IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of Stewart Dolin, Deceased,	)	
Plaintiff,	)	
v.	)	No. 12 C 6403
GLAXOSMITHKLINE LLC,	)	
Defendant.	)	

OPINION AND ORDER

A jury returned a verdict in the amount of $3 million in damages in a wrongful death and survival action in favor of plaintiff Wendy Dolin, executor of the Estate of Stewart Dolin, deceased, and against defendant GlaxoSmithKline LLC ("GSK"). The case was initiated in the Circuit Court of Cook County, Illinois and removed to this court based on diversity of citizenship. A motion to remand to the state court was denied (Dkt. 73).[1] This court has jurisdiction pursuant to 28 U.S.C. §§ 1332 and 1441.

[1]SmithKlineBeecham Corporation, formerly a Pennsylvania corporation, converted into GlaxoSmithKline LLC, a limited liability membership company organized under Delaware law. The sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation, with its principal place of business in Wilmington, Delaware. Dismissed defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. Defendant H.D. Smith Wholesale Drug Co., a Delaware corporation, with its principal place of business in Illinois, was dismissed as improperly joined. The amount involved exceeded $75,000.

The case is now before the court for ruling on the defendant's reserved motions for judgment as a matter of law or for a new trial.

Suit was brought to recover damages arising out of the death of plaintiff's husband, Stewart Dolin, a 57-year old attorney who was suffering from depression. He was prescribed and taking paroxetine, an antidepressant. Paroxetine is a drug designed, labeled and sold by GSK under the brand name Paxil. (The druggist who filled the prescription for paroxetine supplied a generic form of the drug produced and sold with the GSK Paxil label by Mylan Inc.) On July 15, 2010 Mr. Dolin left his office and went to a Chicago "L" train station and leapt in front of a train. Plaintiff alleges he was suffering from drug induced akathisia, a psychomotor agitation disorder.

The case went to trial on the claim that GSK negligently failed to include a warning in the label that the drug can be a cause of adult suicide despite being aware of a significant risk of suicide in adults taking the drug. It is alleged that GSK allowed an affirmative misrepresentation to exist in the label that there is no risk of suicide beyond the age of 24 years. The plaintiff also asserts that the label did not warn of akathisia's association with suicidal behavior. Plaintiff contends that GSK negligently misled the medical profession (including Mr. Dolin's physician and the Food and Drug Administration ("FDA")) by concealing and misrepresenting adult suicide risk data relating to paroxetine.

Prior Rulings

GSK moved for summary judgment three times. It first argued that because Mr. Dolin ingested a generic form of paroxetine it could not be liable for its conduct in creating and controlling the labeling used. The court disagreed. ***Dolin v. SmithKline Beecham Corp.,*** 62 F.

Supp. 3d 705, 713 (N.D. Ill. 2014) (Zagel, J.) (Dkt. 110) ("***Dolin I***"). GSK moved to have the ruling certified under 28 U.S.C. § 1292(b) for an interlocutory appeal. After that motion was denied GSK petitioned the United States Court of Appeals for the Seventh Circuit for a writ of mandamus to compel certification of an appeal. The petition was denied. ***In re GlaxoSmithKline LLC.***, 557 F. App'x 578, 579 (7th Cir. 2014).

GSK's second and third motions for summary judgment focused on Federal preemption as described in ***Wyeth v. Levine,*** 555 U. S. 555, 581 (2009). It argued that any state law claim was preempted because the FDA rejected its efforts to place certain warnings on the label. It was held that GSK failed to show that the FDA would have rejected a Paxil specific warning of the risk of adult suicide. In the third motion GSK urged that Mr. Dolin's physician was aware of the risks of adult suicide associated with the drug and that the label was adequate as a matter of law. Plaintiff's strict liability claims of design defect and failure to warn were dismissed. Negligence and consumer claims were allowed to proceed. ***Dolin v. Smith Kline Beecham Corp.,*** 2016 WL 537949 (N.D. Ill. Feb. 11, 2016) (Zagel, J.) (Dkt. 348) ("***Dolin III***").

In ***Mut. Pharm. Co., Inc. v. Bartlett***, 133 S. Ct. 2466 (2013) and in ***PLIVA v. Mensing,*** 131 S. Ct. 2567 (2011) the Supreme Court held that state-law label design defect claims that turn on the adequacy of label warnings are preempted by Federal law in the case of a generic supplier because a generic supplier has no power to change the label created by a brand-name supplier. *See* ***Bartlett,*** 133 S. Ct. at 2473; ***PLIVA,*** 131 S. Ct. at 2576. Accordingly, defendant Mylan Inc.'s motion to dismiss was granted. (Dkt. 110).

GSK's ***Daubert*** motions to exclude the testimony of plaintiff's expert witnesses (David Healy, M.D., David Ross, M.D., Ph.D., M.B.I. and Joseph Glenmullen, M.D.) were denied. 2015 WL 7351678 (N.D. Ill. Nov. 20, 2015) (Zagel, J.) ("***Dolin II")***.

The parties' motions *in limine* and objections to exhibits were resolved or reserved for ruling at trial. (Dkts. 465, 475, and 499.) Based on Rule 403 of the Federal Rules of Evidence, GSK's motion *in limine* to exclude any reference before the jury to criminal convictions of GSK for promoting Paxil in patients under age 18 and publishing misleading pediatric information with respect to Paxil was granted. The evidence in the case was limited to data dealing with adult suicide issues. Plaintiff was also precluded from offering studies showing minimal efficacy of paroxetine compared with placebo.

Shortly before trial plaintiff moved to amend her complaint to limit her claims to one count of negligence and one count of negligence with intent to injure. Negligence with intent to injure was ruled not to be a plausible claim. (Dkt. 490.) The case went to trial on the negligence claim only. Under Illinois law, plaintiff's burden of proof was to prove every essential element of her claim by a preponderance of the evidence.

The jury was instructed, in substance, as follows: GSK was responsible for the content of the paroxetine label. (21 C.F.R. § 201.80(e) and 121 Stat. 924-926.) GSK is charged both with crafting an adequate label and with ensuring that the warnings remain adequate as long as the drug is on the market. Under FDA regulations, GSK is required to revise and update its label to include a warning as soon as there is "reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved" (21 C.F.R. § 314.80(e)).

The jury was also told that FDA regulations permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning to the FDA for review and approval (21 CFR §§ 314.70(c)(6)(iii)(A), (C)).

In recognition of the learned intermediary doctrine, the jury was told that GSK had a duty to warn only the prescribing physician of the risks of which it knew, or in the exercise of ordinary care, should have known.

Based on the rulings in ***Mason v. SmithKine Beecham Corp.,*** 596 F.3d 387 (7th Cir. 2010) and, more recently, ***In re (Fosamax Alendronate) Sodium Prods. Liab. Litig.,*** 852 F.3d 268 (3d Cir. 2017) the affirmative defense of Federal preemption as set forth in ***Wyeth v. Levine,*** 555 U.S. 555 (2009) was ruled to be a factual question for the jury. The court offered to submit the question to the jury with an appropriate burden of proof instruction. GSK took the position that preemption was a question of law for the court and declined to have its affirmative defense submitted to the jury in the form stated in the court's instructions.

Standards

Federal Rule of Civil Procedure 50(a) provides that if "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party . . . the court may . . . grant a motion for judgment as a matter of law." For a renewed motion for judgment as a matter of law the standard is whether the evidence presented, combined with all reasonable inferences, is sufficient

to support the verdict when viewed in the light most favorable to the nonmovant. ***Dadian v. Vill. of Wilmette,*** 269 F.3d 831, 837 (7th Cir. 2001).

A new trial may be granted if the verdict is against the clear weight of the evidence or the trial was unfair to the moving party. ***Whitehead v. Bond***, 680 F.3d 919, 927 (7th Cir. 2012). When a motion for a new trial is based on a ruling of evidence, it must be shown that the error was such as to deny the party a fair trial. ***Perry v. Larson,*** 794 F.2d 279, 285 (7th Cir. 1986).

The Evidence

Paroxetine hydrochloride is a psychotropic drug of the Selective Serotonin Reuptake Inhibitor class ("SSRIs"). It is used, among other purposes, to treat major depressive disorders. The action of the drug on brain neurons is thought to be responsible for anti-depressant effects. Marketing of the drug began in 1992. Generic formulations have been available since 2003. The New Drug Application (NDA 20-031) was submitted in 1989 with data relating to suicides. In April 1991, the NDA was amended with a report containing data on suicides and suicide attempts. An approval letter for major depressive disorders (MDD) was issued on December 29, 1992. Paxil is not approved in the United States for any treatment in the pediatric population.

The testimony of all of the medical experts who testified reveals that it is recognized in the medical community that some patients treated with SSRIs may be more likely to attempt or commit suicide. An SSRI may activate patients with suicidal ideations or induce symptoms of emotional volatility leading them to attempt or commit suicide in order to escape intolerable feelings.

The so-called "black box" warning on the GSK label, the truth of which, in the case of Paxil, was a main focus of attention in this case (Joint Exhibit 1). Some content and the origin of the label is connected with criminal complaints against GSK by the Attorney General of New York in 2003 and later by United States Department of Justice resulting in a $3 billion fine against GSK for, among other things, withholding paroxetine data from the Food and Drug Administration ("the FDA") and unlawfully promoting the drug for pediatric (under age 18) uses.[2] The FDA conducted a pooled statistical analyses of SSRIs, including paroxetine, finding an increase in suicide and suicide ideation in pediatric cases treated with SSRIs. It then ordered that each SSRI have a standardized "black box" warning which, in the case of Paxil, provides as follows:

Suicidality and Antidepressant Drugs

> 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 the age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

[2] Based on Rule 403 of the Fed. R. Evid., the facts and results relating to the criminal actions and the results of related class actions against GSK were excluded from the evidence heard by the jury.

Another part of the GSK paroxetine/Paxil label which was a focus of attention in the evidence is the **WARNINGS** section:

WARNINGS

> **Clinical Worsening and Suicide Risk:** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond the age of 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.
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> The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1,000 patients treated) are provided in Table 1.

Table 1

Age Range	Drug-Placebo Difference in Number of Cases of Suicidality per 1,000 Patients Treated
Increases Compared to Placebo	
<18	14 additional cases
18-24	5 additional cases
Decreases Compared to Placebo	
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

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 disorder as well as for other indications, both psychiatric and nonpsychiatric. 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.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening of depression or suicidality, especially if those symptoms are severe, abrupt in onset, or were not part of the patients presenting symptoms.

> If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION – Discontinuation of Treatment With PAXIL, for a description of the risks of discontinuation of PAXIL).
>
> **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and non-psychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers.** 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.

Mr. Dolin's attending physician, Dr. Martin Sachman, an internist, testified that he relied on the 2010 Paxil label in deciding to prescribe Paxil for the depression experienced by Mr. Dolin in June of 2010. He said that the label did not warn that the drug could induce suicidal behavior in adults over 24, rather that it stated the risk of suicide did not extend beyond age 24 and that he relied on those representations. It was his testimony that had the label warned of the risk of adult suicidal behavior in persons over the age of 24, he would not have prescribed the drug for Mr. Dolin. Dr. Sachman stated that he had other drug choices available for the treatment of Mr. Dolin's depression.

Plaintiff's experts, Dr. Healy and Dr. Ross, testified in support of Dr. Sachman's interpretation that the label did not warn of adult suicide risks. There was also testimony that the label did not warn that akathisia can lead to suicide.

Notwithstanding a vigorous cross-examination relating to the medical community's knowledge of adult suicide risks, the jury was entitled to accept Dr. Sachman's testimony that he

relied on the statement that the risk of adult suicide did not extend beyond the age of 24 when he prescribed paroxetine for Mr. Dolin.

It was plaintiff's position that the language in the Black Box and Warnings sections of the GSK label stating that "[s]hort-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond the age 24" was based on pooled analyses of 11 antidepressant drugs (SSRIs) not on Paxil data only. It was contended that the statement is not true of data relating only to paroxetine/Paxil.

Plaintiff presented testimony from three experts, two psychiatrists (Drs. David Healy and Joseph Glenmullen) and one physician-expert who has been an examiner at the FDA (Dr. David Ross). Each testified that paroxetine ingestion can cause suicidal behavior in adults. Those opinions were supported by case reports, challenge studies (a patient having an adverse effect while on the drug is given a repeat administration of the drug), clinical-controlled trial data and controlled placebo studies reported in peer-reviewed scientific publications. The testimony and data was found to be admissible under ***Daubert*** standards. ***Dolin II,*** 2015 WL 7351678, at *2-7 *accord* ***Tucker v. SmithKline Beecham Corp.,*** 701 F. Supp. 2d 1040, 1056-66 (Hamilton, J.) (approving, under ***Daubert,*** the opinions of Drs. Healy and Glenmullen relating to paroxetine and suicidality).

The jury heard evidence of an analysis of placebo-controlled Paxil data, conducted by GSK, showing depressed patients of all ages given Paxil, as opposed to placebo, were 6.7 times more likely to engage in suicidal behavior and that the results were statistically significant. There was also testimony about data showing suicidal behavior in patients over 24 and under 65

as high as a 10-fold statistically significant increase in risk for that age group. The jury was also shown an analysis done by the FDA which showed a statistically significant 2.76 times increased risk for Paxil as opposed to placebo, across all psychiatric conditions among patients over 24. In addition to the placebo-controlled data, the jury saw analyses done on uncontrolled Paxil data in the 1980s (using GSK's and FDA's methodology at that time), which showed an 8.9-fold increase suicidality risk versus placebo.

It was shown that studies in support of the original new drug application included among major depressive disorder (MDD) patients 10 completed suicides. Five occurred among patients randomized to paroxetine; three randomized to tricyclic antidepressants. The remaining two completed suicides occurred in patients during the "washout" phase (a period when study patients are given no medication of any kind) before the study had actually begun. These two suicides should not have been assigned to any of the treatment groups, and there was no scientific justification for assigning them exclusively to the group of patients randomized to placebo.

The sponsor reported completed suicide in the Paxil-treated patients as 5/2963 (0.17%) and in placebo-treated patients as 2/554 (0.36%) making it appear as if the incidence of completed suicide in Paxil-treated patients was lower. The actual incidence in placebo-treated patients was 0/554 (0.0%), far lower than the 0.17% incidence in Paxil-treated patients.

The sponsor also misattributed two suicide attempts during the washout phase to the placebo-randomized group. Suicide attempts in the Paxil-treated patients was reported as 42/2963 (1.4%) and in the placebo group as 3/554 (0.54%) with an odds ratio of 2.6. The actual

data, removing the misattribution, is 42/2963 (1.4%) and 1/554 (0.18%) producing an odds ratio for Paxil compared to placebo of 7.8.

Dr. Martin Brecher, of GSK, admitted that attributing suicide or suicide attempts occurring during a wash-out phase to placebo-treated patients is improper.

Following approval of Paxil, GSK staff generated publications to show Paxil did not increase the risk of suicidal behavior in adults.

Dr. David Healy and Dr. David Ross stated, on behalf of the plaintiff, that all of the data, showing confidence intervals, odds ratio, and statistical significance figures together with suicidality incident reports, establish an undisclosed adult suicide risk for persons over 24 years of age taking paroxetine.

Dr. David Ross is board certified in internal medicine. Also, he has a Ph.D in biochemistry and a Master's degree in biomedical informatics. He was an examiner on the staff of the FDA serving as deputy director of the Office of Drug Evaluation at the FDA's Center for Drug Evaluation and Research. He is now Director of a public health program at the U.S. Department of Veterans Affairs. His testimony described FDA procedures and the inadequacy of the Paxil label.

Dr. Ross testified that, in his opinion, paroxetine is associated with an increased risk of suicidal behavior in adults relative to placebo. He stated that the risk is higher than other antidepressants; that it is not restricted to patients less than 25 years of age; that the drug sponsor was aware, since 1989, of the increased risk and aware since 2006 that the risk was not restricted to patients less than 25 years of age; that the 2010 label falsely stated that the risk was restricted to patients less than 25 years of age, and did not provide any information on Paxil-specific

related risks. He stated that GSK was not prevented from inserting adult suicide risk information in the label.

GSK submitted the testimony of a very qualified expert in statistics who discounted all past studies and incident reports that were not based on double-blind, randomized, dose controlled, timed data. Earlier studies and reports were rejected by him as essentially out of date and to be ignored in reaching any conclusions about paroxetine or Paxil. Based on his analysis of controlled data, he was of the opinion that it does not appear that paroxetine presents a risk of adult suicide. A difficulty with his opinion is that data he rejected were used by GSK in submissions to the medical community and to the FDA.

The adequacy of warnings is a question of fact for the jury in prescription drug cases unless the warning is plain, clear and unambiguous and the issue of label adequacy can be resolved as a matter of law. ***Kelso v. Bayer Corp.,*** 398 F.3d 640, 521 (7th Cir. 2005). This is not such a case. The jury was entitled to decide the whether or not the label warnings were adequate. There was sufficient evidence for the jury to conclude that the label was inadequate and misleading.

GSK contends that there was insufficient evidence to show a causal link between paroxetine and Mr. Dolin's death. Dr. Sachman's prescription for 30 Paxil tablets (10 mg per day) was filled by Mr. Dolin on June 27, 2010. An autopsy showed that paroxetine was in Mr. Dolin's system at the time of his death on July 15, 2010. (There was no evidence that the exact number of tablets taken by him was significant).

Plaintiff presented the testimony of Dr. David Healy on the subject of the suicide risk of Paxil and the testimony of Dr. Joseph Glenmullen, a board certified psychiatrist, who is a clinical instructor at the Harvard Medical School, on the topic of Mr. Dolin's death.

Dr. David Healy, a professor of psychiatry at Bangor University, United Kingdom, an expert in pharmacological psychiatric treatment and research, testified about mechanisms by which paroxetine induces suicidal behavior diagnosed as akathisia, emotional blunting and decompensation. It was shown that the *Diagnostic and Statistical Manual of Mental Disorders (*Fifth Edition, DSM-5) of the American Psychiatric Association defines Medication-Induced Acute Akathisia as follows:

> Subjective complaints of restlessness, often accompanied by observed excessive movements (e.g., fidgety movements of the legs, rocking from foot to foot, pacing, inability to sit or stand still), developing within a few weeks of starting or raising the dosage of a medication (such as a neuroleptic) or after reducing the dosage of a medication used to treat extrapyramidal symptoms.

Dr. Glenmullen testified that Mr. Dolin was suffering from paroxetine-induced akathisia which was the cause of his death. Dr. Glenmullen conducted a differential diagnosis of Mr. Dolin's symptoms and behavior during the last week of his life. A differential diagnosis is an accepted methodology for an expert to render an opinion about the identity of a specific ailment. ***Myers v. Illinois Cent. R. Co.,*** 629 F. 3d 639, 644 (7th Cir. 2010). The expert must provide a list of potential causes and determine which should be ruled in and ruled out. Dr. Glenmullen listed 13 potential causes of Mr. Dolin's death and went through each and concluded that death resulted from drug-induced akathisia caused by the ingestion of paroxetine.

Dr. Glenmullen stated that Mr. Dolin did not form an intent to kill himself, rather his death was a drug-induced reaction, a compulsion to kill himself—an accident and not voluntary suicide.

Dr. Glenmullen pointed to facts in Mr. Dolin's medical record and his conduct shortly before and at the time of his death to support his opinion. Paroxetine was prescribed and being taken by Mr. Dolin approximately six days before his death on July 15, 2010. In addition to being treated by Dr. Sachman, Mr. Dolin was consulting two therapists. There was testimony from his long-time therapist who saw him in an emergency session the night before his death. She stated that his anxiety was higher than she had ever seen before, and unlike previous times, it did not come down at the end of the session. Also, for the first time in her 30-year career, because of her concern, she called her client, Mr. Dolin, (the next morning, the day of his death) to advise him to get a prescription for a fast-acting sedative. Mr. Dolin left his office shortly after lunch and went to an L-station. A nurse, who was on the platform and saw Mr. Dolin jump in front of the train, stated that moments before his death he was nervously pacing back and forth. A partner in his firm testified that shortly before his death Mr. Dolin was acting differently and had difficulty processing simple legal issues. The lawyer did not think his death was work-related.

GSK argued that Mr. Dolin's death was a voluntary act caused by a history of depression, the pressures of the practice of law in an international firm and family problems. Medical record evidence was presented including that, in the past, Mr. Dolin had taken Paxil and another SSRI for depression without any adverse incident. Financial and business data were

presented to show professional and practice pressures experienced by Mr. Dolin who was also grieving the loss of family members.

Dr. Anthony Rothschild, a psychiatrist on the faculty of the University of Massachusetts, testified in support of his opinion that Mr. Dolin's death was not due to drug-induced akathisia. He focused on Mr. Dolin's medical history and stated that his voluntary suicide was related to depression brought about by professional and family problems. Dr. Rothschild cited statistics showing the high level of suicides among the lawyer population.

Dr. Rothschild stated that it was his opinion that Mr. Dolin's suicide was not caused by paroxetine. His study of the drug does not show that it can cause suicide. Instead, in his opinion, Mr. Dolin's suicide was caused by his anxiety disorder, possible major depressive disorder, longstanding fears and feelings of inadequacy and inferiority despite apparent outward success. Multiple life stressors, including harsh criticism of Mr. Dolin at work by some of his colleagues, a significant decrease in his performance as group practice leader and a reduction in billable hours, were factors. A decrease in budgeted compensation, difficulties with clients and feeling disconnected from his wife were noted. Dr. Rothschild stated that Mr. Dolin was receiving disorganized mental health treatment from health care providers who did not communicate.

Both sides presented evidence from which the jury could have found for the plaintiff or the defendant on the issue of the cause of death. There is, however, no basis to set aside a jury's finding that Mr. Dolin's death was caused by ingestion of paroxetine.

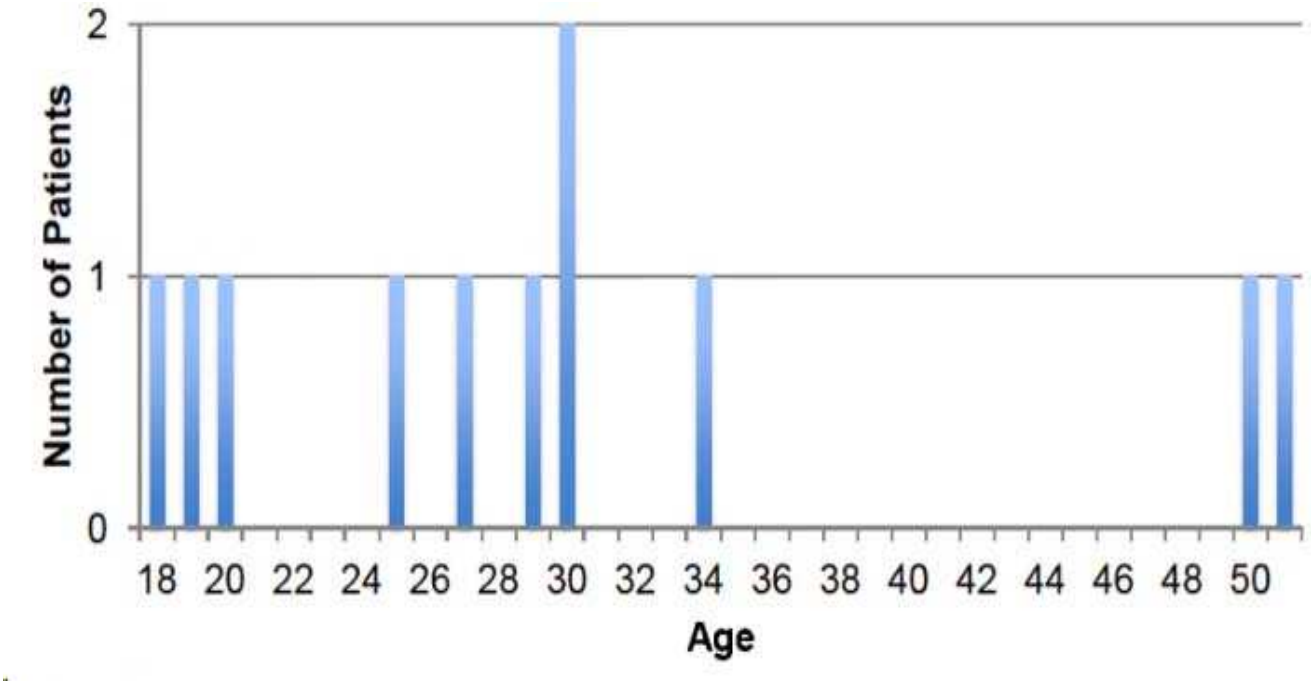
The issue of preemption was presented both factually and legally by GSK. The factual argument is premised on the claim that certain language it proposed to add to the label in 2007 was not permitted by the FDA. Plaintiff responded that the proposed language was inadequate and misleading and that GSK did not prove that the FDA would have refused to permit a warning of the risk of adult suicide. The proposed language is as follows:

> 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 disorder 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 ≥65 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 1/1978 [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 population across psychiatric disorders may extend beyond the age of 24.

Dr. David Ross addressed the proposed language. He stated that it was misleading with respect to the eleven patients referred to in the proposed language. The eleven paroxetine-treated patients who attempted suicide ranged in age from 18 to 51. The distribution of ages did not show any skewing towards younger or older patients. The median age was 29 years. Half the patients were younger than 29 and 50% were older. Only three were under 24. The mean age of these patients (30 years) is similar to the median age. The data do not provide a basis for concluding that the Paxil-associated increase in suicide attempt risk is restricted to any particular range of age. The sponsor chose to do that in stating that 8/11 of the patients were under 30 (not

24) or younger, implying that an increased risk of suicidal behavior was restricted to this younger group. The choice of an age cutoff of 30 was completely arbitrary. Eight of the eleven of the patients were 25 or older. The data do not support the conclusion that the increased risk associated with Paxil is restricted to any group or to those under 24 as claimed in statements made to the medical community and in a proposed label change submitted to the FDA. The data is shown in the following Figure.

Distribution of ages of paroxetine-treated patients with suicide attempts



In Dr. Ross's opinion, the FDA would not have refused to permit GSK to warn about the risk of adult suicide in the label. He stated that GSK should have included a short statement warning of the risk of adult suicide.

Assuming, however, that the language proposed was sufficient, it does not appear that there is "clear evidence" that the FDA would have refused to permit GSK to add a warning of a

risk of adult suicide. "Clear evidence" is required by ***Wyeth*** to prove preemption**.** The FDA informed GSK that product specific language should not be included in the class labeling revision required for the SSRI class of drugs. The FDA stated that "[i]f you would like to discuss this matter further, please submit a formal meeting request." However, GSK never requested a meeting or took any other action to include a Paxil-specific warning outside of the class warning. There is not clear evidence that the FDA would have rejected a Paxil-specific warning outside of the class warning. *Accord* ***Forst v. SmithKline Beecham Corp.,*** 639 F. Supp. 2d 948, 954 (E.D. Wis. 2009).

GSK argues that plaintiff did not prove that the paroxetine taken by Mr. Dolin was bioequivalent of Paxil. The absence of proof of a bioequivalent drug was never an issue in this case. Nevertheless there was testimony from Dr. Healy that paroxetine is Paxil. Also, a generic drug must be approved by the FDA. *See* ***Mut. Pharm. Co., Inc. v. Bartlett,*** 133 S. Ct. 2466, 2471 (2013) (a generic drug to be approved must be "chemically equivalent to the approved brand-name drug: it must have the same 'active ingredient' or 'active ingredients,' 'route of administration,' 'dosage form,' and 'strength' as its brand-name counter-part") (quoting 21 U.S.C. § 355(j)(2)-(8)).

When a fact issue has not been raised before trial, an absence of proof contention can be met, as here, with a prima facie showing of evidence, as appears in this record. There was no failure of proof that the paroxetine taken by Mr. Dolin was the bioequivalent of Paxil.

Judge Zagel rejected the legal argument that GSK cannot be held liable for negligence relating to the Paxil label. ***Dolin I,*** 62 F. Supp. 3d at 713. His careful analysis of the cases will not be repeated. It is proper to observe, however, that since that ruling, the Court of Appeals for the Sixth Circuit has disagreed with this court's interpretation of Illinois negligence law saying "we predict that the Illinois Supreme Court would not recognize brand manufacturers owed generic consumers a duty that can give rise to liability." ***In re Darvocet. Darvon, and Propoxyphene Prods. Liab. Litig.,*** 756 F. 3d 917, 944 (6th Cir. 2014).

The ***Darvocet*** court did not answer the points that liability in this case is based, not on the sale of the drug or drug chemistry, but on GSK's responsibility for the content of the label; that the generic supplier (Mylan) cannot be held liable for the content of the label; and that a jury has found negligence in failing to provide adequate label warning of the risk of adult suicide. Also, in this case, GSK's history of misconduct with this drug by failing to warn and providing false information to consumers and the FDA are factors which militate against providing label immunity based solely on the fact that a generic product was substituted for the prescription of Paxil because Illinois law permitted a druggist to substitute a possible lower cost identical product.

Turning next to the motion for a new trial, GSK argues that the jury instructions were improper; plaintiff's experts testified to undisclosed opinions; the court improperly limited cross-examination and the court permitted improper rebuttal testimony.

The trial of this case required the jury's attention for weeks of expert testimony relating to technical issues. The volume of testimony, exhibits and extensive arguments threatened jury

overload and confusion. The jury instructions, based on familiar Illinois negligence law, were designed to frame the issues without adding to the jury's burden. GSK's proposed additional instructions were, for the most part, unnecessary.

GSK attacks the Contentions instruction. The instruction tracked the allegations of the First Amended Complaint relating to the risk of paroxetine-induced suicide of persons over 24 years of age, inaccurate data and withheld data. GSK's additions and modifications to reflect its positions and contentions were accepted. The Contentions instruction was given together with negligence instructions. As reflected in Illinois Pattern Jury Instructions ("IPI") a plaintiff must allege facts establishing a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach. Illinois Pattern Instructions are presumed to accurately set forth Illinois law. ***Tragarz v. Keene Corp.,*** 980 F.2d 411, 423 (7th Cir. 1992). The jury was instructed to find that one or more of the acts claimed was "negligence" and also that the negligence was a "proximate cause "of injury.

The Causation instruction was improper according to GSK. The instruction given is the verbatim IPI instruction. IPI 15.01. The Seventh Circuit has found that the IPI instructions on proximate cause set forth Illinois law. ***Tragarz,*** 980 F.2d at 423.

GSK proposed instructions explaining distinctions between "cause-in-fact" and "legal cause" that were unnecessary and likely to cause confusion. This instruction was also said by GSK to be necessary to explain a voluntary suicide instruction proposed. That instruction contained argument and did not explain that voluntary suicide following a tortious act only breaks a chain if it appears that the suicide could not be foreseen. This is not such a case. Moreover, Dr. Glenmullen described Mr. Dolin's death as an accident—the result of drug-

induced akathisia—not voluntary suicide. Although these instructions were refused, GSK was allowed to argue that Mr. Dolin's death resulted from voluntary suicide.

The "Defendant's Duty" instruction was based on ***Wyeth,*** 555 U. S. at 570 and FDA regulations. The last paragraph of the instruction informed the jury that it could consider to compliance with FDA regulations as a defense factor. Also, in recognition of the learned intermediary doctrine, the "Duty to Warn" instruction states that defendant had a duty to warn only the attending physician of risks.

GSK's argument that the jury was misled into believing that GSK manufactured the paroxetine ingested by Mr. Dolin is contrary to the record. The court and the parties made the distinction clear.

Other instructions proposed by GSK (Duty to Warn of Risks, How to Assess the Adequacy of the Warning, Not to Infer Fault, Liability if Dr. Sachman Knew, Spoliation, Judicial Admissions, Another Manufacturer's Product, and Preemption) were unnecessary and very argumentative. The parties were permitted full opening and final arguments which included references to many demonstrative exhibits. GSK's defense was fully explored before the jury.

It is claimed that the court committed error by allowing plaintiff's experts to testify to opinions or matters that were not previously disclosed in discovery (i.e., Dr. Ross's testimony on the subjects of what can be included in a label, the effects of akathisia, and about documents not produced at his deposition, [but later appeared on an exhibit list]; Dr. Healy's testimony about suicide signals and GSK's failure to disclose data). Plaintiff's experts provided detailed reports and gave lengthy depositions. Defendant's experts responded in detail. The issues tried in this

case have been the subject of previous litigation presented by some of the same attorneys, some of the same experts and included in many of the same documents. Surprise was not a factor in this case.

GSK states that the court improperly limited its case in the following ways: excluding two additional experts from testifying about suicide statistics; excluding the testimony of an expert on the nature of international law firms; refusing cross-examination of expert witnesses concerning fees paid to them in other cases; refusing cross-examination in order to show bias of Dr. Healy about his research and views with respect to drugs other than Paxil.

Dr. Rothschild and Dr. Gibbons testified on the subject of suicide rates. One study relating to suicide rates in the military population was excluded as being outside the issues in this case. Additional suicide statistical studies would not have assisted the jury.

There was direct testimony from several lawyers in Mr. Dolin's law firm about structure and management. The jury would not have been helped by hearing an expert on law firm structure, procedures and stressors. The topics were extensively covered by several law firm witnesses.

Plaintiff was allowed to recall Dr. Healy in rebuttal over the objection of the defendant. His testimony was in response to testimony given by Dr. Rothschild, Dr. Gibbons and Dr. Kraus during the defense case. It was not on new topics or simply repetitious. The rebuttal was not improper.

Defendant's motion for a new trial will be denied.

IT IS THEREFORE ORDERED AS FOLLOWS:

(1) Defendant's motions for judgment as a matter of law (Dkt. 560 and 561) and its alternative motion for a new trial (Dkt. 576) are each denied.

(2) The clerk of the court will enter judgment on the jury's verdict in favor of plaintiff Wendy Dolin, individually and as Executor of the Estate of Stewart Dolin, deceased, and against defendant GlaxoSmithKline LLC in the amount of $3,000,000 together with costs of suit.

(3) Plaintiff may apply for costs of suit within 14 days. Any cost issues will be resolved in accordance with the local rules.

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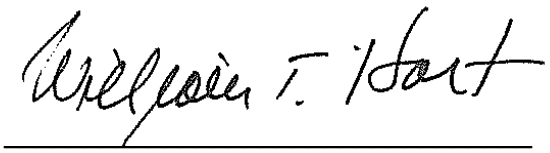

UNITED STATES DISTRICT JUDGE

Dated: SEPTEMBER 14, 2017