Products Liability Law Daily Wrap Up, TOP STORY—WARNINGS ISSUES—Mo. App.: $38 M verdict withstands Abbott's challenge that antiepileptic drug birth defect warnings were adequate, (Nov. 9, 2016)

Products Liability Law Daily Wrap Up

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By Pamela C. Maloney, J.D.

A jury award of $15,000,000 in actual damages against Abbott Laboratories based on the drug maker's failure to warn of the high risk of birth defects associated with the use of Depakote, an antiepileptic drug, during pregnancy was upheld by a Missouri court of appeals. The jury's award of $23,000,000 in punitive damages was also upheld because there was clear and convincing evidence that Abbott deliberately disregarded the rights and safety of others in failing to warn physicians of the risks associated with use of the drug by women of childbearing age and during pregnancy (*Barron v. Abbott Laboratories, Inc.*, November 8, 2016, Sullivan, S.).

The adoptive parents of a child who was born with severe birth defects, including spina bifida, microcephaly, ocular coloboma, brain malformations, cognitive impairment, paralysis, and neurogenic bowel and bladder, joined with 23 other families to bring a lawsuit against Abbott for birth defects suffered by their children as a result of the biological mothers being prescribed and ingesting Depakote, an antiepileptic drug (AED), which was prescribed to treat epilepsy, bipolar disorder, and migraine. The underlying complaint included nine counts related to the manufacture, sale, and marketing of the drug, and a request for punitive damages in addition to compensatory damages.

Following the jury's verdict against it, Abbott moved for a directed verdict and a judgment notwithstanding the verdict on the failure to warn claim, arguing that the Depakote label was adequate as a matter of Minnesota law in that the label (a) attracted the attention of those to whom it was directed, (b) explained the mechanism and mode of injury, and (c) explained how to safely use the product to avoid injury. Abbott also challenged the adequacy of the evidence supporting the jury's punitive damages award.

Adequacy of warnings. Under Minnesota law, which applied in the case at bar, manufacturers of prescription drugs had a duty to warn the prescribing physician of the dangers associated with a drug; the manufacturer had no duty to warn the lay public or patients directly. The manufacturer maintained that its warning about the AED was adequate as a matter of law because (1) it was a black box warning, which is considered the strongest and most significant way to stress a warning about a drug to a learned intermediary; (2) the warning stated the AED could cause neural tube defects, such as spina bifida, when used by pregnant women; and (3) the warning indicated the only way to avoid the possibility of spina bifida from the AED was either to avoid the use of the drug during pregnancy or to avoid getting pregnant while taking the AED.

The court rejected the manufacturer's claim that its warning was adequate, finding that although the manufacturer knew that its AED had an increased overall risk of birth defects versus its competitors and that the drug was significantly more dangerous for use in women of childbearing age, this information was not included in the warning.

In response to the manufacturer's assertion that it was enough to warn of the bottom line risk that the drug could cause birth defects and that it had no added duty to warn that the drug's overall risk for all birth defects was higher than that of all other AEDs on the market, the court explained that as research revealed and it came to light that its drug was the most dangerous for causing birth defects in comparison to other AEDs on the market, it was reasonable for the jury to conclude that the manufacturer should have warned doctors of this fact so that they could make an informed decision about what AED to prescribe to their female patients of childbearing potential and to prescribe the drug only if all others failed.

Knowledge of risks. The court went on to determine that the evidence supported a finding that the manufacturer did in fact know about the risks associated with use of the drug by women of childbearing age and deliberately chose to omit them, claimed ignorance of them, and outright lied about them. First, internal documents and depositions clearly showed that the manufacturer's marketing strategy was to expand the use of its AED by women and to maintain the drug's position as a first line agent for women with epilepsy, bipolar disorder and migraine and that the manufacturer regarded information relating to the risk of birth defects as an obstacle to that goal.

Second, the court explained that the manufacturer could not claim ignorance of the drug's dangers which were known in the field of pharmaceuticals and teratogenicity because, under Minnesota law, a manufacturer is held to the skill of an expert in its particular field of endeavor and is obliged to stay informed of scientific knowledge and discoveries in that field. Furthermore, as a subset of its duty to provide adequate warnings of the dangers associated with use of its product, a manufacturer also has a duty to test its products to discover dangers associated with their use as well as a duty to stay informed of scientific knowledge in its fields. This later responsibility is relevant to whether a manufacturer knew or should have known of the risks in its product.

Treating physician's knowledge of risk. Finally, the court determined that based on the scientific data and statistics regarding the serious dangers associated with the manufacturer's AED, there was sufficient evidence to support the finding that the black box warning was inadequate and that up-to-date warnings were sacrificed in the name of company profits. The prescribing physician indicated that if he had received the full true warning about the drug's dangers, he would not have prescribed the drug to the child's mother. The manufacturer's sales director of neuroscience testified that the drug had been identified within the company as a "dirty drug" with regard to safety issues, yet the company continued its strategy to expand the sale of the drug to women.

Based on the evidence, overriding the jury's verdict on the manufacturer's failure to warn of the drug's dangers would be inappropriate, the court concluded, denying the manufacturer's JDV and JNOV motions.

Punitive damages. In determining that there was clear and convincing evidence to justify the jury's award of punitive damages, the court outlined evidence regarding the severity of the birth defects that were omitted from the warning, the manufacturer's focus on profit as a motivation for concealing the serious hazards to women of childbearing potential (including the fact that the manufacturer spent $50 to $100 million per year marketing the drug), and the manufacturer's failure to correct its label despite its awareness of studies contradicting its warning labels. This evidence, combined with evidence that showing that knowledge of the AED's dangers had reached the highest levels in the company, supported the conclusion that the manufacturer deliberately disregarded the safety of the patient in this case, thereby justifying the jury's award of punitive damages was justified.

Other issues. The court rejected the manufacturer's challenge to testimony presented by a birth defects prevention doctorregarding the higher relative risk of spina bifida associated with the drug. The manufacturer had claimed that expert's opinion on the black box warning was not disclosed prior to trial. However, the expert's opinion focused on the higher relative risk posed by the drug in comparison to other AEDs on the market and any testimony regarding what warnings should have been given based on that relative risk were objected to and sustained.

Also rejected was the manufacturer's objection to the admission of marketing and promotional materials which were never seen by the prescribing physician. According to the court, whether the materials were seen by and influenced the physician's decision to prescribe the drug was not the exclusive, relevant use for these materials. They also provided evidence of the manufacturer's knowledge and motive with regard to the drug's risk and the manufacturer's failure to provide adequate warnings about those risks.

Finally, there was no error in admitting, during the compensatory damages phase of the trial, evidence of the manufacturer's financial condition. The information about the manufacturer's profits from the sale of its AED was relevant to its motive in promoting the drug despite of and without sufficient regard for the danger to pregnant women and women of childbearing age, as well as to the manufacturer's failure to provide adequate warnings about those dangers in order to protect its profits from sales of the drug.

The case is No. ED103508.

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Companies: Abbott Laboratories, Inc.

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