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

MAHASUKH K. SHAH, individually and as Special Administrator of the estate of Manan H. Shah, Deceased,	)	
Plaintiff,	)	
v.	)	**No. 10 C 8163**
FOREST LABORATORIES, INC., et al.	)	
Defendants.	)	

MEMORANDUM OPINION

SAMUEL DER-YEGHIAYAN, District Judge

This matter is before the court on Defendants' motion for summary judgment, Defendants' motions to exclude the testimony of Plaintiff's expert Dr. Michael Hamrell (Hamrell) and the testimony of Plaintiff's expert Dr. Henry Conroe (Conroe), and on Plaintiff's motion to strike. For the reasons stated below, the motion for summary judgment is granted, the motion to exclude the testimony of Hamrell is granted, the motion to exclude the testimony of Conroe is denied, and Plaintiff's motion to strike is denied as moot.

BACKGROUND

On December 1, 2008, Manan M. Shah (Shah) at age 27 allegedly saw

psychiatrist Susan Bank (Bank) for depression and anxiety and was prescribed the drug Lexapro. Taking the Lexapro allegedly caused Shah to suffer increased depression and suicidal thoughts, and on December 7, 2008, Shah committed suicide. Plaintiff contends that Defendants failed to adequately warn Shah about the increased risk of suicide that he faced at age 27 when taking Lexapro. Defendants also point to evidence showing that Shah, who had an Indian cultural heritage, faced an expectation that he would excel academically and professionally, and an expectation that as the youngest son he would financially take care of his parents in their old age. Defendants also contend that there is evidence showing that Shah had been depressed and suffered anxiety for a significant period of time prior to his taking Lexapro due to his perceived lack of success academically and financially. Defendants further contend that evidence shows that Shah had been researching ways to commit suicide before he began taking Lexapro. In addition, Defendants argue that Shah was warned both orally and in writing regarding the increased risk of suicide when he was prescribed Lexapro.

Plaintiff Mahasukh K. Shah, brings claims individually and as the Special Administrator of the estate of Shah. Plaintiff includes in the complaint a wrongful death negligence claim (Count I), a wrongful death strict product liability claim (Count II), a wrongful death breach of express warranty claim (Count III), a wrongful death breach of implied warranty claim (Count IV), a wrongful death negligent misrepresentation claim (Count V), a survival negligence claim (VII), a survival strict product liability claim (Count VIII), a survival breach of express

warranty claim (Count IX), a survival breach of implied warranty claim (Count X), a survival negligent misrepresentation claim (Count XI), and a respondent in discovery claim (Count XII). The court notes that there is no "Count VI" listed in the complaint and the omission of such a count designation appears to have been an inadvertent omission on Plaintiff's part. The instant action was conditionally transferred to the Eastern District of Missouri as part of multi-district litigation (MDL) for certain pretrial proceedings, and was subsequently transferred back to this court. Defendants now move for summary judgment, and move to exclude the testimony of two of Plaintiff's proposed experts. Plaintiff has moved to strike certain substantive testimony of one of Defendants' witnesses.

LEGAL STANDARD

Summary judgment is appropriate when the record, viewed in the light most favorable to the non-moving party, reveals that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Smith v. Hope School*, 560 F.3d 694, 699 (7th Cir. 2009). A "genuine issue" of material fact in the context of a motion for summary judgment is not simply a "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, a genuine issue of material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Insolia v. Philip Morris, Inc.*, 216 F.3d 596, 599 (7th Cir. 2000). In

ruling on a motion for summary judgment, the court must consider the record as a whole, in the light most favorable to the non-moving party, and draw all reasonable inferences in favor of the non-moving party. *Anderson*, 477 U.S. at 255; *Bay v. Cassens Transport Co.*, 212 F.3d 969, 972 (7th Cir. 2000).

DISCUSSION

Since the instant action is before the court based on diversity subject matter jurisdiction and this court sits in the state of Illinois, the court applies the substantive law of the state of Illinois. *See Hahn v. Walsh*, 762 F.3d 617, 629 (7th Cir. 2014)(stating that "the Erie doctrine provides that 'federal courts sitting in diversity apply state substantive law and federal procedural law'")(quoting *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996)).

I. Motions to Exclude and Strike

Defendants move to exclude certain testimony by Plaintiff's experts, and Plaintiff moves to strike changes to a deposition transcript by a witness of Defendants.

A. Defendants' Motions to Exclude Testimony of Hamrell and Conroe

Defendants move to exclude certain expert testimony of Hamrell and Conroe. Federal Rule of Evidence 702 provides the following:

A witness who is qualified as an expert by knowledge, skill, experience,

> training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Before admitting expert testimony, a court must conduct an analysis in accordance with the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Stuhlmacher v. Home Depot U.S.A., Inc.*, 774 F.3d 405, 409 (7th Cir. 2014). Under the *Daubert* analysis, a court must "determine whether the testimony is reliable and whether it will assist the trier of fact in determining some fact that is at issue." *Id.* (explaining that "the district court serves as a 'gatekeeper' whose role is to ensure that an expert's testimony is reliable and relevant"). The court must also determine whether the expert is qualified. *See Myers v. Illinois Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010)(explaining that "[u]nder Federal Rule of Evidence 702 and *Daubert*, the district court must engage in a three-step analysis before admitting expert testimony" and "[i]t must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue")(internal quotations omitted)(quoting *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007)).

1. Motion to Strike Testimony of Hamrell

Defendants move to strike the supplemental report prepared by Hamrell and certain testimony from his deposition. Hamrell was designated in the MDL proceedings to offer opinions regarding Lexapro's labeling. (RSF Par. 18). Hamrell wrote an expert report for the MDL, dated December 17, 2011, in which he assessed the adequacy of warnings during certain time periods for Lexapro and the drug Celexa. (Ham. Rep. 1). Although Hamrell addressed perceived inadequacies in warnings prior to 2005, he did not make findings relating to 2008 when Shah was prescribed Lexapro. (Ham. Rep. 4, 21). At his deposition, Hamrell conceded that the warnings provided in the package insert and medication guide for Lexapro in 2008, when Shah was prescribed the drug, were adequate. (RSF Par. 18-19); (4/12/12 Ham Dep. 50). After this action was transferred back to this court from the MDL, Plaintiff asked Hamrell to review a Lexapro brochure, dated October 2005 (Brochure) that was found in Shah's personal effects after his suicide. (Ham. Sup. Rep. 1). Hamrell then filed a supplemental report, dated October 3, 2014, in which he concluded that the warning section in the Brochure was "inadequate and out-of-date in comparison to what was required by the FDA in the current approved labeling for Lexapro concerning SSRI warnings when it came into the possession of Manan Shah at or about the time he was prescribed Lexapro by Dr. Susan Bank, M.D. on December 1, 2008." (Ham. Sup. Rep. 1).

Hamrell's opinion in his supplemental report can be stricken at the outset because it is untimely. An order issued by the MDL court specifically stated: "*Daubert* briefing on both general causation and warning experts has been

completed." (7/26/13 MDL 8). The MDL court further stated: "The experts the parties intend to rely upon in relation to general causation and warnings should be limited to those experts identified by the parties in these proceedings absent a compelling request." (7/26/13 MDL 8). After an opportunity to conduct expert discovery in the MDL proceedings, and after this case was transferred back to this court, Plaintiff attempted to conduct further expert discovery and gain an opinion from Hamrell, an expert on warning issues, that would rectify the deficiencies in his opinion given at the MDL as it applied to Plaintiff's case. Plaintiff made no compelling request to the MDL court or this court for permission to conduct additional expert discovery. Plaintiff argues that he was allowed by Defendants to conduct expert discovery and that Defendants cannot now object to the new expert opinion. Plaintiff essentially argues that he has already conducted his expert discovery and that it is too late to stop Plaintiff from presenting his new expert opinion at this juncture. However, this court never authorized expert discovery after the transfer back from the MDL proceedings. Nor did Plaintiff even seek leave for such expert discovery. Even if Defendants had not opposed the discovery, the parties cannot dictate the management of these proceedings. The judicial economy gained from the MDL proceedings would be nullified if parties could covertly restart expert discovery after the MDL proceedings to attempt to undo what was done in such proceedings. Plaintiff was given clear warnings that his opportunity to conduct expert discovery had ended. Thus, Hamrell's opinion is untimely.

Even if Hamrell's opinion was timely, the court notes that in his supplemental

report, Hamrell makes several factual and legal conclusions that are based on pure speculation on his part and are beyond the scope of any expertise, even if this court were to admit him to testify as an expert. For example, Hamrell provides no support for his factual conclusions that Shah actually read the Brochure or that the Brochure was procured from Bank's office. Hamrell states that "[t]he inadequacy and incomplete warning contained in [the Brochure] was a substantial cause and contributing factor in the suicide death of" Shah. (Ham. Sup. Rep. 1). Again, Hamrell's conclusion reaches far beyond any supporting facts and offers nothing more than speculation as to whether Shah had even read the Brochure. Thus, Hamrell fails to build a logical bridge of reasoning as to how he could opine with such certainty that the Brochure caused Shah to commit suicide. Hamrell further opined at his deposition, on matters not even included in his supplemental report, his belief that Defendants should have taken the Brochure out of Bank's office. (11/25/14 Ham. Dep. 49). Hamrell failed to show any expertise that would have allowed him to make such a conclusion regarding the duty of Defendants to remove documents from Bank's office.

Defendants also correctly point out that although Hamrell opines that the warnings in the Brochure are inadequate, Hamrell fails to sufficiently explain how the Brochure was incomplete or inadequate or show that his conclusions were based on any reliable methodology. For example, Hamrell was asked about the current warnings that are sometimes referred to as the "black box." (11/25/14 Ham. Rep. 24). Hamrell testified at his deposition that the Brochure was inadequate because it

lacked the information from the warning in the black box. (11/25/14 Ham. Rep. 24). However, when asked at his deposition: "Are you able to tell me what information is in the black box that is not actually in the brochure?," Hamrell responded: "No." (11/25/14 Ham. Rep. 24). Hamrell was then asked if he ever compared the warnings in the Brochure with the black box, and Hamrell could not recall whether he did so or not. (11/25/14 Ham. Rep. 24). Hamrell's statement in his supplemental report that he reviewed a list of documents is not sufficient to build a bridge between such documents and his conclusory statements provided in his supplemental report as to the inadequate warnings in the Brochure. (Ham. Sup. Rep. 1). Hamrell thus speculates as to key facts in this case outside the scope of his expertise and fails to provide a sufficient basis to support his conclusory statements as to causation. Simply because Hamrell seeks to serve as an expert does not mean that he is free to offer his speculation and legal opinions to the jury on any topic. The court finds that Hamrell's testimony would not assist the trier of fact and would actually confuse and mislead the trier of fact in this case. Therefore, the motion to exclude the testimony of Hamrell is granted. The court also notes that even if the court denied the motion to exclude Hamrell's testimony, it would not alter the ultimate result in regard to the motion for summary judgment.

2. Motion to Strike Testimony of Conroe

Defendants also move to strike the testimony of Conroe. Conroe provides an opinion as to specific causation and concludes in his report that it was more likely

than not that Lexapro caused Shah to commit suicide. (Con. Rep. 1). Plaintiff has shown Conroe to have the qualifications to serve as an expert. Conroe indicates that he has practiced psychiatry for over 30 years, is licensed to practice medicine in Illinois, has a full-time psychiatric practice in which he prescribes selective serotonin reuptake inhibitor (SSRI) antidepressants, is a clinical assistant professor of psychiatry at Rush Medical College, is a Fellow, and has a peer-reviewed publication. Defendants contend that Conroe's testimony is not admissible, arguing that Conroe's opinion is not compatible with the opinion of Plaintiff's expert Dr. David Healy (Healy), and that Conroe's opinion is not based on a reliable methodology.

a. Fit with Healy's Opinion

Defendants argue that Conroe's specific causation opinion does not fit with Healy's general causation opinion. General causation involves the determination of "whether a particular agent can cause a particular illness," and "[s]pecific causation addresses whether that agent in fact caused the particular plaintiff's illness." *Aurand v. Norfolk Southern Ry. Co.*, 802 F. Supp.2d 950, 953 (N.D. Ind. 2011). The parties agree that as to general causation, Healy opined that Lexapro causes suicide via three mechanisms: (1) akathisia, (2) emotional blunting, or (3) psychotic decompensation. (Mem. C. Excl. 7); (Ans. C. Excl. 4). Defendants argue that Conroe made clear that he cannot demonstrate that any of those mechanisms resulted in Shah's suicide.

Conroe concluded that Shah met the criteria for psychotic decompensation.

(Con. Dep. 38). Conroe also concluded that the psychotic decompensation was present on the day of Shah's suicide. (Con. Dep. 38). Conroe also provided a detailed explanation as the basis for his conclusions. (Con. Dep. 35-41); (Con. Rep. 3-5). Defendants criticize Conroe's reasoning and accuse him of speculating, but Defendants have not shown that Conroe's opinion should be excluded. Although Defendants disagree as to Conroe's conclusion, that argument relates to the weight that should be given to the opinion, not to its admissibility.

b. Methodology

Defendants also argue that Conroe's opinion is the result of an unreliable methodology. Conroe indicates that he applied a differential diagnosis for his opinion. The Seventh Circuit has acknowledged that "[d]ifferential diagnosis," which when dealing with the cause of an ailment could also be referred to as "differential etiology," is an accepted methodology for experts if the expert's methodology satisfies the reliability requirement of *Daubert* and the expert "faithfully appl[ies] the method to the facts at hand." *Brown v. Burlington Northern Santa Fe Ry. Co.*, 765 F.3d 765, 772 (7th Cir. 2014); *see also Ervin*, 492 F.3d at 904 (stating that "[a] differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods" and "[u]nder *Daubert*, expert opinions employing differential diagnosis must be based on scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out'"). The methodology used by Conroe is one that has been recognized by the Seventh Circuit. *Id.* Defendants criticize Conroe's

reasoning and accuse him of speculation, but again Defendants' arguments would be more appropriate when made as to the weight to be given to the opinion, not as to its admissibility. Conroe has shown that his methodology and analysis are sufficiently reliable. Based on all of the above, Defendants' motion to exclude the testimony of Conroe is denied. This court is making no finding that it agrees with Conroe's opinion or that it is accurate. The court merely is finding that Plaintiff has shown that Conroe's testimony should be admitted for consideration in ruling on the instant motion for summary judgment.

B. Motion to Strike Changes in Deposition

Plaintiff moves to strike proposed changes to the deposition transcript of Ryan Repta (Repta). Plaintiff contends that Repta cannot make substantive changes to his deposition testimony at this juncture. Repta's testimony has no material bearing on the issues discussed below. Therefore, the motion to strike is denied as moot.

II. Strict Liability and Negligence Claims

Defendants move for summary judgment on Plaintiff's strict liability and negligence claims. For a strict liability claim brought under Illinois law, a plaintiff must show: (1) "that the injury resulted from a condition of the product," (2) "that the condition was an unreasonably dangerous one," and (3) "that the condition existed at the time the product left the manufacturer's control." *Hernandez v. Schering Corp.*, 958 N.E.2d 447, 454 (Ill. App. Ct. 2011). A product can be deemed to be

"unreasonably dangerous because of the manufacturer's "failure to warn of [a] danger or instruct on the proper use of the product as to which the average consumer would not be aware." *Id.* (internal quotations omitted)(quoting *Sollami v. Eaton*, 772 N.E.2d 215 (Ill. 2002). For a negligence claim brought under Illinois law, the plaintiff must "establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012)(internal quotations omitted)(quoting *Marshall v. Burger King Corp.*, 856 N.E.2d 1048 (Ill. 2006)). A product manufacturer "has a duty to warn where the product possesses dangerous propensities and there is unequal knowledge with respect to the risk of harm, and the manufacturer or distributor, possessed of such knowledge, knows or should know that harm may occur absent a warning." *Solis v. BASF Corp.*, 979 N.E.2d 419, 443 (Ill. App. Ct. 2012).

A. Basis for Strict Liability and Negligence Claims

Plaintiff acknowledges that his strict liability and negligence claims are mainly premised on an alleged failure by Defendants to warn of increased suicidality in young adults. (RSF Par. 4). Plaintiff asserts that the only other basis for his strict liability and negligence claims is his contention that Lexapro is defective as a result of its creating a greater risk of activating treatment-induced suicidality. (RSF Par. 4). However, as Defendants correctly point out, Plaintiff has failed to provide arguments or point to sufficient evidence showing that Lexapro is inherently dangerous based

on its design. Defendants also correctly point out that even if Plaintiff were to pursue such a theory, the claim would be preempted by federal law. (Mem. SJ. 5, n.1). Plaintiff also failed to put forth arguments as to any unreasonable danger in taking Lexapro that could not be addressed with adequate warnings. Plaintiff relies on expert opinions as to the risks associated with taking Lexapro and the need to warn patients of such risks. (SAF Par. 33).

B. Learned Intermediary Doctrine

Defendants argue that they are entitled to summary judgment based on the learned intermediary doctrine. In *Kirk v. Michael Reese Hospital & Medical Center*, 513 N.E.2d 387 (Ill. 1987), the Illinois Supreme Court adopted the learned intermediary doctrine. *Id.* at 394-97; *see also Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 784 (Ill. App. Ct. 2006) (explaining that "[i]n *Kirk* . . .the learned intermediary doctrine was adopted by our supreme court"). Under the learned intermediary doctrine, "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." *Kennedy*, 851 N.E.2d at 784 (internal quotations omitted)(quoting *Kirk*, 513 N.E.2d at 387). The underlying basis for the doctrine "is that a doctor is considered in the best position to prescribe drugs and monitor their use because he is knowledgeable of the propensities of the drugs he is prescribing and the susceptibilities of his patient." *Id.* Thus, under the learned intermediary doctrine, "in

selling prescription drugs, the manufacturer is only required to warn the prescribing doctor, who then acts as a 'learned intermediary' between the manufacturer and the consumer." *Id.*

In the instant action, Defendants argue that they owed a duty to Bank, not to Shah, to provide warnings regarding the risks associated with taking Lexapro. Bank testified at her deposition that in 2008 she was aware of the increased risks relating to suicide by young people. (Bank Dep. 64, 67). Bank testified that she was informed of the newly discovered risks that were associated with Lexapro "*ad nauseam* at events," and that representatives of Defendants would have met with her to discuss the necessary warnings with her. (Bank Dep. 53). Plaintiff has failed to point to evidence showing that Defendants were in any way deficient in their efforts to inform Bank regarding the risks associated with Lexapro and provide Bank with updated warnings. Thus, the undisputed facts show that Defendants did all that was required to adequately inform the physician, Bank, regarding the risks associated with taking Lexapro, and Defendants are entitled to protection under the learned intermediary doctrine.

Plaintiff argues that other courts have found that the learned intermediary doctrine does not apply where pharmaceutical companies directly advertise their products to consumers or where a physician is compensated by a drug manufacturer. Plaintiffs cite to various state court decisions, such as decisions in New Jersey and West Virginia, but fail to cite to any Illinois state or federal courts that have adopted such a position. (Ans. SJ 10-11). Such cases are not controlling precedent and the

learned intermediary doctrine that has developed under the Illinois common law is separate and district from the doctrine that has been developed under the New Jersey common law. Plaintiff asks this court to recognize this exception under Illinois law. (Ans. SJ 9). This court declines to alter the Illinois common law in such a manner that could effectively allow the exceptions to swallow the rule, particularly since the Illinois Supreme Court made no indication that the doctrine as it stands under Illinois state law would contain such exceptions. Plaintiff argues that, based on modern trends in the practices of pharmaceutical companies, such exceptions may now be warranted. However, the learned intermediary doctrine and the duty to inform physicians have been before the Illinois Appellate Court in the last several years, and the doctrine has been upheld and no exceptions to the doctrine based on developments in the pharmaceutical industry were contemplated by the court. *See, e.g., DiGiovanni v. Albertson's, Inc.*, 940 N.E.2d 73, 75 (Ill. App. Ct. 2010). Nor is Plaintiff's rationale for altering the doctrine applicable under the facts of this case. Plaintiff contends that pharmaceutical companies that advertise directly to consumers should bear the responsibility of providing the necessary warnings directly to consumers. However, in the instant action, there is no evidence presented by Plaintiff that Shah observed any Lexapro advertising. *See Hernandez,* 958 N.E.2d at 454-55 (declining to even consider recognizing exception because the case did "not involve direct-to-consumer advertising" and there was no evidence that the patient had heard of drug prior to it being prescribed). Rather the undisputed facts show that he was examined by Bank and that Bank decided in her professional capacity to

prescribe Lexapro.

Plaintiff also contends that physicians who received compensation from pharmaceutical companies cannot be trusted to be objective and provide warnings. In the instant action, however, there is no evidence that shows that Bank failed to provide the necessary warnings to Shah or that Bank was in any way biased or her judgment was questionable based on any compensation that she received from a pharmaceutical company. Thus, the court declines to make such sweeping changes to the learned intermediary doctrine as proposed by Plaintiff. Under the learned intermediary doctrine, Defendants were obligated to properly convey to physicians the necessary information concerning the risks associated with Lexapro. The undisputed facts show that Defendants met their obligations in every regard when dealing with Bank. Therefore, Defendants are entitled to summary judgment in this case.

C. Warnings Provided to Shah

Defendants argue that even if the learned intermediary doctrine did not apply, the package insert and medication guide that Shah received when getting his prescription for Lexapro filled was adequate as a matter of law to warn Shah of the risk of harm.

1. Adequacy of Package Insert and Medication Guide

It is undisputed that at the time that Shah got his Lexapro prescription filled in

2008 the package inserts for Lexapro contained medication guides with the following boxed warning:

> 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 Lexapro 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 toplacebo 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. Lexapro is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use).

(RSF Par. 17). It is further undisputed that at the time that Shah got his Lexapro prescription filled in 2008 the "Warnings" section of the package inserts for Lexapro contained medication guides with the following:

> WARNINGS-Clinical Worsening and Suicide Risk 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 age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.

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 4400 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 1000 patients treated) are provided in Table 1.

[TABLE 1] (omitted)

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 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 depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's 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 Lexapro, for a description of the risks of discontinuation of Lexapro). 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, 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 health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Celexa should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

(RSF Par. 17). Plaintiff has not presented any evidence indicating that the package insert and medication guides that would have been included in the package that he received would have contained any language other than the above language. It is also undisputed that the above-language was included in the package inserts and medication guides based on the federal Food and Drug Administration's (FDA)

findings and advice and that Defendants' supplemental New Drug Application incorporating the new warnings were approved by the FDA on August 2, 2007. (RSF Par. 14-17). Plaintiff cites to no expert testimony, other evidence or law showing that the warnings that were included in the package inserts and medication guides for Lexapro in 2008 were inadequate at that time. Plaintiff has thus failed to satisfy his burden of proof on this point.

2. Receipt of Insert and Medication Guide

Plaintiffs argue that Shah may not have actually received the insert and medication guide with his Lexapro prescription. However, Defendants have presented evidence showing the contents of the insert and medication guide in effect in 2008 and to evidence showing that in the ordinary course of business the insert and medication guide would have been provided to Shah along with his prescription. Plaintiff, on the other hand, has not pointed to a shred of evidence suggesting that Shah did not receive the insert and medication guide. Plaintiff merely argues that "there is no record evidence to show that those items were received by" Shah. (RSF Par. 17). Thus, Defendant has presented evidence showing that absent some extraordinary circumstances, Shah would have been provided the insert and medication guide. It is undisputed that federal law requires a pharmacy to include an approved current medication guide with any prescription. (RSF Par. 42). Plaintiff seeks to have the trier of fact speculate in the absence of evidence that Shah never received the insert and medication guide. Plaintiff is required at this juncture to point

to sufficient evidence to proceed to trial and has failed to do so on this point. *See Olendzki v. Rossi*, 765 F.3d 742, 749 (7th Cir. 2014)(stating that "[a]t the summary judgment stage of a proceeding, a plaintiff must 'put up or shut up' and 'show what evidence [he] has that would convince a trier of fact to accept [his] version of events'")(quoting *Steen v. Myers*, 486 F.3d 1017, 1022 (7th Cir. 2007)). Thus, no reasonable trier of fact could conclude other than that Shah received the insert and medication guide that was in effect in 2008.

3. Brochure

Plaintiff contends that the Brochure contained warnings that were outdated and that the warnings in the Brochure were inadequate to warn Shah of the risks he faced when taking Lexapro. (Ham. Sup. Rep. 1). However, as Defendants correctly point out, there is absolutely no evidence that Shah ever read the Brochure. Plaintiff cannot in the absence of any evidence proceed to trial and ask the trier of fact to speculate that Shah read the Brochure. *See Perez v. Thorntons, Inc.*, 731 F.3d 699, 716 (7th Cir. 2013)(indicating that a plaintiff cannot ask a jury to "guess or speculate" as to facts and that "guesswork and speculation are not enough to avoid summary judgment"). Plaintiff offers nothing other than speculation to support the assertion that the Brochure even came from Bank's office. Bank acknowledged at her deposition that the Brochure could have come from her office, but failed to indicate that she was doing anything other than guessing. (Bank Dep. 58-59).

Even if Plaintiff had found some evidence linking the Brochure to Bank's

office, Plaintiff has failed to show that Defendants had an obligation to remove the Brochure from Bank's office. Bank testified unequivocally that she did not give the Brochure to Shah. (Bank Dep. 59). Bank testified that she left such brochures laying around in areas where patients could possibly pick them up on their own. (Bank Dep. 59). Bank testified that if Shah took the Brochure from her office, "he took [the Brochure] on his own." (Bank Dep. 62). The record also indicates that Bank's procedure for removing outdated materials from her office was far from exhaustive. Bank testified that if she "happen[s] to notice something is expired," she throws it out. (Bank Dep. 61). Thus, even if for some reason, the Brochure was procured by Shah from Bank's office because Bank failed to remove outdated materials from her office and left such materials where patients could find them, there is no evidence that would place the blame for the finding of the Brochure by Shah upon Defendants.

Finally, even if Plaintiff had presented evidence tying the Brochure to Defendant's duty to warn and to show that Shah read the Brochure, as indicated above, the insert and medication guide provided to Shah at the time he got his prescription would have properly informed him of the risks he faced. Any lack of warning in the Brochure relating to suicidality and Shah's age would have been rectified when he received the warnings with his prescription. In addition, Bank testified that she orally gave all the necessary warnings regarding the risks associated with Lexapro to Shah when she saw Shah at her office. (Bank Dep. 64, 67, 93). It is further undisputed that in 2008 Shah himself conducted an internet search for

"Lexapro side-effects," which would have also provided him with the current risks associated with taking Lexapro. (SAF Par. 26). Plaintiff has not pointed to any evidence indicating that Bank failed to provide the necessary information orally to Shah. Thus, the undisputed facts show that even if Defendants owed a duty to Shah personally to warn him of risks in taking Lexapro, Defendants did not breach that duty. Based on the above, Defendants' motion for summary judgment on the strict liability and negligence claims is granted.

III. Negligent Misrepresentation and Warranty Claims

Defendants move for summary judgment on the negligent misrepresentation and warranty claims. Plaintiff acknowledges that its negligent misrepresentation and warranty claims are mainly premised on an alleged failure by Defendants to warn of increased suicidality in young adults. (RSF Par. 4). Plaintiff alleges that Defendants negligently concealed from Shah and his prescribing physicians the risks associated with taking Lexapro. (Compl. Par. 122). As explained above, the undisputed facts show that Bank and Shah were provided with warnings that adequately explained the risks associated with taking Lexapro. Plaintiff has failed to point to sufficient evidence that indicates that Defendants concealed from Bank or Shah any material facts concerning such risks. Plaintiff further argues that Shah read the Brochure and then relied on a negligent misrepresentation as to the risks associated with taking Lexapro. However, as explained above, there is no evidence that Shah ever read the Brochure or evidence that would place any blame for Shah's

possession of the Brochure upon Defendants. Shah has failed to point to sufficient evidence to support negligent misrepresentation claims and Defendants' motion for summary judgment on such claims is granted.

Plaintiff has also failed to point to sufficient evidence showing that any warranty, implied or express, was breached by Defendants. Plaintiff argues that Defendants breached express and implied warranties because the warnings given by Defendants were inadequate. (Ans. SJ 14). However, the undisputed facts show that Shah was adequately warned concerning the risk of suicide. Although in response to Defendants' motion for summary judgment, Plaintiff states in a conclusory fashion that "Lexapro was not a merchantable product," Plaintiff fails to point to evidence that would enable a reasonable trier of fact to come to such a conclusion. (Ans. SJ 13). Therefore, Defendants' motion for summary judgment on the warranty claims is granted.

In December 2008, the tragic events ensued that resulted in the loss of Shah's life. The record indicates that Shah was driven to succeed professionally and academically, was well liked and enjoyed being around people and socializing, and loved his family. While the loss of such a young man must bring sadness to all those who knew him, that loss cannot, under the law or in fairness, be laid at the doorstep of Defendants. Defendants have shown that they are entitled to judgment as a matter of law in this action. Therefore, based on all of the above, Defendants' motion for summary judgment is granted.

CONCLUSION

Based on the foregoing analysis, Defendants' motion for summary judgment is granted. In addition, Defendants' motion to exclude the testimony of Hamrell is granted and the motion to exclude the testimony of Conroe is denied. Plaintiff's motion to strike is denied as moot.

Samuel Der-Yeghiayan
United States District Court Judge

Dated: May 26, 2015