**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| **KEVIN HUTCHENS, ET AL.,** | ) | **CASE NO.1:14CV176** |
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| **Plaintiffs,** | ) | **JUDGE CHRISTOPHER A. BOYKO** |
| | ) | |
| **vs.** | ) | |
| | ) | |
| **ABBOTT LABORATORIES, INC., ET AL.,** | ) | **OPINION AND ORDER** |
| | ) | |
| | ) | |
| **Defendants.** | ) | |

**CHRISTOPHER A. BOYKO, J:**

This matter is before the Court on Plaintiffs' Motion for a New Trial (ECF # 262). The Motion is brought by Kevin and Christin Hutchens individually and on behalf of their son Z.H. On February 2, 2017, after two weeks of trial, the jury returned a unanimous verdict for Defendants on all Plaintiffs' claims. Thereafter, on March 2, 2017, Plaintiffs moved for a new trial. For the following reasons, the Court denies Plaintiffs' Motion.

According to the First Amended Complaint, Kevin and Christin Hutchens are parents of Z.H. Z.H. was born in 2003 with a number of severe birth defects allegedly caused by Christin's use of Depakote during her pregnancy. Depakote, also known as valproic acid or valproate is an anti-seizure medication formulated, tested, manufactured and marketed by

Defendants. Depakote has been approved and sold in the United States since 1978 for the treatment of certain forms of epilepsy. Depakote is promoted as an effective anti-epileptic drug ("AED"). However, Plaintiffs alleged Depakote is defective and dangerous for its intended use because the primary compound in Depakote, valproic acid, is teratogenic (of, relating to, or causing developmental malformations) - i.e.- causes severe birth defects if taken during the first trimester of pregnancy.

According to Plaintiffs, Defendants failed to communicate the heightened risk of birth defects to doctors and women but instead sought to minimize the risks and downplay the dangers in their product labeling.

Due to Defendants' alleged breaches of their duty of reasonable care, breaches of their express and implied warranties and their misrepresentations and omissions concerning the known risks of Depakote, Plaintiffs alleged they have been injured. Z.H. was born with heart defects, hypospadias, limb defects and developmental delay, as well as other congenital malformations and birth defects as a result of Christin's use of Depakote during pregnancy.

On finding for Defendants, the jury indicated on the Jury Verdict Form that Plaintiffs failed to show by a preponderance of the evidence that Defendants provided an inadequate warning of the risks of Depakote and further failed to show by a preponderance of the evidence that Depakote was defective due to its failure to conform to the representations of Defendants.

Plaintiffs now move for a new trial, alleging the Court erred in issuing a limiting instruction that precluded the jury from considering admissible evidence on causation. Plaintiffs further argue the Court erroneously excluded admissible evidence affecting

Plaintiffs' substantial rights and provided improper instructions to the jury on the law. According to Plaintiffs, these allegedly erroneous rulings require a new trial.

**Standard of Review**

Fed. R. Civ. P. 59 provides the authority for a new trial and reads in pertinent part:

> (a) In General.
>
> (1) *Grounds for New Trial.* The court may, on motion, grant a new trial on all or some of the issues--and to any party--as follows:
>
> (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court;

"Generally courts have interpreted this language to mean that a new trial is warranted when a jury has reached a 'seriously erroneous result' as evidenced by: (1) the verdict being against the weight of the evidence; (2) the damages being excessive; or (3) the trial being unfair to the moving party in some fashion, *i.e.*, the proceedings being influenced by prejudice or bias." *Holmes v. City of Massilon, Ohio,* 78 F.3d. 1041, 1045-46 (6th Cir. 1996), citing *Montgomery Ward & Co. v. Duncan,* 311 U.S. 243, 251 (1940). "The trial court should deny such a motion if the verdict is one that reasonably could be reached, regardless of whether the trial judge might have reached a different conclusion were he the trier of fact." *Walker v. Bain,* 257 F.3d 660, 670 (6th Cir. 2001). On motions for new trial, the trial court may weigh the evidence. See *United States v. L.E. Cooke Co.*, 991 F.2d 336, 343 (6th Cir. 1993).

The Sixth Circuit has held:

> [w]hen reviewing a motion for a new trial, a court should indulge all presumptions in favor of the validity of the jury's verdict. A court should refrain from interfering with a jury's verdict unless it is clear that the jury reached a seriously erroneous result. The simple fact that the grant of a new

> trial might result in a different outcome is not a valid basis for disturbing a jury's verdict which is otherwise based upon legally sufficient evidence.

*Brooks v. Toyotomi Co., Ltd.,* 86 F.3d 582, 588 (6th Cir.1996), *abrogation on other grounds recognized by United States v. Webb,* 157 F.3d 451, 452-53 (6th Cir.1998) ( *per curiam* ), *abrogated by Dillon v. United States,* 184 F.3d 556 (6th Cir.1999). The Sixth Circuit has further admonished courts "not to set aside the verdict simply because it believes that another outcome is more justified." *Denhof v. City of Grand Rapids,* 494 F.3d 534, 543 (6th Cir. 2007).[1]

In light of the above standard of review, the Court will consider Plaintiffs' Motion.

**The Court Erroneously Excluded Evidence Contained in Scientific Studies**

Plaintiffs' first claim of error concerns the Court's ruling that scientific studies and articles considered by Plaintiffs' labeling and regulatory expert, Dr. Cheryl Blume, Ph.D, were admissible only to show that Defendants were on notice of the dangers of Depakote and not for the truth of the matters asserted in the scientific studies themselves. The Court's

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[1] This Court is also mindful of the following admonition by the Sixth Circuit:

> Where no undesirable or pernicious element has occurred or been introduced into the trial and the trial judge nonetheless grants a new trial on the ground that the verdict was against the weight of the evidence, the trial judge in negating the jury's verdict has, to some extent at least, substituted his judgment of the facts and the credibility of the witnesses for that of the jury. Such an action effects a denigration of the jury system and to the extent that new trials are granted the judge takes over, if he does not usurp, the prime function of the jury as the trier of the facts. It then becomes the duty of the appellate tribunal to exercise a closer degree of scrutiny and supervision than is the case where a new trial is granted because of some undesirable or pernicious influence obtruding into the trial. Such a close scrutiny is required in order to protect the litigants' right to jury trial. *Lee v. City of Columbus,* Ohio, No. 2:07CV1230, 2010 WL 1741335, 3 (S.D.Ohio, April 29,2010) quoting *Duncan v. Duncan,* 377 F.2d 49, 54 (6th Cir. 1967).

Instruction was as follows:

> I previously instructed you that certain evidence, including the charts presented through Dr. Blume listing certain articles or studies, could only be considered by you for purposes of notice. As I explained at that time, and now reiterate, you may only consider those charts as evidence of what Abbott should have been aware of and maybe what they should have done as a result of these studies, but not for the truth of what's contained in those studies themselves.
>
> I am now expanding that limitation to cover your consideration of the studies themselves. You may consider reports of studies, or letters to the editors of journals, or other literature references only as evidence of what was being reported, but not as evidence of the accuracy or truth of what was being reported. Otherwise, unless further restricted, you may consider Dr. Blume's remaining testimony, along with the other evidence.

(ECF # 254 at 2801:12–2802:3).

"The district court has broad discretion to determine questions of admissibility; an evidentiary ruling is not to be lightly overturned." *Decker v. GE Healthcare Inc.*, 770 F.3d 378, 396 (6th Cir. 2014). "An erroneous evidentiary ruling amounts to reversible error, justifying a new trial, only if it was not harmless; that is, only if it affected the outcome of the trial." *Id*. (Internal citations omitted).

During trial a dispute arose between the parties regarding a limiting instruction sought by Defendants on a demonstrative chart used by Plaintiffs. Plaintiffs were about to commence with the direct examination of their labeling and regulatory expert, Dr. Cheryl D. Blume Ph.D. As part of the examination, Plaintiffs wanted to use a chart listing 27 medical studies indicating that Depakote had the highest rate of congenital abnormalities when compared to other AEDs. Plaintiffs contend their claims of inadequate warnings depended upon proof of the state of the scientific knowledge at the time of Z.H.'s conception and birth. These studies demonstrated the state of the scientific knowledge at the time of Z.H's conception. According to Plaintiffs, Dr. Blume testified on these matters, however, the Court

erroneously instructed the jury it could not consider the scientific data and the studies offered by Plaintiffs through Dr. Blume for the truth of the matter asserted. Because Federal Rule of Evidence 803(18) provides a hearsay exception for learned treatises, the limiting instruction was improper and the jury should have been permitted to consider the studies for the truth of the matter - i.e. that Depakote had a higher rate of birth defects than other anti-seizure medications. Instead, the jury was instructed it could only consider such studies for purposes of notice.

Defendants objected to the use of the chart on the grounds that Plaintiffs laid no foundation for the reliability of the studies themselves. Defendants further argued the information on the demonstrative chart was hearsay and Defendants were unable to cross-examine Dr. Blume on the validity of the studies due to the large number of studies listed. The parties argued the matter to the bench as follows:

THE COURT: Mr. Strain is saying this is Rule 1006 controlled, and you're saying it's not, Mr. Sampson?

MR. SAMPSON: Yes, Your Honor.

THE COURT: And the reason you're not saying it's controlled by 1006, when you say demonstrative, in what sense?

MR. SAMPSON: In the sense that I will not be offering this summary into evidence. It is a demonstrative aid for the witness to talk through the information on it, but not to offer it.

THE COURT: But what's the purpose of you using these exhibits? What's the purpose?

MR. SAMPSON: The purpose is --
THE COURT: His scare is the truth of the matter contained therein. That's what the scare is. In
other words, the jury will infer that what they see as percentages is true. That's the concern.

MR. SAMPSON: Right. Right.

THE COURT: How do we alleviate that? If that's not your intention, how do we alleviate that for
the jury?

MR. SAMPSON: I understand your point. So she, as an expert, she will be discussing the truth of the matters within those studies, the numbers that come out of the studies. An expert may rely on hearsay in order to -- I don't know if this is hearsay because of the way that it's published treatise.

THE COURT: We have to always ask what is the evidence being used for before I can determine
hearsay. It's not automatically hearsay.

MR. SAMPSON: Sure. It is for her to be able to reflect what is in the medical literature. This is not stuff she's done. She is discussing what's in the medical literature, what does it reflect. Therefore, what does Abbott know, what is it on notice of. It's really all about notice to be honest with you. It's about what Abbott is on notice of. Abbott is on notice of --

THE COURT: I'll allow it with that instruction to the jury, used only for notice, and nothing further than that.

MR. SAMPSON: Okay.

(ECF # 228 (pg 831-32.)

Thus, based on Plaintiffs' counsel's representation that the demonstrative chart was used to show notice to Abbott, the Court issued the limiting instruction to the jury. Plaintiffs did not object to the instruction at that time. Defendants point to Plaintiffs' representation to the Court at a sidebar wherein Plaintiffs represented to the Court that they intended to object to a portion of Defendants' cross-examination of Dr. Blume for going beyond notice as proof that both parties agreed the studies were to be considered for notice only. Because the Court instructed the jury that it could only consider the demonstrative chart for notice purposes based on Plaintiffs' representation that they were offered for notice, Defendants contend Plaintiffs' challenge to the Court's limiting instruction on the chart fails.

Having considered the evidence and arguments, the Court finds Plaintiffs claim fails

because the Court's instruction was based on Plaintiffs' own representation on the purpose of the chart. Plaintiffs were permitted to use the chart for the purpose of which Plaintiffs intended; that being notice. Plaintiffs cannot now complain that the jury was prejudiced by an instruction that reiterated Plaintiffs' own stated purpose for the chart.

Plaintiffs' next challenge the Court's expanded instruction that the studies themselves as listed in the chart could not be considered for the truth of the matter asserted -i.e. the conclusions of the studies- but instead limited the jury's consideration of the studies to what Abbott knew was being reported on the effects of Depakote in the studies. According to Plaintiffs, this limiting instruction prohibited the jury from considering any studies which concluded that Depakote carried a higher risk of birth defects than other AEDs. According to Plaintiffs, this crippled their case because the jury was later instructed that on a strict product liability claim based on inadequate warnings or instructions " a manufacturer need not instruct or warn unless and until the state of medical, scientific, and technical research and knowledge has reached a level of development that would make a reasonably prudent manufacturer aware of the unreasonable risks of harm created by the product and aware of the necessity to instruct or warn against such risks of harm." (ECF # 254 pg. 2806). With the Court's instruction that the jury could not consider the truth of the conclusions of the studies, that Depakote posed a higher risk of birth defects than other AED's, the jury was prohibited from considering the key evidence in Plaintiffs' case.

Furthermore, Plaintiffs contend their fraud claim was similarly hamstrung by the Court's limiting instruction. To prove fraud, Plaintiffs had to demonstrate that Defendants made a knowingly false representation on the label of Depakote. By limiting the jury's

consideration of the truth of the conclusions of the scientific studies discussed by Plaintiffs' witnesses, the Court improperly excluded competent evidence that Defendants' representations were indeed false. In fact, Dr. Blume laid an adequate foundation for the studies under Rule 803(18) such that the studies themselves should have been presented to the jury for their truth.

Defendants contend the Court's added instruction that the jury could not consider the studies for the truth of the matter asserted applied only to Dr. Blume's testimony discussed by her as listed in her demonstrative chart. In fact, the Court's limiting instruction expressly stated the jury could consider Dr. Blume's remaining testimony along with other evidence. During their closing remarks, Plaintiffs recapped fact and expert witness testimony about the studies listed on Dr. Blume's chart regarding Depakote's higher birth defect rate. Thus, Plaintiffs presented substantial evidence of Depakote's greater teratogenicity relative to other AEDs. Furthermore, Defendants point out that Plaintiffs only objected to the limiting instruction after deliberations had commenced.

Defendants further argue Plaintiffs' Motion should be rejected under the doctrine of invited error because Plaintiffs informed the Court they intended the studies to be used only for notice. Therefore, even if the Court's instruction were legally incorrect, it was due to Plaintiffs' own representation on the purpose of Dr. Blume's testimony concerning the chart.

Lastly, Defendants oppose Plaintiffs motion because Plaintiffs failed to timely object to the instructions. No formal objection was made when the Court gave the limiting instruction on notice. Plaintiffs' only post-deliberation objection on the expanded limiting instruction reads as follows: "So there was an instruction on Dr. Blume regarding evidence

for notice purposes only. Plaintiffs object that that should not have been included." (ECF #258 pg.2937). According to Defendants, this vague objection does not concern the use of all learned treatises and cannot form the basis for an objection to the same as it fails to preserve the point, concerns the purpose to which Plaintiffs had already consented and did not mention the Court's handling of other evidence and fails to acknowledge six other instructions on the handling of evidence. Because no specific objection was made, Defendants contend the Court's standard of review must be a plain error review and under such review, Plaintiffs' objection fails.

Upon review, the Court denies Plaintiffs' Motion based on the Court's expanded limiting instruction. The Court's instruction clearly applied only to the studies listed in the demonstrative chart by Dr. Blume. The expanded instruction reads:

> I am now expanding ***that limitation*** to cover your consideration of ***the studies*** themselves. You may consider reports of studies, or letters to the editors of journals, or other literature references only as evidence of what was being reported, but not as evidence of the accuracy or truth of what was being reported. Otherwise, unless further restricted, you may consider ***Dr. Blume's remaining testimony***, along with the other evidence. (Emphasis added).

The highlighted portions clearly reference the studies listed in the demonstrative chart of Dr. Blume. "That limitation" refers to the limiting instruction on the demonstrative chart listing 27 studies. It is these 27 studies that the Court then refers to as "the studies themselves." The Court's instruction further evidences the previous limiting instruction regarding the 27 studies testified to by Dr. Blume by instructing the jury they could consider Dr. Blume's remaining testimony along with other evidence.

However, even if the Court were to find the instruction unclear as to what the jury could consider, the jury heard ample evidence that Depakote presented a higher risk of birth

defects as compared to other AED's. "A district court's error 'with respect to the admission of evidence is subject to harmless error analysis, and it is well settled that an error which is not of a constitutional dimension is harmless unless it is more probable than not that the error materially affected the verdict.'" *United States v. Logan*, 542 F. App'x 484, 494 (6th Cir. 2013) quoting *United States v. Davis*, 577 F.3d 660, 670 (6th Cir.2009). For instance, the jury heard testimony from Dr. Foldvary-Schaefer, Christin's treating physician, that the medical literature at the time demonstrated Depakote was more teratogenic than other AEDs. ( ECF # 228 pg 784-85). Dr. Foldvary-Schaefer also testified that, prior to her treatment of Christin in 2002, she reviewed 196 studies on the risks of birth defects associated with the use of AEDs before writing a chapter and article on treatment issues for women with epilepsy. Dr. Foldvary-Schaefer testified she prescribed Christin Depakote based on Dr. Foldvary-Schaefer's own knowledge of the drug taken from the current studies. (*Id*.at 787). Plaintiffs also presented the testimony of Dr. Tracey Heimberger, director of medical services and post-marketing safety director for Defendants. Heimberger testified that Defendants were aware in 2002 that the Holmes study showed higher rates of birth defects from valproic acid than other AEDs. (ECF # 234 pg ID 9745). She discussed the Holmes study abstract, acknowledged it was sent to her via email, thus its information was known to Defendants in 2002 and discussed its data and findings along with Defendants' response to the same. (*Id* at 9749-54). Dr. Charles Schwamlein, M.D., former chief epidemiologist with Defendants, testified that the NAEED registry showed that Depakote had a higher rate of birth defects than other AEDs as follows:

Q: And you would agree, then, that the result of the NAAED study was that, when compared as a group, to the other drugs as a group, that valproate was significantly higher risk for birth

defects?

A. It had a higher rate of birth defects. (ECF # 221 pg549).

Dr. Schwamlein discussed the August 2002 Holmes/ Wyszynski letter and the 2005 Wyszynski report, both of which evidenced that Depakote showed increased birth defects as compared to other AEDs. (*Id* at 552-557). Dr. Schwamlein's testimony was not subject to the limiting instruction given for Dr. Blume's testimony. In fact, none of the testimony of Drs. Foldvary-Schaefer, Heimberger or Schwamlein were subject to the limiting instruction. Finally, Dr. Blume testified extensively on the greater teratogenicity of Depakote when compared to other AEDs as was reflected in the medical literature at the time of Z.H.'s conception. Thus, the jury heard ample evidence of the Depakote's greater teratogenicity from several witnesses, including some who worked for Defendants, such as Dr. Michael Jarvis, who testified Defendants were aware of the data in studies showing Depakote's greater teratogenicty relative to other AEDs (ECF # 237 pg. 2115, 2133-34). Yet, the jury obviously rejected Plaintiffs' theory of the case. Therefore, even if the instruction were erroneous, which the Court believes it was not, Plaintiffs were able to present to the jury ample evidence of Depakote's greater teratogenicity as compared to other AEDs and the jury still found for Defendants. Plaintiffs simply cannot show prejudice to their case.

The jury also heard from Dr. Foldvary-Schaefer that she warned Plaintiffs about the dangers and instructed Christin to talk with her before Christin became pregnant. The next time Christin visited Dr. Foldvary-Schaefer she was already several weeks pregnant. Furthermore, the jury also heard that Christin had already tried several other AED's, none of which were effective in controlling her seizures. Depakote, on the other hand, effectively

controlled her seizures, a fact evidenced by Christin's continued use of Depakote long after Z.H.'s birth. These all were factors weighed by the jury in arriving at their conclusion wholly apart from, and unaffected by, the Court's limiting instruction.

Therefore, for all the foregoing reasons, the Court denies Plaintiffs' Motion for New Trial based on the limiting instructions.

**The Court's Exclusion of Certain Medical Records**

According to Plaintiffs, they attempted to introduce into evidence the impressions of Z.H.'s treating geneticist, Dr. Laura Konczal, concerning the likely cause of Z.H.'s developmental and medical problems as Depakote exposure. The statements made by Dr. Konczal, a geneticist who examined Z.H. approximately six years after his birth, relates to the cause of his birth defects. In her patient notes of August 5, 2009, Dr. Konczal wrote: "I agree with Dr. Zinn's initial assessment that the most likely cause of all of or at least many of Z.H.'s developmental and medical problems as well as his dysmorphic facial features is the exposure to Depakote (valproate) as a developing embryo/fetus. Therefore, the most likely diagnosis for Z.H. is fetal valproate syndrome." (ECF # 229-1 pg ZHOO1897). Upon objection by Defendants that the medical records contained embedded hearsay of undisclosed experts, the Court excluded portions of Plaintiffs' medical records. According to Plaintiffs, this exclusion was harmful legal error because they had disclosed Dr. Konczal as a fact witness in 2014, thus negating Defendants' 'failure to disclose" argument. Defendants were on notice that Dr. Konczal was a fact witness and could have deposed her but did not.

Furthermore, the parties stipulated that the medical records were business records which qualified them as an exception to the hearsay rule. Other experts relied on Dr.

Konczal's medical records in forming their opinions as medical records are the type of records reasonably relied on by experts. Plaintiffs did have causation experts but argue that the best evidence was the excluded portion of Z.H.'s geneticists records, including Dr. Zinn and Dr. Konczal, both of whom treated Z.H. While the Court admitted into evidence some of their records, the excluded portion represented Dr. Konczal's final impression after years of testing, study and analysis. Excluding those portions severely hampered Plaintiffs' case, warranting a new trial. Furthermore, Defendants' own experts relied on the records in reaching their own conclusions.

Defendants counter that although medical records themselves may fall under Rule of Evidence 803 exceptions to hearsay, the contents of those records are still subject to evidentiary scrutiny. The Court properly excluded three lines of causation hearsay from the medical records because they constituted "embedded hearsay." Defendants further objected that Plaintiffs never disclosed Drs. Konczal and Zinn as experts in their initial disclosures, thus depriving Defendants of the opportunity to cross-examine them. Furthermore, as geneticists, Drs. Zinn and Konczal were not qualified to diagnose the cause of Z.H.'s birth defects beyond ruling out genetic causation. The Court properly excluded the evidence based on Rule 403 that the prejudice to Defendants outweighed the evidences probative value. Lastly, even if the exclusion were error, that error was harmless as Plaintiffs were able to present to the jury substantial causation evidence, including diagnoses from Z.H's. treating physicians and Plaintiffs' causation expert. Defendants contend that in spite of all this evidence the jury never reached the causation issue because its interrogatories clearly demonstrate the jury found against Plaintiffs on the failure to warn and loss of consortium

claims and fraud claims.

Having reviewed the arguments, trial transcripts and supporting materials, the Court finds its exclusion of the causation statements contained in Dr. Konczal's records was not error. In their Initial Disclosures of May 2014, Plaintiffs identified Dr. Konczal and Dr. Zinn as healthcare providers of Z.H. Plaintiff never identified either geneticist as an expert. On the record, after arguments by both sides, the Court excluded the Depakote causation opinions of Dr. Zinn and Dr. Konczal in the medical records. The Court excluded them for multiple reasons, including that the opinions were presented after the expert disclosure cut off date and therefore, Defendants were unable to timely depose. The records themselves were hearsay within hearsay and the conclusions went beyond both physicians' expertise and the probative value was substantially outweighed by the prejudice to Defendants. Finally, the Court determined the exclusion did not affect Plaintiffs' evidence in the case regarding causation. (ECF # 264-10 pg 1016).

The Court determined that Drs. Konczal and Zinn were geneticists, not teratologists and thus, were not qualified to opine on the cause of Z.H.'s birth defects resulting from Depakote exposure in utero.

The Court ultimately determined exclusion was proper because the probative value of the three lines in the record relating to Depakote as a possible cause of Z.H.'s birth defects were substantially outweighed by the prejudice to Defendants. The statements themselves were speculative in nature. For instance, in Dr. Konczal's Note from July 2, 2009 she wrote, " It was suspected at that time (Dr. Zinn's evaluation of Z.H. when Z.H. was ten months old) that many of Z.H.'s delays, medical problems and his dysmorphic facial features were related

to exposure to Depakote in utero." This does not qualify as a diagnosis but merely a hypothesis that required further exploration. Dr. Konczal then writes, "I agree with Dr. Zinn's initial assessment that the most likely cause of all of or at least many of Z.H.'s developmental and medical problems as well as his dysmorphic facial features is the exposure to Depakote (valproate) as a developing embryo/fetus. Therefore, the most likely diagnosis for Z.H. is fetal valproate syndrome." However, that characterization exceeds what Dr. Zinn actually concluded. The speculative nature of this conclusion is supported by Dr. Konczal later in her July 2009 Notes wherein she wrote, "At this point, (2009) while it is possible that fetal exposure to Depakote may be the main cause of his developmental and medical problems, it remains a diagnosis of exclusion and additional testing is warranted." Given the highly speculative nature of Dr. Konczal's conclusions, the Court determined these statements' prejudicial value substantially outweighed their probative value, particularly in light of the substantial evidence of Depakote exposure as the cause of Z.H's birth defects presented by Z.H.'s treating physicians, neurologists and experts. The jury heard ample evidence ruling out a genetic cause to Z.H.'s medical issues and ample evidence on causation relating to Depakote exposure from numerous expert and treating physicians. Even if error, such error was harmless in light of all the above.

**Ommission of Plaintiffs' Proposed Jury Instructions on the Adequacy of Warnings**

Plaintiffs offered a jury instruction entitled "Adequacy of a Prescription Drug Label" that included the instruction that "a warning may be unreasonable in its factual content, its expression of the facts, or the method or form in which the warning is conveyed...Merely

mentioning a possible injury or adverse effect is not necessarily adequate." According to Plaintiffs, by omitting this proposed instruction the jury was not adequately informed that a warning label may be unreasonable in its factual content or expression of the facts of method of conveying those facts.

Defendants contend the Court's instruction largely tracks the Ohio pattern instruction on failure to warn and properly presents Ohio law.

"A district court's refusal to give a jury instruction constitutes reversible error if (1) the omitted instruction is a correct statement of the law, (2) the instruction is not substantially covered by other delivered charges, and (3) the failure to give the instruction impairs the requesting party's theory of the case." *Decker*, 770 F.3d at 396. The "inquiry into jury instructions is limited to whether, taken as a whole, the instructions adequately inform the jury of the relevant considerations and provide the jury with a sound basis in law with which to reach a conclusion." *Troyer v. T.John.E. Prods., Inc.*, 526 F. App'x 522, 525 (6th Cir. 2013). "Jury instructions are proper if, as a whole, they 'fairly and adequately submitted the issues and applicable law to the jury.'" *Id.* quoting *Arban v. West Publ'g Corp.*, 345 F.3d 390, 404 (6th Cir.2003).

Plaintiffs proposed the following jury instruction on the Adequacy of a Prescription Drug Label:

> The adequacy of a prescription drug's warnings and instructions is measured not only by the content of what is stated, but also by the manner in which it is stated and the method or delivery of the warnings and instructions. A warning may be unreasonable in its factual content, its expression of the facts, or the method or form in which the warning is conveyed. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity required by the nature of the risk. Merely mentioning a possible injury or adverse effect is not necessarily adequate.

Rejecting Plaintiffs' proposed instruction, the Court instead used the following instruction:

> A prescription drug is defective due to inadequate warnings or instructions if, at the time the prescription drug left the control of the manufacturer, both (1) the manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the prescription drug and that allegedly caused the Plaintiffs' harm; and (2) the manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the prescription drug would cause harm of the type claimed by the Plaintiffs and in light of the likely seriousness of that harm.
>
> A prescription drug manufacturer is held to the skill of an expert in their business and to an expert's knowledge of the arts, materials, and processes involved in the development, production, and marketing of the product. The manufacturer has the duty to remain reasonably current with scientific knowledge, development, research, and discoveries concerning the product. However, a manufacturer need not instruct or warn unless and until the state of medical, scientific, and technical research and knowledge has reached a level of development that would make a reasonably prudent manufacturer aware of the unreasonable risks of harm created by the product and aware of the necessity to instruct or warn against such risks of harm.
>
> A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.
>
> A prescription drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that prescription drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that prescription drug is to be given directly to the ultimate user of it.
>
> When a prescription medicine label is inadequate, there is a presumption that the prescribing physician would have heeded a different, adequate warning. However, this presumption does not apply if the evidence shows that a different warning would not have changed the physician's decision to prescribe the medicine.

The Court's instruction largely tracked the Ohio Pattern Jury Instruction 451.07, which reads:

> A product is defective due to an inadequate warning or instruction if:

(A) when the product left the control of its manufacturer, both

(1) the manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused the plaintiff's harm; and

(2) the manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type claimed by the plaintiff and in light of the likely seriousness of that harm;

(1) the manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused the plaintiff's harm; and

(2) the manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type claimed by the plaintiff and in light of the likely seriousness of that harm.

MANUFACTURER'S STANDARD OF CARE/KNOWLEDGE. One who manufactures a product for sale is held to the skill of an expert in that business and to an expert's knowledge of the arts, materials, and processes involved in the development, production, and marketing of the product. The manufacturer has the duty to remain reasonably current with scientific knowledge, development, research, and discoveries concerning the product. The manufacturer must communicate its superior knowledge to those who, because of their own limited knowledge and information, would otherwise be unable to protect themselves. However, a manufacturer need not instruct or warn (regarding the use of its product) unless and until the state of medical, scientific, and technical research and knowledge has reached a level of development that would make a reasonably prudent manufacturer aware of the unreasonable risks of harm created by the product and aware of the necessity to instruct or warn (ordinary users of the product) against such risks of harm.

OJI CV 451.07 Statutory failure to warn R.C. 2307.76.

The Sixth Circuit has held, "a trial court has broad discretion in crafting jury instructions and does not abuse its discretion unless the jury charge 'fails accurately to reflect the law.'" *United States v. Geisen*, 612 F.3d 471, 485 (6th Cir. 2010). Here, the Court's jury instruction tracked Ohio's Pattern Jury Instruction for O.R.C. 2307.76, which is the Ohio statute for failure to warn. O.R.C. 2307.76 reads:

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate

warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

(C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code Ann. § 2307.76 (West)

When comparing the relevant Ohio law to the Court's jury instruction, it is clear the Court's instruction accurately reflects Ohio law on the adequacy of the warning on a drug label and was not erroneous.

Therefore, for the foregoing reasons, the Court denies Plaintiffs' Motion for New Trial.

IT IS SO ORDERED.

s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge

Dated: November 22, 2017