Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—N.D. Ohio: Depakote® birth defect claims pared down to inadequate warning and fraud claims, (Oct. 4, 2016)

Products Liability Law Daily Wrap Up

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By Susan Lasser, J.D.

In an action brought by the parents of a minor child who was born with severe birth defects allegedly caused by the child's mother's taking a prescribed anti-seizure medication during her pregnancy, judgment as a matter of law was granted to the manufacturer on the parents' claims for strict liability design defect, negligent design, breach of express and implied warranties, negligent misrepresentation, and punitive damages under the Ohio Product Liability Act (OPLA). The parents could proceed only on claims for strict liability due to inadequate warning and fraud. The court also allowed a punitive damages claim as to the parents' common-law fraud claim. In addition, the court found genuine issues of fact precluded summary judgment for the drug maker on the learned intermediary doctrine (*Z.H. v. Abbott Laboratories, Inc.*, September 30, 2016, Boyko, C.).

The child was born in 2003 with a number of severe birth defects allegedly caused by the mother's use of Depakote®, an anti-seizure medication formulated, tested, manufactured, and marketed by Abbott Laboratories, Inc., and Abbvie, Inc. (collectively, Abbott), during her pregnancy. Approved and sold in the United States since 1978 for the treatment of certain forms of epilepsy, the drug is promoted as an effective anti-epileptic drug (AED). The child's parents, however, alleged that the drug is defective and dangerous for its intended use because its primary compound, valproic acid, is teratogenic—*i.e.*, of, relating to, or causing developmental malformations/ birth defects if taken during the first trimester of pregnancy. The parents further alleged that Depakote is riskier than other AEDs for women who are/may become pregnant and that Abbott was aware of the heightened risks of birth defects from the drug yet continued to market and distribute it in the U.S. without adequate warnings. The parents claimed that Abbott failed to communicate the heightened risk of birth defects to doctors and women and, instead, minimized the risks and downplayed the dangers in their product labeling. The parents asserted Ohio state-law claims against the drug maker, including strict products liability for design defect and inadequate warning, nonconformance with representations, and negligence.

Strict products liability design defect and negligent design claims. Because the parents' brief in opposition to Abbott's summary judgment motion failed to offer any argument or evidence rebutting Abbott's challenges to the defective design claim, the court ruled that the parents had waived their defense and Abbott was entitled to summary judgment on the strict liability design defect claim. Also, because elements of strict liability are identical to those for breach of implied warranty, the parents' failure to prove a defect was fatal to that claim, as well as to and their negligent design claim. Even if the parents had provided a response, however, their defective design claims would have failed because they did not offer any expert testimony that Depakote's formulation's risks outweighed its benefits. Summary judgment, therefore, was granted under a risk-benefit theory. The parents' also failed under a consumer-expectations theory also failed as they did not point to any evidence of consumer expectation. Moreover, their design claim could not proceed because they failed to show that there was no a "practical and technical feasible alternative design" that would have prevented their injuries, and they offered no expert testimony on a viable alternative. Thus, summary judgment was granted to the drug maker on the parents' defective design, negligent design, and breach-of-implied-warranty claims.

Strict liability due to inadequate warning and negligent failure to warn. The court found there were genuine issues of fact to preclude summary judgment for Abbott on the parents' inadequate warning claims. While courts agree that black box warnings on drug labels are the strongest warnings available under the FDA regulations, the court was unaware of any court holding that such a warning was *per se* adequate as a matter of law. Neither

was the warning label *per se* adequate if the label indicated that the FDA assigned a Category D designation to the drug. Courts have rejected the assertion that such a designation was sufficient as an adequate warning on its own because the label still pointed the reader to additional warnings contained elsewhere. Therefore, the court agreed with Illinois and Ohio court decisions finding the black box label and Category D designation did not render the label adequate as a matter of law when opposed by competent evidence creating an issue of fact that the label warningit was inadequate. The court found that the parents pointed to several alleged inadequacies on the Depakote label, creating issues of fact for a jury's consideration when determining the adequacy of the Depakote label.

Preemption. Finding that the FDA rejected attempts by Abbott in 2006 and 2008 to amend its Depakote warning label to include warnings of developmental delay due to Depakote use were rejected by the FDA, the court determined that the parents' claims for inadequate warnings of developmental delay were preempted by federal law.

Abrogation. Abbott argued that all of the parents' Ohio common-law claims were abrogated by the OPLA, as each sought damages for personal injuries caused by the maker's failure to warn of the risks associated with use of Depakote. However, because the injury occurred in 2002 before the abrogation clause was added to the applicable statute, the parents argued their claims were not abrogated by the OPLA.

Because the abrogation amendment was not to be retroactively applied, the OPLA did not abrogate common-law causes of action that accrued before April 7, 2005. In addition, Ohio Supreme Court precedent held that a cause of action did not arise and/or accrue until a plaintiff discovered an injury was caused by wrongful conduct. Because the parents did not discover their child's injuries were allegedly caused by the manufacturer's wrongful conduct until they filed their complaint, their causes of action did not arise or accrue until after the effective date of the abrogation clause. Thus, all the parents' Ohio common-law products liability claims were barred—including claims for negligence, gross negligence, negligent misrepresentation and fraud, breach of implied and express warranties, and intentional and negligent infliction of emotional distress. Courts considering the OPLA's preemption of common-law causes of action also have determined that the OPLA bars strict liability claims. Because the parents' negligence, gross negligence, breach of implied and express warranties and intentional and negligent infliction of emotional distress claims all arose out of Abbott's alleged failure to warn of Depakote's dangers, each was a product liability claim barred by the OPLA. However, because the parents' fraud claim alleged a violation of the manufacturer's general duty not to deceive consumers and physicians, the claim was not abrogated by the OPLA. and summary judgment on the parents' fraudulent representation claim was denied.

Punitive damages. Although the court granted summary judgment for the manufacturer on the parents' OPLA punitive damages claim, the court ruled they could pursue punitive damages under a state-law fraud claim because the allegations and evidence created a genuine issue of fact as to whether Abbott's alleged misrepresentations on the safety of Depakote evidenced a conscious disregard of the rights and safety of persons.

The case is No. 1:14CV176.

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Companies: Abbott Laboratories, Inc.; AbbVie, Inc.

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