UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Z.H. by and through KEVIN HUTCHENS AND CHRISTIN HUTCHENS, individually, and as parents and next friends of Z.H.,	)	**CASE NO. 1:14CV176**
	)	**JUDGE CHRISTOPHER A. BOYKO**
Plaintiffs,	)	
vs.	)	**ORDER**
ABBOTT LABORATORIES, INC. and ABBVIE, INC.,	)	
Defendants.	)	

CHRISTOPHER A. BOYKO, J.:

This matter comes before the Court upon various Motions in Limine filed by both Plaintiffs and Defendants. (ECF DKT #94, #95, #98, #99, #101 and #120).

I. INTRODUCTION

Plaintiff Z.H. is a minor child who suffers from serious birth defects. Z.H.'s injuries were allegedly caused by *in utero* exposure to Depakote, an anti-epileptic drug prescribed to his mother, Christin Hutchens. Plaintiffs allege that Defendants, Abbott Laboratories, Inc. and Abbvie, Inc. ("Abbott") failed to provide adequate warnings regarding the risk of birth defects associated with Depakote use.

II. LAW AND ANALYSIS

Motions in Limine

"Motions in Limine are generally used to ensure evenhanded and expeditious management of trials by eliminating evidence that is clearly inadmissible for any purpose." *Indiana Insurance Co. v. General Electric Co.*, 326 F.Supp. 2d 844, 846 (N.D.Ohio 2004) (citing *Jonasson v. Lutheran Child and Family Serv.*, 115 F.3d 436, 440 (7th Cir.1997)). A "motion *in limine*, if granted, is a tentative, interlocutory, precautionary ruling by the trial court reflecting its anticipatory treatment of the evidentiary issue . . . the trial court is certainly at liberty '* * * to consider the admissibility of the disputed evidence in its actual context.'" *State v. Grubb*, 28 Ohio St.3d 199, 201-202 (1986) (citing *State v. White*, 6 Ohio App.3d 1, 4 (1982)). "Indeed, even if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous in limine ruling." *Luce v. United States*, 469 U.S. 38, 41 (1984).

The Sixth Circuit has instructed that the "better practice" is to address questions regarding the admissibility of broad categories of evidence "as they arise." *Sperberg v. Goodyear Tire & Rubber Co.*, 519 R.2d 708, 712 (6th Cir. 1975). "[A] court is almost always better situated during the actual trial to assess the value and utility of evidence." *Owner-Operator Independent Drivers Ass'n v. Comerica Bank*, No. 05-CV-0056, 2011 WL 4625359, at *1 (S.D.Ohio Oct.3, 2011). It is noteworthy that denial of a motion in limine does not necessarily mean that the evidence, which is the subject of the motion, will be admissible at trial. *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F.Supp. 2d 844, 846 (N.D.Ohio 2004).

Fed.R.Evid. 401 defines relevant evidence as evidence tending to make the existence

of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. Moreover, Fed.R.Evid. 402 provides that evidence that "is not relevant is not admissible."

With these precepts in mind, and upon consideration of the parties' briefs and arguments, the Court rules as follows:

PLAINTIFFS' MOTION IN LIMINE TO EXCLUDE EVIDENCE, ARGUMENT AND TESTIMONY REGARDING ANY ALLEGED NEGLIGENCE OR FAULT OF CHRISTIN HUTCHENS AND/OR CHRISTIN AND KEVIN HUTCHENS' PRE-PREGNANCY KNOWLEDGE OF RISKS (ECF DKT #94)

Plaintiffs anticipate that Abbott will encourage the jury to blame the mother for taking Depakote and getting pregnant, when the issue before the fact-finder should be whether Abbott's warnings, owed to the mother's physicians, of Depakote's side effects were inadequate.

Defendants respond that they do not intend to blame Mrs. Hutchens for Z.H.'s injuries. However, Abbott argues that what Dr. Nancy Foldvary told Mr. and Mrs. Hutchens, what Mr. and Mrs. Hutchens knew about the teratogenic risks of Depakote, and the decisions they made in the face of that knowledge, are relevant to proximate causation.

In a failure to warn case, a plaintiff must demonstrate proximate cause, that is: (1) whether lack of adequate warnings contributed to plaintiff's ingestion of the drug, and (2) whether ingestion of the drug constitutes a proximate cause of plaintiff's injury. *Fulgenzi v.*

PLIVA, 711 F.3d 578, 587 (6th Cir. 2013), citing *Seley v. G.D. Searle & Co.*, 67 Ohio St.2d 192, 200 (1981).

Therefore, Plaintiffs' Motion (ECF DKT #94) is GRANTED IN PART AND DENIED IN PART. Christin and Kevin Hutchens' pre-pregnancy knowledge of risks is relevant to the element of proximate cause; however, Abbott will not be permitted to use evidence, argument or testimony of such knowledge to blame Christin or suggest that she was negligent in any way.

PLAINTIFFS' MOTION IN LIMINE TO EXCLUDE EVIDENCE, ARGUMENT AND TESTIMONY REGARDING ANY ALLEGED NEGLIGENCE OR FAULT OF CHRISTIN HUTCHENS' PRESCRIBING PHYSICIANS (ECF DKT #95)

Plaintiffs request that the Court preclude Defendants from introducing any evidence, references, inferences, testimony, documents or argument, whether at voir dire or during trial, that suggest that Christin Hutchens' physicians were negligent in prescribing Depakote.

Defendants respond that their experts do not opine that any prescribing physicians' actions fell below any applicable standard of care; and Defendants confirm that they have no intention of offering evidence or argument, or otherwise asserting, that the medical care provided to Mrs. Hutchens by any of the physicians who prescribed her Depakote failed to satisfy any applicable standard of care.

Therefore, the Plaintiffs' Motion (ECF DKT #95) is GRANTED.

DEFENDANTS ABBOTT LABORATORIES INC. AND ABBVIE INC.'S MOTION IN LIMINE (NO. 1) TO EXCLUDE EVIDENCE, TESTIMONY OR ARGUMENT ABOUT POST-CONCEPTION LABELING AND REGULATORY COMMUNICATIONS (ECF DKT #98)

At the time that Z.H. was conceived in November 2002, the Depakote labeling included a "black box" warning and a 10-paragraph warning about the risk of birth defects.

The Depakote label was revised in 2006 to include the results of a study by the North American Antiepileptic Drug Pregnancy Registry, which began gathering data in 1997 and which published its results in 2005. The Registry found that the risk of all birth defects associated with the use of Depakote was approximately four times higher than the risk associated with the risk associated with the group of all other antiepileptic drugs studied.

Abbott requested a label change in 2009 to add warnings regarding developmental delay. In 2011, the FDA gave official approval to revise the label accordingly.

In 2013, the Depakote label was further amended to provide stronger warnings about use during pregnancy and to acknowledge the results of the Neurodevelopmental Effects of Antiepileptic Drugs ("NEAD") study. The results showed that children exposed to valproate *in utero* had decreased IQ's at age six compared to children exposed to other AED's.

In their Motion, Defendants insist that FDA-approved Depakote product labeling that post-dates Z.H.'s conception in 2002 and the regulatory communications supporting that labeling are irrelevant, prejudicial and inadmissible as subsequent remedial measures under Fed.R.Evid. 407.

Plaintiffs represent that they will not introduce any post-conception Depakote labels to prove negligence, culpable conduct, a defect in the product or its design, or a need for a warning or instruction. (ECF DKT #138 at 3). However, Plaintiffs object to excluding vaguely-described regulatory communications; and anticipate that instances may arise at trial requiring the introduction of post-2003 Depakote labeling for permissible purposes under Fed.R.Evid. 407. Plaintiffs do not offer any clarification of what these "permissible instances" might be.

The Court GRANTS Defendants' Motion (ECF DKT #98) to exclude references to post-conception labeling and post-conception communications with the FDA as irrelevant and prejudicial. The Court reserves the right to re-visit this ruling during trial if Plaintiffs can demonstrate relevance and a permissible purpose under the Evidence Rules.

DEFENDANTS ABBOTT LABORATORIES INC. AND ABBVIE INC.'S MOTION IN LIMINE (NO. 2) TO EXCLUDE EVIDENCE, TESTIMONY, ARGUMENT AND REFERENCES ABOUT FOREIGN LABELING (ECF DKT #120)

Medications containing valproic acid, the active ingredient in Depakote, are distributed throughout the world. Defendants anticipate that Plaintiffs will attempt to introduce foreign product labels and documentation for medicines that Dr. Foldvary did not prescribe for Mrs. Hutchens. Defendants argue that these other medicines are subject to laws, regulations and standards unique to other countries. Also, the wording on labels that is approved or required elsewhere in the world has no relevance to the adequacy of the FDA-

approved warnings that accompanied Depakote in 2002.

Plaintiffs affirm that they will not offer evidence of foreign labels to show that Abbott failed to comply with another countries' drug regulations nor to suggest that Depakote's warning was inadequate because it did not mirror its foreign counterparts.

Under Ohio law, the adequacy of Defendants' label is determined by the risks Abbott knew or should have known. Evidence of foreign labeling, prior to Z.H.'s conception, is relevant to Abbott's knowledge of the risks of Depakote. The probative value is not outweighed by the prejudice to Defendants. Furthermore, the Court will not allow mini-trials on foreign laws and regulatory decisions; so, Abbott's fear of undue delay or protracted proceedings should be allayed.

Thus, Defendants' Motion (ECF DKT #120) is DENIED.

DEFENDANTS ABBOTT LABORATORIES INC. AND ABBVIE INC.'S MOTION IN LIMINE (NO. 3) TO PRECLUDE DR. IRA T. LOTT, M.D. FROM TESTIFYING THAT DEPAKOTE CAUSES OR CAN CAUSE MICROCEPHALY (ECF DKT #99)

Defendants move to exclude testimony from Ira T. Lott, M.D. that Depakote can cause the birth defect microcephaly or caused Plaintiff Z.H. to be born with microcephaly. Defendants point out that Dr. Lott testified at deposition that he does not intend to provide any affirmative causation opinions in this case. Moreover, in neither of Dr. Lott's reports does he opine regarding Depakote's capacity to cause microcephaly (general causation) or that Depakote caused Z.H.'s microcephaly (specific causation).

In response, Plaintiffs represent that they do not intend to have Dr. Lott testify that Depakote causes microcephaly or caused Z.H. to be born with microcephaly. (ECF DKT #141 at 2).

Therefore, Defendants' Motion (ECF DKT #99) is GRANTED.

DEFENDANTS ABBOTT LABORATORIES INC. AND ABBVIE INC.'S MOTION IN LIMINE (NO. 6) TO EXCLUDE REFERENCES TO PROMOTIONAL ACTIVITIES, PROMOTIONAL MATERIAL AND SALES AND MARKETING PRACTICES (ECF DKT #101)

Defendants ask the Court to preclude Plaintiffs from presenting argument, testimony and evidence regarding Abbott's promotional activities, distribution of promotional materials and sales and marketing practices related to Depakote. Defendants argue that there is no evidence that promotional activities impacted the prescribing decisions of Dr. Foldvary, Plaintiff Christin Hutchens' neurologist leading up to and during her pregnancy with Z.H. Also, Defendants argue that use of such evidence would only serve to improperly portray Abbott in a bad light – i.e., as a company more concerned with marketing, sales and profits than patient safety. Evidence of promotional activities, in Defendants' view, would result in unfair prejudice, confusion and wasted time.

Plaintiffs respond that evidence of Abbott's promotional activities is relevant to their failure-to-warn claim. It is relevant to what Abbott knew about Depakote's risks and Depakote's proper use for women of childbearing years.

The Court agrees with Plaintiffs' contentions as to marketing efforts pre-dating Z.H.'s birth only. Abbott's promotional, sales and marketing evidence is relevant to what Abbott knew or should have known – an element of a failure-to-warn cause of action. Abbott's marketing efforts and strategies, in light of Abbott's knowledge of Depakote's risks, are also relevant to Plaintiffs' claim for a punitive damages award. This evidence could serve to demonstrate a conscious disregard for the safety of patients taking Depakote and their babies who may be exposed *in utero*.

Therefore, Defendants' Motion (ECF DKT #101) is DENIED as to promotional activities pre-dating Z.H.'s date of birth.

IT IS SO ORDERED.

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

Dated: January 5, 2017