**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF MISSOURI**
**EASTERN DIVISION**

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| B.F., a minor, BETH FORBES, individually and as next friend of B.F., and THOMAS FORBES, individually and as next friend of B.F., | ) | No. 4:12-CV-1760 CAS |
| Plaintiffs, | ) | |
| v. | ) | |
| ABBOTT LABORATORIES, INC., et al., | ) | |
| Defendants. | ) | |

**MEMORANDUM AND ORDER**

This matter is before the Court on defendant Abbott Laboratories, Inc.'s ("Abbott") motion for summary judgment on plaintiffs' claim for punitive damages. Plaintiffs oppose the motion. The motion is fully briefed and ready for decision. For the following reasons, the motion will be denied.

**Background**

In this products liability action, plaintiffs Thomas and Beth Forbes and their minor son B.F. ("plaintiffs") assert claims against Abbott arising out of injuries resulting from B.F.'s exposure *in utero* to the medicine Depakote. Beth Forbes began taking Depakote two years before B.F.'s birth to treat her bipolar disorder. Plaintiffs allege B.F. was diagnosed with spina bifida as a result of his mother's ingestion of Depakote during pregnancy.

Plaintiffs brought this action against Abbott in seven counts, only two of which remain: Strict Liability—Failure to Warn (Count I) and Negligence—Failure to Warn (Count III). In both of these counts, plaintiffs seek an award of punitive damages. Abbott moves for summary

judgment on plaintiffs' claim for punitive damages, stating they have failed to present sufficient evidence to support such a claim under Missouri law.

**Summary Judgment Standard**

The standards applicable to summary judgment motions are well settled. Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

In passing on a motion for summary judgment, this Court is required to view the facts in a light most favorable to the non-moving party and the Court must give the non-moving party the benefit of any inferences that can logically be drawn from those facts. Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Buller v. Buechler, 706 F.2d 844, 846 (8th Cir. 1983). Moreover, this Court is required to resolve all conflicts in favor of the non-moving party. Robert Johnson Grain Co. v. Chemical Interchange Co., 541 F.2d 207, 210 (8th Cir. 1976).

**Facts**

Beginning in 1999, Beth Forbes began suffering from mental illness, for which she received medical treatment. During a June 2002 hospitalization, she was diagnosed as suffering from bipolar disorder/manic depression.

In or around April 2003, Beth Forbes came under the care of Dr. Raziya Mallya ("Dr. Mallya"), a psychiatrist, who began treating Mrs. Forbes for her bipolar disorder. Starting in April 2003, Dr. Mallya prescribed Depakote Extended Release ("Depakote") tablets, as well as

Geodon and Wellbutrin, for treatment of Mrs. Forbes' bipolar disorder. Dr. Mallya prescribed Depakote as a mood stabilizer.

In January 2005, Mrs. Forbes became pregnant with B.F. She testified that she had been taking Depakote at that time for treatment of her bipolar disorder. Mrs. Forbes stopped taking Depakote after she found out that she was pregnant with B.F.

In September 2005, Beth Forbes gave birth to B.F. B.F. has been diagnosed with spina bifida as well as some other conditions that plaintiffs claim are secondary to spina bifida, namely: hydrocephalus, Chiari type II malformation, club feet deformity, bilateral hip dislocations, tethering of spinal cord (now untethered), sensorineural hearing loss in right ear, and neurogenic bowel and bladder leading to incontinence of feces and urine. Plaintiffs claim all of B.F.'s physical limitations stem from and are attributable to B.F.'s spina bifida.

At all relevant times when Mrs. Forbes was taking Depakote from 2003 to 2005, Depakote's label included specific warnings regarding the risk of spina bifida due to *in utero* exposure. The Depakote prescribing information (often referred to as "the label") included a block box warning in all caps that warned of the risks of neural tube defects. The black box provided:

> **TERATOGENICITY:**
> VALPROATE [DEPAKOTE] CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA), ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS. THIS IS ESPECIALLY IMPORTANT WHEN THE TREATMENT OF A SPONTANEOUSLY REVERSIBLE CONDITION NOT ORDINARILY ASSOCIATED WITH PERMANENT INJURY OR RISK OF DEATH (E.G., MIGRAINE) IS CONTEMPLATED. SEE WARNINGS, INFORMATION FOR PATIENTS.
> AN INFORMATION SHEET DESCRIBING THE TERATOGENIC POTENTIAL OF VALPROATE IS AVAILABLE FOR PATIENTS.

(Abbott SOF ¶ 15.)

A ten-paragraph warning in the "Usage in Pregnancy" subsection of the 2003 and 2004 Depakote labels provided in relevant part:

> ACCORDING TO PUBLISHED AND UNPUBLISHED REPORTS, VALPROIC ACID MAY PRODUCE TERATOGENIC EFFECTS IN THE OFFSPRING OF HUMAN FEMALES RECEIVING THE DRUG DURING PREGNANCY. THE DATA DESCRIBED BELOW WERE GAINED ALMOST EXCLUSIVELY FROM WOMEN WHO RECEIVED VALPROATE TO TREAT EPILEPSY. THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS.
> THE INCIDENCE OF NERUAL TUBE DEFECTS IN THE FETUS MAY BE INCREASED IN MOTHERS RECEIVING VALPROATE DURING THE FIRST TRIMJESTER OF PREGNANCY. THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 TO 2%.
> OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE.
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> * * * * *
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> The prescribing physician will wish to weigh the benefits of therapy against the risks in treating or counseling women of childbearing potential. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
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> * * * * *
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> Tests to detect neural tube and other defects using current accepted procedures should be considered a part of routine prenatal care in childbearing women receiving valproate.

(Abbott SOF ¶¶ 16-17.)

**Discussion**

In its motion, Abbott seeks summary judgment on plaintiffs' claim for punitive damages, stating that the claim fails as a matter of law because the Depakote labeling has always contained safety information about the risks of spina bifida, the precise injury suffered by B.F. Plaintiffs respond that they are entitled to punitive damages because they have presented substantial evidence that demonstrates Abbott acted with conscious disregard and reckless indifference for the safety of B.F.

Under Missouri law the test for punitive damages is a strict one. Bhagvandoss v. Beiersdorf, Inc., 723 S.W.2d 392, 397 (Mo. banc 1987) (holding that inadequate warnings does not amount to conscious disregard). Punitive damages may be awarded in a negligence case or a products liability case. See Ford v. GACS, Inc., 265 F.3d 670, 677-78 (8th Cir. 2001). "Punitive damages are appropriate under either theory of recovery only if the defendant showed a complete indifference to or conscious disregard for the safety of others. Ultimately, the defendant must have acted with some degree of wantonness or bad motive." Id. at 678 (internal punctuation and citations omitted); see also Drabik v. Stanley-Bostitch, Inc., 997 F.2d 496 (8th Cir. 1993) (vacating award of punitive damages, finding no indication of complete indifference and an element of outrage).

Abbott argues that at the time Mrs. Forbes was prescribed Depakote, the label included a FDA-mandated black box warning regarding teratogenicity, and specifically warned of the risk of spina bifida, the very injury suffered by B.F. Because Abbott warned of the known risks and

of the harm suffered by plaintiff, it argues that it cannot be found to have acted outrageously due to evil motive or reckless indifference to the rights of plaintiffs.

Plaintiffs have presented evidence, however, that Abbott knew as early as the 1980s that (1) there was a cause and effect relationship between Depakote and serious birth defects; (2) if used in women of childbearing age, Depakote should only be used with effective contraception; (3) the risk of spina bifida in children exposed to Depakote *in utero* is a 10 to 20 fold increase over the background rate; and (4) Depakote can produce multiple congenital malformations in the same child. Plaintiffs submit evidence that Abbott strategically diluted Depakote's warning and disseminated misleading information regarding the risks posed by Depakote. Plaintiffs also submit evidence that Abbot's failure to warn of the full extent of Depakote's teratogenic danger was profit-driven. Plaintiffs' evidence of Abbott's alleged dilution of Depakote's warning and its dissemination of misleading information associated with Depakote use during pregnancy creates a genuine issue of material fact regarding whether Abbott's actions rose to a level of culpable behavior.

Abbott's contention that it could not be subject to punitive damages because the FDA expressly approved the marketing and labeling of Depakote is not dispositive. In Blanks v. Flour Corporation, 450 S.W.3d 308, 402-04 (Mo. Ct. App. 2014), for example, defendants argued that they could not be subject to punitive damages because they had done everything that was required by the EPA and the DNR, and had cooperated with federal, state, and local authorities concerning lead contamination. The Blanks defendants, like Abbott here, argued that punitive damages were unavailable against a party that complied with an ongoing regulatory program intended to address the issues on which plaintiffs based their claims. Id. Plaintiffs, however, presented evidence that defendants had hidden information from regulators, resisted

regulatory changes, and had not complied with industry standards. Thus, even though defendants arguably complied with regulatory programs, plaintiffs presented sufficient evidence of defendants' evil motives or reckless disregard to submit the claim of punitive damages to the jury.

Here, the fact that the FDA approved the marketing of Depakote and allowed for it to be prescribed to women of child-bearing age for treatment of bipolar disorder weighs against the submission of the punitive damages claim to the jury, but it does not foreclose it. See id. (citing Alcorn v. Union Pacific R.R. Co., 50 S.W.3d 226, 248 (Mo. 2001)). Abbott's compliance with FDA requirements does not necessarily negate a jury finding that Abbott acted with complete indifference to or conscious disregard for the safety of others, particularly in light of plaintiffs' evidence that Abbott diluted Depakote's warning and disseminated misleading information regarding its risks.

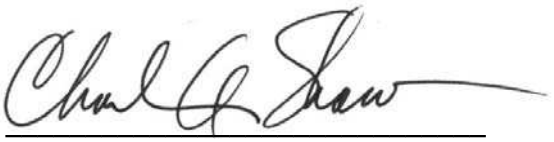
Viewing the evidence in the light most favorable to plaintiffs, it remains a disputed issue whether Abbott knew or had reason to know that there was a high degree of probability that its conduct would result in injury. The Court will deny Abbott's motion for summary judgment on plaintiffs' claim for punitive damages.

**Conclusion**

For the foregoing reasons, Abbott has not established a right to summary judgment with respect to the issue of punitive damages.

Accordingly,

**IT IS HEREBY ORDERED** that defendant Abbott Laboratories, Inc.'s motion for summary judgment as to plaintiffs' claim of punitive damages is **DENIED**. [Doc. 64]



**CHARLES A. SHAW**
**UNITED STATES DISTRICT JUDGE**

Dated this 8th day of April, 2016.