IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

TAMMY MUZICHUCK, as the Administratrix of the Estate of BRUCE MUZICHUCK, AND on behalf of her minor child, HANNA MUZICHUCK,

Plaintiff,

v. // **CIVIL ACTION NO. 1:07CV16**
(Judge Keeley)

FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC.

Defendants.

MEMORANDUM OPINION AND ORDER
GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT [DKT. NO. 77],
AND DISMISSING CASE WITH PREJUDICE

Pending before the Court is the motion for summary judgment (dkt. no. 77) filed by the defendants, Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. (collectively, "Forest"). After careful consideration, for the reasons that follow, the Court **GRANTS** Forest's motion.

I. PROCEDURAL BACKGROUND

In December 2006, the plaintiff, Tammy Muzichuck ("Tammy"), filed a wrongful death action in the Circuit Court of Marion County, West Virginia, alleging that Forest had failed to warn her decedent-husband, Bruce Muzichuck ("Bruce"), and his prescribing physicians about the risk of suicide associated with its

antidepressant drug, Lexapro.[1] After Forest removed the case to this Court, it was transferred to MDL No. 1736, In re: Celexa and Lexapro Products Liability Litigation, in the Eastern District of Missouri in 2007.

Ultimately, Tammy opted out of the global settlement achieved in the MDL, and, in 2013, her case was remanded to this Court. In September 2014, Forest filed the pending summary judgment motion, in which it asserts that (1) federal law preempts Tammy's state law claims, (2) Forest provided Bruce with an adequate warning, (3) there is no evidence that a different warning would have prevented Bruce's suicide, and (4) there is no evidence to support an award of punitive damages. The Court heard oral argument on these and other issues on January 9, 2015. The motion is now ripe for review.

[1] Her complaint included counts of negligence, strict liability, fraud, wrongful death, breach of warranty, and punitive damages. However, the parties have stipulated to the dismissal of Tammy's claims for fraud and breach of warranty. (Dkt. No. 107). Also, Tammy has agreed not to seek "any of the wrongful death recovery in this case," and has stipulated that her minor daughter, Hanna Muzichuck ("Hanna"), "is the sole statutory beneficiary for all damages recoverable under the [Wrongful Death Act]." (Dkt. No. 102).

II. FACTUAL BACKGROUND

A. Lexapro Labeling

In August 2002, the Food and Drug Administration ("FDA") approved Forest's new drug application for an antidepressant known as Lexapro. (Dkt. No. 81-5). In July 2003, the FDA requested that Forest perform "data analyses to assess the risk of pediatric suicidality with [Lexapro]." (Dkt. No. 81-16). As a result of these analyses, in March 2004, the FDA issued a Public Health Advisory after making the following determination:

> [W]e believe that labeling changes are warranted in order to caution practitioners and patients about the need for close observation of patients being treated with antidepressants for clinical worsening, for the emergence of suicidality, and for the emergence of a variety of other symptoms that may represent a precursor to suicidality. The committees felt that it would be important to warn prescribers and families of the need to be vigilant for such behaviors, regardless of the role antidepressants may have in the emergence of suicidal ideation/attempts in patients taking antidepressants.

(Dkt. No. 82-8).

In accordance with that advisory, on April 30, 2004, Forest utilized the FDA's "changes being effected" ("CBE") process to seek approval for a label change, which, in relevant part, included the following warning:

Clinical Worsening and Suicide Risk
Patients with major depressive disorder, 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. Although there has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been established. **Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases.** Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and nonpsychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and nonpsychiatric disorders.

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, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such

> symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.
>
> **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, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health-care providers.** Prescriptions for LEXAPRO should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.
>
> 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 . . . .
>
> It should be noted that LEXAPRO is not approved for use in treating any indications in the pediatric population.
>
> A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion in unknown. However, prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that LEXAPRO is not approved for use in treating bipolar depression.

(Dkt. No. 82-10) (emphasis in original). The FDA approved Forest's proposed labeling change on May 20, 2004. (Dkt. No. 82-11).

Following that approval, Forest started distributing Lexapro with a package insert containing the updated warning no later than May 31, 2004. (Dkt. No. 82-10).

Later that year, on October 15, 2004, the FDA issued another Public Health Advisory, and advised Forest that, notwithstanding its earlier labeling change, "additional labeling changes are warranted in order to caution practitioners, patients, family members or caregivers about an increased risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders who are taking antidepressant medications." (Dkt. No. 82-12). However, the FDA cautioned Forest that, "[a]lthough we are still requiring that sponsors submit this supplement within 30 days of our 10-15-04 letter, the prescriber labeling and Medication Guide should not be implemented until you have received notification from the Agency." (Dkt. No. 82-13).

Forest submitted additional proposed labeling changes to the FDA for approval on November 12, 2004. (Dkt. No. 82-14). On December 24, 2004, the FDA advised Forest that "there is interest in re-examining data from trials of antidepressants in adults," and requested that Forest perform such analyses. (Dkt. No. 82-15).

Based on the results of those analyses, in May 2007 the FDA made the following determination:

> [W]e believe that additional changes are needed in antidepressant labeling and medication guides to alert practitioners, patients, family members and caregivers about an increased risk of suicidal thinking and behavior (suicidality) in young adults with major depressive disorder (MDD) and other psychiatric disorders who are taking antidepressant medications. Changes are also needed to inform practitioners about an apparent favorable effect of antidepressants on suicidality in older adults and to remind them that the disorders being treated with antidepressants are themselves associated with an increased risk of suicidality.

(Dkt. No. 83-5). Forest then submitted a proposed labeling update, which the FDA approved in August 2007. (Dkt. No. 83-8).

B. Bruce Muzichuck

Bruce was born in 1957. While still in high school, he began dating Tammy in 1974, and the couple married in 1980. Marital distress was evident early on, but Tammy attributed it to "adjusting to living together." (Dkt. No. 45-20 at 7). The couple had their only child, Hanna, in 1997. From the outside, the family appeared to be relatively happy, and, as Tammy explained, "[w]hatever [Hanna] wanted, she pretty much got [Bruce's] attention." Id. at 10.

In 2004, however, Tammy began counseling sessions with Nancy A. Rush ("Rush") at Progressive Preventive Health Care, Inc.

("Progressive") because she was having romantic feelings for another man. Id. at 11. During a visit to Progressive on June 9th, Rush documented that Tammy presented with "decreased mood, increased agitation, restlessness related to marital issues." (Dkt. No. 87-7). Tammy informed Rush that "she never loved [Bruce] because of severe abuse," that she had "had a long term affair with a furniture store owner (over 10 years)," and that "[t]here's been no marriage in many years." Id. Rush advised Tammy that she should ask Bruce to move out of their house to give her time to sort out her feelings. (Dkt. No. 45-20 at 14).

Pursuant to Rush's advice, Tammy told Bruce that she had been attending counseling sessions because she was unhappy with their marriage, and that she wanted him to move out in order to give her time to sort things out. (Dkt. No. 45-20 at 12, 14). Bruce became upset at this, and Tammy persuaded him to visit Progressive for treatment. Thus, on June 23rd, he presented to Progressive with complaints of "marital issues/anxiety." (Dkt. No. 87-6 at 10). A social worker named Greg Sanders ("Sanders") completed a psycho-social assessment of Bruce, and noted "no destructive thoughts/intent." Id. Nevertheless, Sanders referred Bruce to Medbrook Medical Associates ("Medbrook"), a walk-in clinic in

Bridgeport, West Virginia, for "evaluation for anti-anxiety meds." Id.

On the same day, Bruce visited Medbrook, where Dr. Robert Bowers ("Bowers") diagnosed him as depressed and suffering from situational anxiety. (Dkt. No. 87-10 at 4-5). Based on this, Bowers placed Bruce on a prescription of ten milligrams per day of Lexapro. Id. Although not transcribed in his office notes, Bowers also gave Bruce a Lexapro sample pack. (Dkt. No. 91-18 at 2).

After he took some of the pills from the sample pack, Bruce returned to Progressive on July 6th. As Sanders noted in Bruce's chart, "[h]e reported Lexapro working well. He took it for 2 days, symptoms lessened, so he stopped. Symptoms returned, so he began taking again. [H]as taken for 10 days. [I]t is working well." (Dkt. No. 87-6 at 10). Three days later, Bruce filled his Lexapro prescription at The Drug Store, and refilled it on August 16th, and again on September 22nd. (Dkt. No. 87-11 at 3).

In late August, Bruce moved to a trailer a few miles away from Tammy. (Dkt. No. 45-20 at 26). Tammy explained that "[i]t was hard on him, you know, but he seemed to be handling it okay." Id. Although at the outset the couple's separation appeared benign, by October 2004, Bruce's behavior began spiraling downward.

On the night of October 16th, Tammy came home from work to find that Bruce had broken in and taken two guns. Id. at 28. When she confronted him about it, he told her that he had taken the guns for her safety because he believed "women that go through menopause sometimes think about suicide." Id. at 29. On October 18th, Bruce showed up at Tammy's work appearing "very agitated" and pacing back and forth. Id. He told Tammy he wanted to talk, but she was too busy. Id. Although he eventually left, he told Tammy that he was going to harm himself. Id. Concerned for his safety, Tammy called Progressive, but was unable to reach Sanders. Id. Later that night, Bruce showed up at her house and told her he had thought about committing suicide but could not bring himself to do it. Id. at 30.

The following day, Bruce had a "crisis intervention" with Sanders, who noted that Bruce had "almost ended it yesterday b/c he can't deal with all the stress of not being with [Tammy]." (Dkt. No. 87-6 at 9). Sanders's note also stated that "[Bruce] will consider returning handgun to wife's possession." Id. He never returned the gun. (Dkt. No. 45-20 at 34).

The next incident occurred on November 6th, while Bruce was watching Hanna and her friend so Tammy could run errands. Id. at 35. The girls were playing and Bruce asked them to quiet down.

Id. When Hanna talked back to Bruce, he spanked her, which he had never done before. Id. When Tammy came home, Bruce told her he was "devastated that he had lost it." Id.

Six days later, on November 12th, Bruce returned to Medbrook, where, due to Bowers's unavailability, he saw another physician, Dr. Kelly Nelson ("Nelson"). In his medical note, Nelson observed: "Been on Lexapro since June. Initially worked real well and now not working very well. Bump his Lexapro up to 20 mg [per] day." (Dkt. No. 87-10 at 3). Bruce filled this prescription for what amounted to a doubled dosage of Lexapro at the Medbrook pharmacy the same day. Id.

About a week later, Bruce told Tammy that "they increased his medicine and that was helping a lot." (Dkt. No. 91-18 at 21). However, on December 4th, Bruce showed up to Tammy's house appearing "agitated, irritable, hostile, and aggressive." (Dkt. No. 45-20 at 39). As before, he was pacing back and forth, and then he became assaultive toward Tammy. Id. at 40. Bruce forced her upstairs where they "got into a tussle." Id. When his daughter, Hanna, tried to intervene, he locked her in her bedroom. Id. While struggling with Tammy, he suddenly collapsed, got up, and walked out the door. Id. at 41.

Late that night, Bruce called Tammy. Id. at 43. When she asked him where he was, he replied that "[i]t doesn't matter." Id. Eventually he said, "I'm with my mom and dad," at which point Tammy knew he was at the cemetery where his parents were buried. Id. Tammy immediately called the police to tell them where Bruce was, and that he was potentially suicidal. Id. She then left the house to drive to the cemetery, which was approximately five miles away. Id. at 44. While she was on her way, the police arrived at the cemetery, where they observed Bruce acting irrationally, ranting, and holding a gun. Id. After they attempted to engage him in conversation, Bruce ran into the woods, shot himself in the chest, and died within seconds. Id. at 45. Tammy arrived a few minutes later. Id.

III. STANDARD OF REVIEW

Summary judgment is appropriate where the "depositions, documents, electronically stored information, affidavits or declarations, stipulations . . ., admissions, interrogatory answers, or other materials" show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed R. Civ. P. 56(a), (c)(1)(A). When ruling on a motion for summary judgment, the Court reviews all the evidence "in the light most favorable" to the nonmoving party. Providence

Square Assocs., L.L.C. v. G.D.F., Inc., 211 F.3d 846, 850 (4th Cir. 2000). The Court must avoid weighing the evidence or determining the truth and limit its inquiry solely to a determination of whether genuine issues of triable fact exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

The moving party bears the initial burden of informing the Court of the basis for the motion and of establishing the nonexistence of genuine issues of fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party has made the necessary showing, the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 256 (internal quotation marks and citation omitted). The "mere existence of a scintilla of evidence" favoring the nonmoving party will not prevent the entry of summary judgment; the evidence must be such that a rational trier of fact could reasonably find for the nonmoving party. Id. at 248–52.

IV. ANALYSIS

Forest posits several arguments on summary judgment. First, it asserts that impossibility preemption bars Tammy's failure to warn claim because FDA regulations would not have permitted any warning beyond that already contained in its package insert. Next, Forest argues that no dispute exists concerning the adequacy of its

warning about the risk of suicide associated with Lexapro. Further, Forest contends that the evidence is uncontroverted that Bruce actually read the updated package insert.

A. Preemption

Tammy eliminated most, if not all, of the debate regarding preemption by acknowledging in her response brief that she "does not claim that Forest could have added a BLACK BOX warning to Lexapro's label, or could have provided a Patient Medication Guide, without prior FDA approval." (Dkt. No. 91 at 8). Indeed, it is hard to see how preemption continues to play any role in this case. Nevertheless, Forest maintains that there is clear evidence demonstrating that the FDA would not have approved any other warning.

The FDA's CBE process permits pharmaceutical manufacturers to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling." 21 C.F.R. § 314.70(c)(6)(iii)(A). Importantly, "[w]hen making labeling changes using the CBE process, manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label." PLIVA, Inc. v. Mensing, __ U.S. __, __, 131 S. Ct. 2567,

2575 (2011). That said, such changes are to be made only "to reflect newly acquired information." § 314.70(c)(6).

In Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court of the United States addressed whether approval of warning labels by the FDA provided a pharmaceutical manufacturer with a complete defense to a consumer's claims of negligence and strict liability. In that case, Levine, had received an injection of the drug Phenergan manufactured by Wyeth for treatment of nausea. Id. at 559. Because of the way in which Levine's health care provider had injected the Phenergan, gangrene had set in and spread throughout Levine's arm, ultimately resulting in amputation. Id.

In her lawsuit, Levine alleged that Wyeth's labeling regarding the administration of Phenergan was defective because "it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method." Id. at 560. As Forest has here, Wyeth moved for summary judgment, "arguing that Levine's failure-to-warn claims were pre-empted by federal law." Id. That argument failed before both the trial court and the state supreme court in Vermont. Id. at 562-63.

On certiorari to the Supreme Court, Wyeth argued, in pertinent part, that "Levine's state-law claims are pre-empted because it is impossible for it to comply with both the state-law duties

underlying those claims and its federal labeling duties." Id. at 568. Specifically, it relied on the CBE process's "newly acquired information" requirement, and urged that "Levine has not pointed to any such information concerning the risks of IV-push administration." Id.

Justice Stevens, writing for the majority, first observed that "newly acquired information is not limited to new data, but also encompasses new analyses of previously submitted data." Id. at 569 (internal quotation marks and citation omitted). With that in mind, he found that, "as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug." Id. at 570. Next, Stevens reaffirmed that "the manufacturer [not the FDA] bears responsibility for the content of its label at all times." Id. at 570-71. Finally, he concluded that, "when the risk of gangrene from IV-push injection of [the drug] became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. at 571.

After rejecting Wyeth's impossibility preemption argument, Justice Stevens suggested that the presentation of "clear evidence that the FDA would not have approved a change to [the drug's]

label" might form the basis for impossibility preemption. Id. Several years later, in Mensing, the Supreme Court clarified the suggestion in Levine, explaining that, in order to invoke the exception to the CBE process, a manufacturer must demonstrate by clear evidence that "it would in fact have been impossible to do under federal law what state law required." 131 S. Ct. at 2581 n.8.

In this case, Tammy contends that the CBE process was triggered in June 2001, when, based on newly acquired information about suicidality, Forest was obligated to provide Lexapro patients with an enhanced warning. In his report, Tammy's general warnings/regulatory expert, Dr. Michael Hamrell ("Hamrell"), stated:

> Had [Forest] reviewed the FDA data, as it should have done to comply with its post marketing safety surveillance requirements, it would have observed a number of positive rechallenge cases. . . . In the scheme of evidence of a causal relationship with individual reports, positive rechallenge cases represent some of the strongest evidence. . . . Overall, the adverse event data and particularly the dechallenge/rechallenge data are reasonable evidence of an association between SSRIs and suicidality. This is true no later than June 30, 2001. . . . [A] review of the adverse event data as of June 2001 shows that not only were there a significant number of suicidal related adverse event reports associated with the use of SSRIs, but there were several reports of psychiatric and suicidal rechallenge cases. The dechallenge/rechallenge data is particularly concerning because it is suggestive of a direct drug related effect

> as opposed to the underlying condition. This data alone was sufficient to enhance the warning with respect to suicidality.

(Dkt. No. 91-20 at 15-18). Thus, according to Hamrell, Forest should have strengthened its warning regarding the risk of suicide associated with Lexapro no later than June 2001.

Despite the newly acquired FDA data advanced by Hamrell, Forest contends that "there is clear evidence that FDA would have rejected the precise label changes [Tammy] claims Forest should have implemented before Lexapro was prescribed to [Bruce]."[2] (Dkt. No. 78 at 9). Forest contends that "[t]he totality of FDA's analysis of the issue - and its conclusions - over several decades is clear evidence there never was, and is not now, any scientific substantiation for including a warning that Lexapro increases the risk of suicide or suicidality in adult patients." (Dkt. No. 78 at 9). In support, it cites one district court decision finding "clear evidence that the FDA would have rejected an expanded Effexor warning for patients in [the decedent's] age group prior to

[2] Public policy recognizes a danger in "overwarning" consumers of potential drug-related risks. See 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("Exaggeration of risk could discourage appropriate use of a beneficial drug."); 44 Fed. Reg. 37434, 37447 (June 26, 1979) ("[I]ncluding theoretical hazards as contraindications in drug labeling would cause that very important section of the labeling to lose its significance.").

his 2002 suicide." Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1277 (W.D. Okla. 2011). The Dobbs court itself, however, explicitly recognized that its decision diverged from that of every other court that had addressed the issue. Id. ("[O]ther courts applying the Levine clear evidence standard in the context of [anti-depressant] label warnings have universally rejected the manufacturers' evidence as insufficient.") (emphasis added) (citing Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010); Baumgardner v. Wyeth Pharm., 2010 WL 3431671 (E.D. Pa. Aug. 31, 2010); Dorsett v. Sandoz, Inc., 699 F. Supp. 2d 1142 (C.D. Cal. 2010); Aaron v. Wyeth, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010); Forst v. SmithKline Beecham Corp., 639 F. Supp. 2d 948 (E.D. Wis. 2009)).

The Court is unconvinced by the reasoning in Dobbs, and concludes that Forest has failed to establish by clear evidence that the FDA would have rejected an expanded warning concerning the correlation between adult suicide and antidepressant drugs. Thus, Forest's compliance with any state law duty to warn was not impossible given federal regulations. See Baumgardner, 2010 WL 3431671, at *1 ("Other cases examining the warning labels on antidepressants have reached the same conclusion. The reasoning in those cases is persuasive.") (internal citations omitted). Based

on the foregoing, the Court rejects Forest's impossibility preemption defense, and turns next to examine Forest's contention that there are no material issues of fact are in dispute that would preclude an award of summary judgment as to Tammy's failure to warn claim.

B. Failure to Warn

Tammy has alleged failure to warn based on theories of negligence and strict liability. "Each theory contains different elements which plaintiffs must prove in order to recover." Syl. Pt. 6, Ilosky v. Michelin Tire Corp., 307 S.E.2d 603, 605 (W. Va. 1983). That said, "[t]he distinction between the two lessens considerably in failure to warn cases since it is clear that strict liability adds little in warning cases." Werner v. Upjohn Co., 628 F.2d 848, 858 (4th Cir. 1980).

Indeed, both theories involve a manufacturer's duty to warn of foreseeable risks associated with the product. See Johnson by Johnson v. Gen. Motors Corp., 438 S.E.2d 28, 37 n.5 (W. Va. 1993) (explaining that "we have not addressed the issue of whether the duty to warn under a negligence theory in a product liability case differs" from the duty owed under a strict liability theory). Also, "[u]nder West Virginia law, a claim for negligence . . . and strict liability requires that the element of causation be

satisfied." White v. Dow Chem. Co., 321 Fed. App'x 266, 273 (4th Cir. 2009) (citing Tolley v. Carboline Co., 617 S.E.2d 508, 511-12 (W. Va. 2005)). Forest argues that there is no factual dispute in this case concerning (1) the adequacy of its warning of the risk of suicidality in its package insert, (2) the adequacy of its efforts to warn, (3) the fact that Bruce actually read the package insert, or (4) that the lack of an adequate warning regarding the risk of suicide associated with the use of Lexapro proximately caused Bruce's death.

1. Adequacy of the Warning's Contents

According to Tammy's specific causation expert, Dr. Joseph Glenmullen ("Glenmullen"), Forest's warning about the risk of suicide was inadequate because it

> provided no information about how the precursor side effects could be early warning signs of incipient suicidality, no information about the particularly high risk in the early months of treatment or whenever the dose is changed, nor any suggestion that Bruce needed to be observed closely. Patients need to be specifically warned that Lexapro may paradoxically make them worse and suicidal.

(Dkt. No. 45-20 at 52). Forest contends that the warning, contained in the Lexapro package insert as of May 31, 2004, included precisely the information that Glenmullen would have

required. Specifically, under "Clinical Worsening and Suicide Risk," Forest's warning provided as follows:

> **[P]atients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases.** Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms.
>
> . . .
>
> 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, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.
>
> **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, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health-care providers.** Prescriptions for LEXAPRO should be written for the smallest quantity of tablets

> consistent with good patient management, in order to reduce the risk of overdose.

(Dkt. No. 82-10 at 9) (emphasis in original).

Hamrell, Tammy's general warnings/regulatory expert, acknowledged that this warning "was placed in [Lexapro's] April, 2004 label."[3] (Dkt. No. 91-20 at 19). However, because Forest did not include a black box warning or an updated medication guide until February 2005, he concluded that "[a]t no time before 2005 was the Celexa/Lexapro label adequate with respect to suicidality." Id. at 22.

Despite Hamrell's conclusion, Tammy has conceded:

> Plaintiff does not claim that Forest could have added a BLACK BOX warning to Lexapro's label, or could have provided a Patient Medication Guide, without prior FDA approval. Forest relies on the portion of the expert report of Dr. Hamrell, Plaintiff's regulatory expert, in which he addressed the inadequacy of the warning at all times prior to 2005, and proffered a warning that would have been adequate. But Dr. Hamrell does not opine, and Plaintiff does not contend, that Forest could have added a boxed warning, or a medication guide . . . .

(Dkt. No. 91 at 8).

Without the possibility of a black box warning or an updated medication guide, Hamrell's opinion is reduced to a ratification of

[3] According to Forest's documentation, the updated package insert accompanied all Lexapro product distributed "on or before May 31, 2004." (Dkt. No. 82-10).

Forest's warning that he admits "was placed in [Lexapro's] April, 2004 label." Thus, the Court concludes there is no material question of fact in dispute about whether Forest's warning regarding the risk of suicide associated with the use of Lexapro was adequate.

2. Adequacy of Forest's Efforts to Warn

In addition to requiring an adequate warning about the risk of suicide to patients using Lexapro, West Virginia law requires a manufacturer such as Forest to undertake adequate efforts to communicate that warning. In Syl. Pt. 4, Ilosky v. Michelin Tire Corp., 307 S.E.2d 603, 605 (W. Va. 1983), the West Virginia Supreme Court of Appeals held that "[t]he determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." It based that holding on the fact that the plaintiff, through her expert, had "concentrated her case" on providing the jury with an alternative means of warning. Id. at 610, 616.

Notably, the two alternatives proposed by Hamrell -- a black box warning and a medication guide -- have been abandoned by Tammy in order to avoid Forest's preemption defense. Nevertheless, Tammy's lawyers, both at oral argument and in their briefing, contend there are several ways, other than the package insert, by

which Forest could have more effectively communicated the warning about the risk of suicidality associated with Lexapro.

First, counsel contend that "[f]ederal law did not prohibit Forest from sending the [March 2004] Public Health Advisory directly to prescribing doctors using a 'Dear Doctor' letter," or "sending a communication to Bruce Muzichuck." (Dkt. No. 91 at 10). Second, counsel point out that Forest's Medical Affairs Department actually drafted a "consumer Lexapro suicidality standardized response letter" in the spring of 2004, but decided against sending it. (Dkt. No. 91-23 at 4). Finally, at oral argument, counsel contended that an updated warning should have been provided based on the FDA's October 15, 2004 Public Health Advisory.

Critically, none of these alternatives is based on expert testimony. See Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 682 (W. Va. 1979) ("In [a] product liability case, the expert witness is ordinarily the critical witness. He serves to set the applicable manufacturing, design, labeling and warning standards based on his experience and expertise in a given product field.") (emphasis added). They also are not viable for other reasons.

A "Dear Doctor" letter, for example, would not have provided Bruce's physicians with any information they had not already seen. Bruce's prescribing physician, Bowers, confirmed that he routinely

read package inserts "in order to stay current on antidepressant medications." (Dkt. No. 87-13 at 3). As for the idea that Forest should have sent a warning directly to Bruce, there is no evidence of record that Forest knew or could have known he was a consumer prior to the date on which he filled his prescription. Even after that, it is unclear how Forest could have known to send Bruce any direct communication.

Tammy also urges that Forest should have sent Bruce the standardized consumer response letter it had drafted. Notably, however, that letter was designed to be sent "in response to inquiries" about Lexapro, something Bruce never made. (Dkt. No. 91-23 at 5). Moreover, it is undisputed that the letter simply restated the same warning already contained in Forest's package insert. (Dkt. No. 91-24).

Finally, as to the FDA's October 15, 2004 communication, the FDA specifically directed Forest not to implement any labeling changes "until you have received notification from the Agency." (Dkt. No. 82-13). That notification was not provided until January 2005, a month after Bruce's suicide. (Dkt. No. 82-16).

For these reasons, Tammy's contention that, based on syllabus point 4 of Ilosky, the question whether a manufacturer's efforts to warn were adequate is always for the jury regardless of the state

of the evidence is erroneous. She has submitted no expert testimony supporting her proposed alternative means of warning; nor is there any evidence that her proposed alternative means of warning were viable. Thus, there is no material question of fact in dispute about whether Forest's efforts to warn by way of its package insert were adequate.

3. Bruce Read the Package Insert

Next, Forest contends that the evidence is uncontroverted that Bruce actually read the package insert that was in his Lexapro sample pack. During Tammy's deposition in 2011, the following exchange occurred:

> Q. Do you have any knowledge or reason to believe that [Bruce] actually [read the package insert]? For instance, did he ever tell you "I read this"?
>
> A. Yes, I -- I would say yes to that.
>
> Q. Well, you said you would say yes. Did Bruce tell you that he read --
>
> A. Yes.
>
> Q. -- the package insert? Did you actually see him read the package insert or he just told you about it?
>
> A. He told me some things about it.
>
> Q. What do you remember him telling you?
>
> A. That it changed like his sex drive and I think that he -- there'd be times when he couldn't sleep.

(Dkt. No. 93-2 at 3). As Forest points out, corroboration for Tammy's testimony exists because the updated package insert discusses the potential side effects (sexual dysfunction and insomnia) she described in her deposition testimony.[4] (Dkt. No. 82-10 at 9-10). Furthermore, Forest's director of quality assurance has filed a declaration verifying that, based on its lot number, the sample pack given to Bruce by Bowers contained the updated package insert. (Dkt. No. 80).

Tammy's effort to controvert her deposition testimony is unavailing. In a declaration signed the day before she filed her responsive brief, Tammy asserts that "the only documents Bruce Muzichuck could have reviewed prior to his death, that I am aware of, were the Lexapro Patient Starter Kit/Sample Packet and/or the 'Guide for Patients,'" but not the package insert.[5] (Dkt. No. 91-13 at 3).

[4] Tammy attempts to rebut this by explaining that similar side effects were also included in the sample pack's "Guide for Patients." However, the Court has stricken that piece of evidence based on Tammy's late disclosure of it. (Dkt. No. 76).

[5] It is unclear how Tammy is competent to testify as to what Bruce did or did not read prior to his death.

This attempt by Tammy to create a contested issue of fact by disputing her own earlier deposition testimony is unconvincing. In the Fourth Circuit, a plaintiff

> cannot create a dispute about a fact that is contained in deposition testimony by referring to a subsequent affidavit [or declaration] of the deponent contradicting the deponent's prior testimony, for "it is well established that a genuine issue of fact is not created where the only issue of fact is to determine which of the two conflicting versions of a party's testimony is correct."

In re Family Dollar FLSA Litig., 637 F.3d 508, 512 (4th Cir. 2011) (quoting Erwin v. United States, 591 F.3d 313, 325 n.7 (4th Cir. 2010)). Therefore, the Court concludes that there is no material question of fact in dispute concerning whether Bruce read Forest's package insert.

4. Heeding Presumption

During oral argument, counsel for Tammy urged the Court to apply a "heeding presumption," which would give rise to a legal conclusion that Bruce did not read the warning since he did not stop taking Lexapro. In some states, "[t]here is a presumption in strict liability cases that a plaintiff would have read and heeded an adequate warning if it had been given." Waterhouse v. R.J. Reynolds Tobacco Co., 162 Fed. App'x 231, 234-35 (4th Cir. 2006) (applying Maryland law).

Forest's Lexapro warning provided in relevant part that "[c]onsideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms." Because Bruce continued to use Lexapro even as his depression worsened, Tammy contends that he could not have read the warning.

As Tammy's counsel readily conceded at oral argument, however, the West Virginia Supreme Court of Appeals has never adopted a heeding presumption. Nevertheless, Tammy urges the Court to follow the holdings in Giles v. Wyeth, Inc., 500 F. Supp. 2d 1063 (S.D. Ill. 2007); and Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038 (Kan. 1984), and adopt the presumption. A careful reading of these cases undermines counsel's argument.

In Giles, the district court expressly declined to determine whether a heeding presumption would apply under Illinois law. 500 F. Supp. 2d at 1069 ("For better or worse, the Court need not decide this issue . . . ."). Moreover, in Syl. Pt. 11, Wooderson, 681 P.2d at 1042, the Supreme Court of Kansas adopted the presumption, but, in doing so, explained in the same syllabus point that "[t]his operates to the benefit of the manufacturer where

adequate warnings are in fact given." Indeed, courts that have applied the presumption generally permit manufacturers to rebut it with evidence contrary to the presumed fact. See, e.g., Technical Chem. Co. v. Jacobs, 480 S.W.2d 602, 606 (Tex. 1972) ("The presumption may, however, be rebutted if the manufacturer comes forward with contrary evidence that the presumed fact did not exist.").

Here, as already discussed, there is no genuine dispute that a warning regarding suicidality was contained in Forest's package insert, that the warning was adequate, and that the sample pack Bruce received from Bowers contained a package insert. Moreover, the uncontroverted facts establish that Bruce actually read the warning from the package insert. Thus, even if a heeding presumption were applied in this case, based on the evidence of record, it would not raise a genuine dispute of material fact.[6]

V. CONCLUSION

Although Tammy's claims are not preempted, Forest has satisfied its burden of demonstrating the absence of any genuine issue of material fact regarding its alleged failure to warn.

[6] Based on its conclusion that no genuine dispute exists regarding Forest's alleged failure to warn, the Court need not address the additional issues of proximate cause and punitive damages briefed by the parties.

Therefore, the Court **GRANTS** Forest's motion for summary judgment, **DISMISSES** this case **WITH PREJUDICE**, and **CANCELS** the final pretrial conference scheduled for January 22, 2015, and the trial of this case scheduled to begin on January 28, 2015.

It is so **ORDERED.**

The Clerk is directed to transmit copies of this Memorandum Opinion and Order to counsel of record, and to enter a separate judgment order dismissing this case with prejudice and removing it from the Court's active docket.

DATED: January 16, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE