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

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| **IN RE DEPAKOTE:** | ) | |
| | ) | |
| **E.R.G., a minor, by CHRISTINA RAQUEL, as parent and next friend of E.R.G.,** | ) | |
| | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **vs.** | ) | |
| | ) | **Case No. 12-CV-55-NJR-SCW** |
| **ABBOTT LABORATORIES, INC.,** | ) | **Case No. 15-CV-702-NJR-SCW** |
| | ) | |
| **Defendant.** | ) | |

# MEMORANDUM AND ORDER

**ROSENSTENGEL, District Judge:**

Plaintiff E.R.G. is one of six hundred and seventeen claimants in the Depakote mass action revolving around the teratogenicity warning in the Depakote label and the alleged failure of Defendants[1] to adequately warn of the true risks of birth defects. On June 26, 2015, as part of the original bellwether strategy, E.R.G.'s individual case was selected to proceed to trial ahead of the remaining claimants. Several unforeseeable intervening events delayed the start of the case until May 19, 2017. At the conclusion of Plaintiff's case-in-chief, Abbott orally moved for judgment as a matter of law under Rule 50(a) and filed a written brief in support of the motion. (Doc. 301). On June 6, 2017, Plaintiff filed a response in opposition to the motion. (Doc. 305). The Court took the motion under advisement, and the case proceeded through Abbott's case-in-chief. At the conclusion of all the evidence Abbott filed a renewed motion for judgment as a matter of law. (Doc. 307).

[1] In 2013, Defendant Abbott Laboratories Inc. split off part of its business, including the rights to Depakote, into a separate publicly traded company, Abbvie, Inc. Accordingly, plaintiffs filing claims after 2013 have included both Abbott and Abbvie as defendants in the litigation.

After thirteen trial days, including two days of deliberation, the jury found Abbott liable on Plaintiff's claim of negligent failure to warn and awarded fifteen million dollars in compensatory damages. (Doc. 316). In a separate proceeding the same jury found that the evidence did not support a claim for punitive damages. (Doc. 318). After these developments, Abbott filed a post-verdict motion for judgment as a matter of law or, alternatively, a motion for a new trial under Rule 59. (Doc. 332).

**Discussion**

Federal Rule of Civil Procedure 50(a) states:

> If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may:
>
> (A) resolve the issue against the party; and
>
> (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

Judgment as a matter of law should only be granted where, in viewing the evidence in a light most favorable to the non-moving party, there is no legally sufficient evidentiary basis for a reasonable jury to find for the non-moving party. *Payne v. Milwaukee Cty.*, 146 F.3d 430, 432 (7th Cir. 1998). When a case turns on credibility, judgment as a matter of law is not proper unless the objective evidence shows that it would be unreasonable to believe a critical witness from one side. *Payne*, 146 F.3d at 433.

Abbott raises four grounds in support of the Rule 50(a) motion: (1) Plaintiff did not produce evidence demonstrating Abbott inadequately warned of the risk of spina bifida and, because that is E.R.G.'s primary injury, Abbott is entitled to summary judgment or at a minimum partial summary judgment; (2) Plaintiff did not produce evidence demonstrating Abbott failed to warn of other non-spina bifida birth defect risks; (3) Plaintiff failed to prove

proximate causation because no doctor testified a stronger warning would have altered his prescribing decision; and (4) the evidence did not support punitive damages. (Doc. 301).

Federal Rule of Civil Procedure 59(a)(1)(A) provides that after a jury trial a court may grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." A court may only exercise this power when the verdict is against the manifest weight of the evidence or the trial was in some other way unfair to the moving party. *Willis v. Lepine*, 687 F.3d 826, 836 (7th Cir. 2012) (*quoting Marcus & Millichap Inv. Servs. v. Sekulovski*, 639 F.3d 301, 313 (7th Cir. 2011). The verdict is against the manifest weight of the evidence only when the verdict "cries out to be overturned or shocks our conscience." *Prime Choice Servs., Inc. v. Schneider Logistics Transloading & Distribution, Inc.*, No. 16-4197, 2017 WL 2791080, 1 (7th Cir. June 28, 2017) (*citing Latino v. Kaizer*, 58 F.3d 310, 315 (7th Cir. 1995)). A court should only grant a new trial on the basis of improperly admitted evidence if the evidence had a "substantial influence over the jury," and the result reached was "inconsistent with substantial justice." *Christmas v. City of Chicago*, 682 F.3d 632, 640 (7th Cir. 2012) (*quoting Schick v. Ill. Dep't of Human Servs.*, 307 F.3d 605, 611 (7th Cir. 2002)). Overturning a verdict should not be done lightly. *Massey v. Blue Cross-Blue Shield of Illinois*, 226 F.3d 922, 925 (7th Cir. 2000).

Abbott raises five grounds in support of the Rule 59 motion: (1) Erroneous exclusion of Ms. Raquel's testimony; (2) Improper admission of Dr. Oakley's "top 3" opinion; (3) Improper admission of marketing evidence; (4) Improper comments made during closing argument; and (5) The verdict is against the manifest weight of the evidence. (Doc. 332).

## I. Judgment as a Matter of Law

### A. Warnings concerning the adequacy of the label and the risk of spina bifida

Abbott challenges the sufficiency of the evidence based on a specific warning provided in the label. "Courts applying California law have not hesitated to rule that warnings are adequate as a matter of law when those warnings describe the very injury complained of in plain and explicit terms." (Doc. 301, p. 3). Abbott asserts that because experts agreed that the 1-2% risk of spina bifida was provided for in the label and because that was the primary injury claimed by E.R.G., his claim must fail. This assertion rests on a number of faulty assumptions and an incorrect review of the evidence.

Abbott contends that, "[a]n adequate warning about one injury is not rendered inadequate because the product maker failed to warn about a 'completely separate' injury." (Doc. 301, p. 5). None of the authorities relied on by Abbott involve cases which align with the facts of this case. Instead, those cases all revolve around an alleged injury that was the very risk warned of in the label, without any other challenges to the label's adequacy. *See e.g. Utts v. Bristol-Myers Squibb Co.*, No. 16CV5668 (DLC), 2017 WL 1906875, at *20 (S.D.N.Y. May 8, 2017) ("Eliquis label were, as a matter of law, sufficient to warn of the excessive bleeding risks which are the focus of each of the claims brought in the SAC."); *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 992 (1991) ("Plaintiff [who suffered from asbestos exposure] alleged that [manufacturers of products containing asbestos] marketed their products with specific prior knowledge…that there was a high risk of injury and death from exposure to asbestos or asbestos-containing products….") From these cases Abbott would have this Court adopt the view that even if other aspects of the label were materially misleading and inadequate below the required standard of care, *and* Plaintiff could

demonstrate the medication would not have been taken with a proper warning, recovery should be barred. While the facts of the cases cited appear to create ambiguity on this issue, what is clear is that California tort law contains a "broad principle enacted by the Legislature that one's failure to exercise ordinary care incurs liability for *all the harms that result*." *Kesner v. Superior Court*, 1 Cal.5th 1132, 1143 (Cal. 2016) (emphasis added).

Even assuming Abbott's interpretation of California law is correct, the motion nevertheless fails. Plaintiff at no point "conceded" that the spina bifida warning was adequate. Two of Plaintiff's experts did agree that the 1-2% spina bifida rate was correct and that it was located in the label, however, they never testified that the warning concerning spina bifida was adequate. To the contrary, throughout the course of trial there was an abundance of evidence from the experts indicating that the relevant 2006 label was inadequate *including* the spina bifida risk. For example, Plaintiff's regulation and drug labeling expert, Dr. Kessler, testified that the 2006 label should have included instructions for doctors to use Depakote in women of childbearing potential only as a last resort. (Doc. 286, p. 121). Dr. Kessler's "last resort" warning opinion did not *exclude* the risk of spina bifida but instead explicitly *included* it. (Doc. 289, pp. 57-58). A reasonable jury could infer from Dr. Kessler's testimony that the 1-2% risk of spina bifida did not alone provide an adequate label without the proffered last resort warning.

Dr. Kessler further testified that, as of 1992, there was sufficient scientific evidence for Abbott to know that Depakote was much more dangerous than other antiepileptic drugs, specifically as it related to the risk of spina bifida. (Doc. 289, pp. 47-48, 57, 63). The jury could reasonably infer from the label and Dr. Kessler's testimony that claiming "all antiepileptic drugs carry a risk of birth defects," while a true statement, is materially

misleading. A jury may, for example, draw the inference that by claiming "all antiepileptic drugs carry a risk of birth defects," Abbott negligently watered down the risk profile of Depakote by associating it with a class of drugs that carried a much lower risk of spina bifida. A jury may reasonably wonder why Abbott mentioned other competitor drugs *at all* in the label, especially when Depakote was known to carry *four times* the risk of the next competitor in the class. Ultimately, there was more than enough evidence presented in Plaintiff's case-in-chief to support an argument that the label, including the spina bifida warning, was inadequate.

**B. Inadequacies of the label beyond the spina bifida warning**

Abbott next challenges Plaintiff's evidence concerning general inadequacies of the label because, "[t]he warning about other birth defect beyond spina bifida were also adequate as a matter of law." (Doc. 299, p. 124). While Abbott's argument is not entirely clear on this point, there was more than enough evidence presented for a reasonable jury to determine that the label was inadequate. For example, Dr. Kessler testified that the label should have contained a "last resort warning." He further testified that the label should have but did not contain the total rate of major malformation. The fact that Depakote was labeled as a Category D drug—or that it had a boxed warning—also was addressed by Plaintiff's expert. Dr. Kessler clearly indicated that these features did not make the label *per se* adequate. He repeatedly stressed that the content of the label was the determinative factor, stressing that the Depakote label did not adequately "describe the human data" as required by the applicable regulation. A reasonable jury could easily find that (aside from the spina bifida warning) the Depakote label was inadequate.

### C. Evidence of proximate causation that a stronger warning would have prevented E.R.G.'s injuries

Abbott challenges the proximate causation evidence adduced by Plaintiff at trial by pointing to testimony that the prescribing physicians "were aware of the teratogenic effects of Depakote when they prescribed it to Ms. Raquel." (Doc. 301, p. 7). Abbott asserts that Plaintiff failed to produce testimony that "different warnings more likely than not would have prevented E.G.'s prenatal exposure to Depakote." (Doc. 301, p. 7). Plaintiff counters by noting that his theory of the case was not whether "Abbott failed to warn generally of 'teratogenic effects;' rather, [the case was about whether] Abbott's failure to provide full, accurate, and complete information about Depakote's total teratogenic risks and instructions on the safe use of Depakote in women of childbearing age would have prevented E.G.'s exposure to Depakote." (Doc. 305, p. 5).

Plaintiff's mother, Christina Raquel, was prescribed Depakote by four physicians prior to his conception. The last two physicians to treat Ms. Raquel were Dr. Han and Dr. Giese. Dr. Han testified live at trial and made a number of assertions which supported Plaintiff's theory on proximate causation. First, Dr. Han testified that there were other treatment options available to Ms. Raquel in the relevant 2006 timeframe. He further testified that, even without regard to the birth defect risks, he was on the fence about whether to prescribe Depakote because it was unclear whether it was having any therapeutic effect. (Doc. 299, p. 45). The prior physicians did not order a blood serum level for Ms. Raquel to test whether she was actually receiving a therapeutic dose of Depakote and, therefore, Dr. Han testified he could not be certain whether Depakote was actually working, or whether her Depakote use simply coincided with an asymptomatic period that was naturally occurring. (Doc. 299, pp. 76-77).

Finally, Dr. Han testified on direct and redirect that had he been told to use Depakote as a last resort, he would have advised Ms. Raquel to get off Depakote. (Doc. 299, p. 44; 112). On cross examination, Dr. Han did testify (in response to a very long hypothetical question) that he would not have "taken away" the Depakote, assuming Ms. Raquel had insisted on taking it. (Doc. 305, p. 110-111). In the Court's view, however, this merely created a factual issue to be resolved by the jury. Given the totality of Dr. Han's testimony, a reasonable jury could find that regardless of the actions taken by previous physicians, a stronger warning would have caused Dr. Han (who was already on the fence about the efficacy of Depakote for Ms. Raquel) to stop prescribing the drug.

If the jury believed that Dr. Han would have discontinued Ms. Raquel's Depakote prescription in favor of a different mood stabilizer, then the jury could reasonably infer that she would still have been off of Depakote when she went to see Dr. Giese for her final visit to the El Hogar clinic. Nothing in the testimony of Dr. Giese[2] indicates that if Ms. Raquel had shown up for her appointment on a mood stabilizer, other than Depakote, he would have independently restarted the Depakote prescription. Dr. Giese testified that, while he did make an independent assessment of Ms. Raquel at her last visit, he repeatedly asserted that he was "refilling" her medication. *See* (Doc. 301-5, pp. 1; 13; 18).

At Ms. Raquel's last visit to the El Hogar clinic, she informed Dr. Giese that she was moving away from California and she needed to secure a sufficient supply of medication for the transition period until she could find another treating physician in her new state. *See* (Doc. 301-5, p. 18). A reasonable jury might infer from the nature of her visit that Dr. Giese would have been disinclined to "alter her medications" and restart Depakote, given the fact that she was going to be in a transition period without easy access to a primary psychiatrist

[2] Dr. Giese was the last physician to treat Ms. Raquel before the conception of E.R.G.

for some time. The testimony of Dr. Han, coupled with the absence of evidence that Dr. Giese would have restarted Ms. Raquel on Depakote if she presented at the clinic on a different mood stabilizer, is sufficient for a reasonable jury to find proximate causation in this case.

**D. Punitive damages**

Finally, Abbott challenges the sufficiency of the evidence presented to support an award of punitive damages. Given that the trial proceeded in a bifurcated manner and that the jury returned a verdict in favor of Abbott as to punitive damages, the motion on this issue is moot. *See* Advisory Committee Notes to Rule 50 (noting that "a jury verdict for the moving party moots the issue"); *see also Phillips v. Community Ins. Corp.*, 678 F.3d 513, n.3 (7th Cir. 2012) (citing Advisory Committee Notes to Rule 50 regarding mootness); *see also Jackson v. Pfeiffer*, No. 03 C 941, 2006 WL 3488844, at *n.1 (E.D. Wisc. Dec. 4, 2006) ("Defendant Perales' oral motions for judgment as a matter of law under Rule 50(a) . . . are moot in view of the jury's finding with respect to him").

**II. Motion for New Trial**

**A. Exclusion of Ms. Raquel's testimony**

Abbott seeks a new trial based on the Court's denial of its motion to compel a *de bene esse* deposition of Ms. Raquel,[3] as well as the Court's exclusion of a small portion of her deposition testimony regarding her knowledge of the risk of birth defects.

Ms. Raquel is the biological mother of E.R.G., and prior to trial Abbott deposed her utilizing a standard stenographer which yielded a deposition transcript. Despite the myriad

[3] Abbott also alleges, in the alternative, that the Court should have compelled Ms. Raquel to appear at trial, but counsel does not provide any case law or argument as to what mechanism compelled Ms. Raquel to appear in person at trial. Abbott does acknowledge, however, that Ms. Raquel lives in California, well beyond the Court's 100 mile subpoena power.

of video and audio recording equipment available to the average citizen, Abbott did not record the deposition using any such means. In the final days before trial, Abbott discovered that Plaintiff did not intend to call Ms. Raquel as a witness and that she would not be present at trial. Upon discovering this information, Abbott filed a motion seeking leave for an additional deposition so Ms. Raquel could be shown to the jury at trial.

The motion failed to provide any explanation as to why the deposition transcript did not accurately capture her testimony; instead, Abbott rested the request on the low burden on Ms. Raquel and the preferable nature of video depositions. The Court sought clarification from Abbott at a telephonic status conference, however, no additional information was provided. If Abbott had articulated that Ms. Raquel's body language or cadence needed to be captured to understand the context of the plain language in the transcript (such as the presence of eye rolling or unusually long pauses at her original deposition), then the Court might have ordered a *de bene esse* deposition. No such evidence was provided, however, and no argument was made concerning the inadequacies of the deposition.

Regarding the excluded testimony of Ms. Raquel, the Court first notes that despite being Plaintiff's mother, the introduction of Ms. Raquel's deposition was part of Abbott's case-in-chief, not Plaintiff's. Abbott put forward Ms. Raquel's testimony specifically for the purpose of letting the jury hear numerous affirmative statements that defense counsel clearly believed helped Abbott's case. The idea that Abbott experienced "grave prejudice" from the exclusion of evidence impugning the credibility of a witness that Abbott itself was relying on for affirmative truthful statements is meritless. This is especially true given that the excluded testimony directly contradicted Abbott's theory of the case throughout trial

(the theory being that Ms. Raquel needed Depakote so badly that she would have taken it no matter what).

What makes Abbott's argument so difficult to follow is that at trial, counsel repeatedly asked questions and presented evidence to prove that Ms. Raquel was in fact properly warned about the risks of birth defects[4]—and yet now Abbott claims her testimony regarding lack of knowledge should be taken as both true and false. On the one hand, Abbott spent significant time introducing evidence that Ms. Raquel was warned about the risks of birth defects, and at the same time Abbott tried to introduce statements by Ms. Raquel that she was not properly warned. Abbott then attempts to argue that those same statements it claims are beneficial to its case are in fact false and call into question the credibility of the witness. It is not clear that the evidence would have benefitted Abbott, but it is quite clear that this evidence could easily have confused the jury concerning the correct application of the learned intermediary doctrine.

**B. Dr. Oakley's "top 3" opinion**

Abbott next challenges the admission of Dr. Oakley's opinion that Depakote was one of the three most teratogenic drugs included in the Physicians' Desk Reference ("PDR"), arguing that the opinion was not sufficiently supported by reliable methodology. Following the *Kaleta* trial in March 2015, Plaintiff provided a supplemental report from Dr. Oakley which included his opinion that based on his lifetime of studying birth defects and their sources, Depakote was one of the most teratogenic drugs in the PDR. *See* (Doc. 282, pp. 5-12).

[4] For example, during trial Abbott introduced a written acknowledgement signed by Ms. Raquel that demonstrated she was counseled regarding the risks of birth defects. (Doc. 332, p. 16) (Indeed, Abbott's own motion for a new trial points to multiple times Ms. Raquel was warned of the risk of birth defects.).

First, it must be noted that Dr. Oakley is one of *the* premier teratologists, and his career has been studying the rates of birth defects and the severity of the defect that results from exposure to different compounds. While Dr. Oakley's opinion appears quantitative on its face and is certainly based on quantitative data, it is ultimately a qualitative opinion. Dr. Oakley testified that this opinion was based on the rate at which Depakote causes birth defects as well as the severity of the birth defect that it causes, both of which are plainly rooted in medical evidence. (Doc. 282, pp. 20-21). While a different expert may come to a different conclusion or may even use a different methodology to determine what the three worst drugs are in terms of teratology, that is not the test for excluding an opinion under *Daubert*.

**C. Marketing evidence**

Abbott also challenges the admission of certain evidence consisting of marketing materials relating to the sale of Depakote. Abbott challenges the admission of this evidence on the grounds that some of the marketing materials were related to indications other than bipolar disorder (such as migraines or polycystic ovary syndrome) and that the evidence was irrelevant to the adequacy of the Depakote label and thus unfairly prejudicial.

Breach of duty is fundamentally at issue in cases alleging negligence, and thus evidence showing what a defendant's motivation may have been for breaching its duty is plainly relevant. Regardless of whether or not the marketing evidence was relevant to the adequacy of the label, it was plainly relevant as to why Abbott may have breached its duty. That is true even for marketing materials relating to indications other than bipolar disorder. The birth defects associated with Depakote do not vary based on indication, so Abbott's marketing behaviors in light of those birth defects is still probative on the issue of whether

or not Abbott breached its duty in this case where Depakote was prescribed for bipolar disorder.

Indeed, Plaintiff produced evidence beyond the generic "culture of the company evidence" in this case. Emails were produced at trial showing that the same marketing department, which was under great stress in light of the falling sales and the pending loss of Depakote's patent protection, directly attempted to influence language in a scientific research paper.

Finally, in addition to the clear evidence of motive for the breach of duty, much of the marketing evidence adduced at trial demonstrated what Abbott knew and when it new it, a required element of Plaintiff's negligence claim.

**D. Improper comments in Plaintiff's closing argument**

Abbott also argues that it is entitled to a new trial due to comments made by Plaintiff's counsel during closing argument. The comments fall under the following three categories: (1) Comments invoking concepts of or comparisons to criminal law; (2) Comments about damages; and (3) Comments about placing any damages recovered by Plaintiff into a trust fund.

During closing argument Plaintiff's counsel stated that Abbott was "guilty as hell," and relayed an anecdote about asking a criminal defense attorney what his strategy was for defending murderers and rapists. (Doc. 133, pp. 109:2-25, 110:1-6). Abbott objected to these comments, and the Court made clear to the jury that this was not a criminal trial. (Doc. 133, p. 110:7-10). Additionally, while these comments were improper, their prejudicial effect was limited when viewed in context. At the time of the statement, Plaintiff's counsel was attempting to explain to the jury that attempts to blame the mother, much like blaming a

victim of a crime, is not part of the jury's decision, and it demonstrates weakness in a defendant's case.

Next, Abbott points to counsel's comments on damages as overly prejudicial. Plaintiff's counsel began to make an argument in relation to noneconomic damages suggesting that the award should be based off of Abbott's behavior. (Doc. 133, p. 55:6-13). Abbott objected at the time on the basis that this was an argument for punitive damages, and the Court prevented Plaintiff's counsel from continuing the argument. (Doc. 133, pp. 55:14-25, 56:1-8). Similarly, counsel stated that the jury "had a chance to make a decision about what kind of a world [they] want to live in." (Doc. 133, p. 30:6-8). Again, the context of this comment is important to assess whether it was improper and whether it was overly prejudicial. Part of Plaintiff's burden is to prove that Abbott's conduct was not reasonable. Counsel's argument goes directly to the concept that the jury decides what is reasonable. Counsel went on to say:

> And it's not—Judge Rosenstengel's a federal judge. With all due respect, it's not her decision today. It's not the government's decision. It's not the FDA's decision. The nine of you get to decide, and what you decide will say a lot about what we should be valuing in this society."

(Doc. 333, p. 30). This comment, in light of its context, was not improper, and it certainly was not overly prejudicial.[5]

Finally, as for counsel's comments about any potential award going into a trust, Abbott did not object to this argument at trial, and regardless, it does not undermine the

[5] It is evident that the jury was not inflamed by such comments and that the jurors properly followed the instructions as provided. Critically, the jury was given the chance to award punitive damages in this case and decided against doing so. To the extent that the jury did award damages, it only awarded approximately two million dollars more than what Plaintiff estimated economic damages to be. A nonexistent award of punitive damages and a relatively small (relative to both economic damages and what the jury could have potentially awarded) award of noneconomic damages simply aren't consistent with a theory that the jury was so affected by these statements that it gave an award that was inconsistent with substantial justice.

verdict because it does not go to any element of the case. While not critical to the analysis, the Court notes that by operation of law, minors are prohibited from owning property, and a trust will be established for E.R.G.'s care and benefit.

**E. The verdict is against the manifest weight of the evidence**

Abbott's argument that the verdict is against the manifest weight of the evidence is duplicative of its argument for judgment as a matter of law. For the reasons discussed above in response to Abbott's motion for judgment as a matter of law, the Court does not find that the verdict "shocks the conscience" or "cries out to be overturned" and is thus not against the manifest weight of the evidence.

**Conclusion**

For these reasons, Abbott's motion for judgment as a matter of law pursuant to FED. R. CIV. P. 50(a) (Doc. 301) is **DENIED**. Additionally, nothing raised in Abbott's motion for judgment as a matter of law at the close of all the evidence (Doc. 307) alters the Court's analysis of the sufficiency of the evidence, accordingly, it too is **DENIED**. The same is true for Abbott's newest motion for judgment as a matter of law (Doc. 332), and it is also **DENIED**. Finally, as explained above, Abbott's motion in the alternative for a new trial (Doc. 332) does not meet the necessary standards, consequently, it is also **DENIED**.

**IT IS SO ORDERED.**

**DATED: July 19, 2017**

**NANCY J. ROSENSTENGEL**
**United States District Judge**