribed Paxil if they had the information which plaintiffs propose in their three theories of liability.[21]

1. Dr. Crane

Plaintiffs have not attempted to discredit Dr. Crane's testimony that even with the information he has today (such as the DHCP letter in May of 2006), he would not have changed his decision to prescribe Paxil for Mr. Vanderwerf.

2. Dr. Creek

Plaintiffs do attempt to discredit Dr. Creek's testimony that he would have prescribed Paxil even if he had known that it increases the risk of suicidal behavior. Their sole argument, however, is that Dr. Creek "may not have given Mr. Vanderwerf Paxil if he'd known of the increased suicidality risk." Plaintiffs' Memorandum (Doc. #180) at 6 (citing Creek Depo. at 95-98). Dr. Creek testified as follows:

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[20] Plaintiffs do not attempt to address these elements separately or to apply them to their various failure-to-warn theories.

[21] The Court addresses below plaintiffs' theory that the prescribing physicians would have monitored Mr. Vanderwerf more closely. See infra text, Part II.B.2.

Q: If there were a warning to you back in the 2001 time period that Paxil increased the risk of suicide, that's something you would have liked to have known to incorporate into your practice. Is that true?

A: Yes. That is true.

Q: And if you had such a warning from the drug company that's something you would have passed along to a patient such as Mr. Vanderwerf. Is that true?

A: Yes. Also I would have watched him considerably closer and had him come in more often. He didn't like it a lot. But you've got to do what you've got to do. And, you know, after they get better though they really do appreciate it. But, yes, it would help me stay on top of him a little bit or passed it along to him. I would have watched him a little closer. And in fact I may not even have used that product in a certain individual.

Creek Depo. at 95-96 (objections omitted). The above testimony establishes that Dr. Creek may not have used Paxil "in a certain individual," but it does not explain what type of individual or why Dr. Creek may not have given Paxil to that type of individual. The reference has no apparent relation to Mr. Vanderwerf. Dr. Creek clearly testified that even today, he would still prescribe Paxil for Mr. Vanderwerf. The speculative argument that Dr. Creek "may not" have used Paxil "in a certain individual" does not raise a genuine issue of material fact whether Dr. Creek would have declined to prescribe Paxil for Mr. Vanderwerf if he had received any of the three warnings which plaintiffs propose. Moreover, as noted above, Mr. Vanderwerf did exceptionally well on Paxil under Dr. Creek's care, see Creek Depo. at 104-05, and after 2001, Dr. Creek was not prescribing Paxil to Mr. Vanderwerf or monitoring his care because he was no longer his doctor.

B. Other Evidence That Proper Warning Would Have Prevented Injury

To establish proximate causation, plaintiffs can also present evidence that had GSK issued a proper warning to the prescribing physicians, they would have altered their behavior and the injury would have been avoided. See Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 856 (10th Cir.

2003); Eck, 256 F.3d at 1018; Miller, 196 F. Supp.2d at 1128; Mazur, 742 F. Supp. at 262. Plaintiffs claim that if the doctors had been warned that Paxil thus increases the risk of suicidal behavior and suicide precursors, they would have acted differently by (1) not prescribing Paxil, (2) monitoring Mr. Vanderwerf more closely and/or (3) warning Mr. Vanderwerf and his family of the increased risk, and that Mr. Vanderwerf would not have committed suicide. Id.

1. Not Prescribing Paxil

As noted, plaintiffs have not demonstrated a genuine issue of material fact whether Dr. Creek and Dr. Crane would still have prescribed Paxil if they had received (1) information that Paxil increases the risk of suicidal behavior; (2) information that Paxil increases the risk of suicide precursors such as activation, over-stimulation, anxiety, insomnia and agitation; or (3) the results of the meta-analysis which GSK disclosed in its DHCP letter in May of 2006.

2. Additional Monitoring

Plaintiffs allege that Mr. Vanderwerf would not have committed suicide if his doctors had more closely monitored him. Dr. Creek testified that he would have monitored Mr. Vanderwerf more closely, but as explained above, Mr. Vanderwerf did well on Paxil under Dr. Creek's care in 2001 and after 2001, Dr. Creek was no longer his doctor and had no opportunity to monitor him. Plaintiffs offer no evidence that additional monitoring by Dr. Creek in 2001 would have prevented Mr. Vanderwerf's suicide in February of 2003. Moreover, plaintiffs have cited no evidence that Dr. Crane would have monitored Mr. Vanderwerf more closely, or succeeded in preventing his suicide, if he had received different warnings. GSK's DHCP letter in May of 2006 advised physicians that all patients on Paxil should receive "careful monitoring," and the Court assumes that Dr. Crane would have followed such advice. Nothing in the record, however, suggests that Dr. Crane failed

to carefully monitor Mr. Vanderwerf or that any level of further monitoring would have prevented his suicide.

3. Additional Risk Information

Plaintiffs have demonstrated a genuine issue of material fact whether Dr. Creek and Dr. Crane would have altered their behavior by giving Mr. Vanderwerf additional risk information. Cf. Miller, 196 F. Supp.2d at 1128 (sustaining defendants' motion for summary judgment because treating physician testified that even if with additional warnings, he would have prescribed Zoloft "without further warning or instructions"). Both Dr. Creek and Dr. Crane testified that they would have passed the additional information along to Mr. Vanderwerf. See Creek Depo. at 95-98; Crane Depo. at 70-73, 89-90. Even so, plaintiffs offer no evidence on the second element, i.e. that if the physicians had provided additional warning information to Mr. Vanderwerf, the injury would have been avoided.[22] Thom, 353 F.3d at 856; Miller, 196 F. Supp.2d at 1128; Mazur, 742 F. Supp. at 262. Absent evidence on this issue, no reasonable jury could find that GSK proximately caused Mr. Vanderwerf's suicide by failing to give the prescribing physicians the warning information which plaintiffs advocate.[23]

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[22] The Court recognizes that such evidence may be difficult to obtain, particularly in a tragic case such as this. Plaintiffs have an especially difficult burden because as noted in the precautions on the Paxil labeling from 2001 to 2004, the possibility of suicide is inherent in major depressive disorder and may persist until significant remission occurs. Nonetheless, after defendant rebuts the presumption of causation, if plaintiffs do not present evidence which discredits the physicians' testimony, they have the burden to otherwise demonstrate that the alleged failure to warn was the proximate cause of their injuries. See Eck, 256 F.3d at 1019.

[23] A reasonable jury might infer, as a matter of common sense, that Mr. Vanderwerf would have paid some attention to additional warning information. It would be entirely speculative, however, to conclude that he would use this information to prevent his own suicide. See Conaway, 853 F.2d at 784 (plaintiffs must rely on more than speculation or suspicion). As explained above, (continued...)

Plaintiffs argue that Dr. Creek and Dr. Crane would have warned Mrs. Vanderwerf if they had known that Paxil increases the risk of suicidal behavior, and that she would have acted differently to prevent the suicide if the doctors had so warned her. Pretrial Order (Doc. #160) at 4; Plaintiffs' Memorandum (Doc. #180) at 6 (citing Creek Depo. at 95-98; Crane Depo. at 70-74, 89-90). In the cited portion of the depositions, however, neither doctor testified that he would have passed along any information to Mrs. Vanderwerf. See, e.g., Creek Depo. at 95 (would pass along information to patient); id. at 98 (would pass along information to Mr. Vanderwerf); Crane Depo. at 73-74 (would pass along information to patient). In any event, even if Dr. Creek or Dr. Crane had advised Mrs. Vanderwerf that Paxil increases the risk of suicide or suicidality, plaintiffs have presented no evidence that based on that information, Mrs. Vanderwerf could have prevented her husband's suicide. Speculation about how this tragedy might have been avoided is absolutely understandable and perhaps inevitable, but plaintiffs cannot escape summary judgment based on speculation. See Conaway, 853 F.2d at 784.

For these reasons, the Court sustains GSK's motion for summary judgment on plaintiffs' claims.

IT IS THEREFORE ORDERED that Defendant's Motion To Exclude The Testimony Of Peter R. Breggin (Doc. #150) filed August 10, 2007 be and hereby is **SUSTAINED**.

IT IS FURTHER ORDERED that Defendant's Motion For Summary Judgment (Doc.

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[23](...continued)
plaintiffs have not presented a genuine issue of material fact on the issues of general or specific causation. Even if plaintiffs could do so, they have not presented evidence as to Mr. Vanderwerf's psychological state which would suggest that additional warning information would have changed his course of conduct. This is particularly true because Mr. Vanderwerf had a history of depression and anxiety, with significant stressors in his life in February of 2003, and such factors themselves put Mr. Vanderwerf at risk of suicide.

#163) filed August 31, 2007 be and hereby is **SUSTAINED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion For Leave To File Sur-Reply Memorandum In Opposition To Motion To Exclude The Testimony Of Peter R. Breggin, M.D. (Doc. #181) filed September 24, 2007 be and hereby is **OVERRULED**.

IT IS FURTHER ORDERED that all other pending motions are **OVERRULED as moot**.

Dated this 9th day of January, 2008 at Kansas City, Kansas.

s/ Kathryn H. Vratil
KATHRYN H. VRATIL
United States District Court