

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS**

E.G., a minor, by CHRISTINA RAQUEL, individually and as parent and next friend of E.G.,)	
)	
)	Case No. 15-cv-702-NJR-SCW
)	
Plaintiffs,)	TRIAL DEMANDED
)	ON ALL COUNTS
)	
v.)	
)	
ABBOTT LABORATORIES INC.,)	
)	
Defendant.)	

**DEFENDANT’S RULE 50(a) MOTION FOR JUDGMENT
AS A MATTER OF LAW AT THE CLOSE OF EVIDENCE
WITH SUPPORTING BRIEF**

Abbott’s oral motion for judgment at the close of Plaintiffs’ case on June 5, 2017, and its written Motion for Judgment as a Matter of Law filed on June 6, 2017 (Doc. 301), identified multiple grounds on which the Court should grant judgment as a matter of law for Abbott. None of the evidence admitted during Abbott’s defense provides legally sufficient proof remedying the deficiencies in Plaintiffs’ case raised in the First Motion for JMOL. If anything, that evidence strengthened the grounds Abbott asserts. It is still the case that “a reasonable jury would not have a legally sufficient evidentiary basis” to find for Plaintiffs under Fed. R. Civ. P. 50(a):

- Abbott’s warnings to Ms. Raquel’s prescribing physicians about the risk of spina bifida still were adequate as a matter of law.
- It is still the case that no legally sufficient evidence supports a finding that Abbott negligently failed to warn about birth defects other than spina bifida, but in any case, any inadequacy in those warnings is irrelevant to Plaintiffs’ claim based on spina bifida.
- Plaintiffs still have no legally sufficient evidence that any alleged inadequacy in the warnings was a substantial factor in causing E.G.’s injuries. Neither Dr. Meer’s nor Ms. Raquel’s testimony provides that evidence—if anything, their testimony

strengthens the conclusion that different warnings would not have changed the outcome.

- It is still the case that no reasonable jury could find that Plaintiffs have shown by clear and convincing evidence that Abbott's conduct amounted to malice, oppression, or fraud, or that any conduct they claim is blameworthy caused E.G.'s injuries. In fact, Abbott's evidence reinforces the conclusion that an award of punitive damages in this case would violate California substantive law and federal due process.

At the close of evidence, Plaintiffs' still have failed to submit legally sufficient evidence that (1) Abbott knew or reasonably should have known that Depakote was dangerous or unreasonably dangerous when prescribed by physicians in a reasonable foreseeable manner; (2) Abbott knew or reasonably should have known of the danger; (3) Abbott failed to adequately warn Ms. Raquel's prescribing physicians of the danger or instruct on the safe use of Depakote; (4) a reasonably prudent manufacturer under the same or similar circumstances would have warned of the danger or instructed on the safe use of Depakote; and (5) Abbott's alleged failure to warn was a substantial factor in causing E.G.'s injuries. Plaintiffs' proof is also legally insufficient to prove that one or more officers, directors, or managing agents of Abbott committed, authorized, or knew of and adopted and approved conduct constituting "malice," "fraud," or "oppression," as defined by California law, or that any such conduct or action was a substantial factor in causing E.G.'s injuries.

ARGUMENT

For the sake of brevity and clarity, rather than repeat the points and legal authorities set forth in Defendant's Rule 50(a) Motion for Judgment as Matter of Law With Supporting Brief (Doc. 301) ("First JMOL Motion."), Abbott renews, reasserts, and incorporates by reference (1) that motion and the exhibits to it; (2) the oral argument its counsel presented in support of that motion judgment on June 5, 2017; and (3) the oral argument presented by its counsel in support

of this motion on June 6, 2017. Abbott files this motion without waiving, and instead while preserving, each previously stated or argued ground on which the Court should enter judgment.¹

I. No reasonable jury could find that Abbott failed to act in a reasonably prudent manner in providing warnings to Ms. Raquel’s prescribing physicians.

Abbott incorporates and reasserts the arguments, authorities, and evidence set out at pp. 2-6 (subsections I(A)-(C)) in its First JMOL Motion. No evidence admitted during Abbott’s defense demonstrates any inadequacy in Abbott’s spina bifida warning or Abbott’s warnings about other birth defects. Rather, that evidence did nothing but make clearer the failure of Plaintiffs to present evidence from which a jury could conclude that Abbott failed in any way to provide reasonable and adequate warnings to physicians.

II. Plaintiffs failed to proffer legally sufficient evidence that any different warning proposed by them would have prevented E.G.s prenatal exposure to Depakote.

Abbott incorporates and reasserts the arguments, authorities, and evidence set out at pp. 6-10 (subsections II(A)-(B)) in its First JMOL Motion. None of the evidence admitted in Abbott’s defense would permit a reasonable juror to conclude that different warnings would have prevented E.G.’s prenatal exposure to Depakote. Rather, the evidence admitted during that portion of the trial undermines Plaintiffs’ arguments on this score.

All four of Ms. Raquel’s prescribers—including now Dr. Meer, the last of the four whose testimony was presented—have testified that they were aware of the teratogenic effects of Depakote when they prescribed it to Ms. Raquel. (Ex. I, 2/10/16 Deposition of Sadou Meer played on 6/6/17 (“Meer Dep.”) 26:12-17; *see* discussion and exhibits cited at p.7 of Abbott’s

¹ New exhibits filed with the present motion (Exs I-K) are attached hereto. Exhibits attached to Abbott’s First Motion for JMOL (Exs. A-H; Doc. Nos. 301-1 through 301-7) are not reattached to this motion, but are incorporated herein by reference.

First JMOL Motion.) That alone is a sufficient ground to grant Abbott judgment as a matter of law on Plaintiffs' negligent failure to warn claim.

Dr. Meer's testimony also confirms that Plaintiffs have no legally sufficient evidence that different warnings more likely than not would have prevented E.G.'s prenatal exposure to Depakote. Dr. Meer re-prescribed Depakote for Ms. Raquel on February 10, 2006 when Ms. Raquel complained that she was not doing well on Tegretol and "wanted to be restarted on the Depakote," because she "felt normal on that medication." (Ex. I, Meer Dep. at 18:22-23:25, 20:2-11, 21:14-21:21.) Dr. Meer, like the other three prescribers, did not testify that she would not have prescribed Depakote for Ms. Raquel had she been given different warnings, including a warning about the 10% overall risk Plaintiffs rely on. Plaintiffs could have asked Dr. Meer at her deposition whether this information or any other different warnings or information would have made a difference, or called her live at trial to ask those questions. They did not, and this failure precludes them from demonstrating Dr. Meer would not have prescribed Depakote to Ms. Raquel.

Additionally, Dr. Meer's testimony coupled with that of Ms. Raquel—which the jury heard for the first time in Abbott's defense—further undermines the already speculative inferences that Plaintiffs seek to substitute for legally sufficient proof of causation. Dr. Meer, like Dr. Franklin, testified she would have warned Ms. Raquel about Depakote's risk of birth defects and not getting pregnant while taking it. (*E.g.*, *id.* at 25:5-25:7, 26:20-22, 26:24-25.) And the only reasonable inference from Ms. Raquel's testimony is that birth defect risk was not something she considered in choosing to take Depakote. She testified she did not use contraception, and was not using contraception at the time E.G. was conceived, *because she did not think she could become pregnant.* (Ex. J, 11/03/15 Deposition of Christian Raquel played on

6/6/17 (“Raquel Dep.”) at 138:20-140:5 (emphasis added).) This testimony breaks any (hypothetical) causal link between the purported inadequacy of the Depakote birth defect warnings and E.G.’s injuries.

In sum, after the close of evidence, no reasonable jury could find that any putative inadequacy in the 2006 Depakote warnings was a substantial factor in causing E.G.’s prenatal exposure to Depakote and injuries.

III. No reasonable jury could find by clear and convincing evidence that Abbott engaged in malice, oppression, or fraud that caused E.G.’s injuries, or constitutionally impose punitive damages in this case.

Abbott incorporates and reasserts the arguments, authorities, and evidence set out at pp. 10-11 in its First JMOL.² For the reasons stated therein and in its Opposition (Doc. 273) to Plaintiffs’ Motion to Seek Relief Pursuant to Rule 54(c), Abbott objects to a bifurcated proceeding on punitive damages due to the prejudice caused by Abbott’s inability to address bifurcation and inability to adequately prepare its defense to a belated punitive damage claim.

The evidence admitted in Abbott’s defense does not change the conclusion that Plaintiffs have failed to present legally sufficient clear and convincing evidence entitling them to punitive damages under California state law. Rather, it further demonstrates that no reasonable juror could find by clear and convincing evidence that Abbott engaged in conduct amounting to malice, oppression, or fraud under California law, much less that any such conduct impacted

² Abbott also notes that, since Plaintiffs failed to plead punitive damages, or raise the issue until shortly before trial—and until during trial, punitive damages were not in play—it is not entirely clear what conduct Plaintiffs contend is worthy of punitive damages. At any rate, what evidence that was admitted in Plaintiffs’ case falls woefully short of that needed to support a jury finding of malice, oppression or fraud. No evidence admitted in Abbott’s defense changes that conclusion. If necessary, Abbott will seek additional relief as to punitive damages at the appropriate time.

E.G., as required for punitive damages as a matter of federal due process. The testimony of Dr. Feigal, Abbott's regulatory and epidemiology expert, established among other things that:

- Shortly after the North American registry study was published, Abbott requested a label change in the Patient Information Leaflet for Depakote ER in April 2005. The proposed change included further information about birth defect risk, including a "key finding" of the registry that Depakote had a higher rate of birth defects than drugs used for the same condition. (Ex. K, 6/5/17 Trial Tr. at 1351:10-17, *id.* at 1353:1-1354:22.)
- The FDA approved the change in January 2006 and the label was put in distribution and available on the internet in March of 2006 (*Id.* at 1352:6-14.)
- While the FDA considered this change, it would not have been appropriate for Abbott to send the study to physicians. (*Id.* at 1355:14-1356:2.)
- Abbott did not withhold or conceal any data from the FDA. (*Id.* at 1348:3-5.)
- Abbott made extensive study data, including data from the North American pregnancy registry study, available to physicians requesting additional information in a Medical Information letter (*Id.* at 1348:16-25.) This information could not all have been included in the label in the "concise summary" required by the FDA. (*Id.* at 1348:23-25, *see id.* at 1303:16-25.)

This evidence only underscores that no reasonable jury could find by clear and convincing evidence that Abbott engaged in conduct warranting punitive damages under California law. Dr. Feigal's testimony puts the lie to Plaintiffs' accusations that Abbott concealed or hid information from the FDA or physicians.

Thus, at the close of the evidence, the conclusion remains the same: To impose punitive damages in this case would contravene California substantive law and federal due process. Accordingly, in addition to Abbott's previously-stated reasons for opposing the presentation of punitive damages under Rule 54, Abbott requests judgment as a matter of law under Rule 50(a) on punitive damages.

CONCLUSION AND PRAYER

A reasonable jury would not have a legally sufficient evidentiary basis to find for Plaintiffs under Fed. R. Civ. P. 50(a) at the close of evidence. For the reasons stated above, in oral argument, and in Abbott's First JMOL Motion, Abbott respectfully renews its initial motion and again asks the Court to enter complete judgment as a matter of law in its favor.

Alternatively, it asks for partial judgment as a matter of law as to Plaintiffs' (1) negligent failure-to-warn claim based on spina bifida, and (2) punitive damages.

Date: June 7, 2017

Respectfully submitted,
BRYAN CAVE LLP

By: /s/ Dan H. Ball

Dan H. Ball
dhball@bryancave.com
Stefan A. Mallen
samallen@bryancave.com
211 North Broadway, Suite 3600
St. Louis, MO 63102
(314) 259-2000 (telephone)
(314) 259-2020 (facsimile)

Joel H. Smith
joel.smith@bowmanandbrooke.com
BOWMAN AND BROOKE LLP
1441 Main Street, Suite 1200
Columbia, SC 29201
(803) 726-7420 (telephone)
(803) 726-7421 (facsimile)

and

Kelly R. Kimbrough
kelly.kimbrough@bowmanandbrooke.com
Randall L. Christian
randall.christian@bowmanandbrooke.com
2901 Via Fortuna Drive, Suite 500
Austin, TX 78746
(512) 874-3800 (telephone)
(512) 874-3801 (facsimile)

Paul F. Strain
Stephen E. Marshall
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, MD 21202
(410) 244-7400 (telephone)
(410) 244-7742 (facsimile)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 7, 2017, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court’s electronic filing system on all counsel of record.

/s/ Dan H. Ball _____