Products Liability Law Daily Wrap Up, TOP STORY—DRUGS—N.D. Ill.: Drug maker loses bid to revisit $3M award to paroxetine-taking suicide victim's widow, (Sept. 15, 2017)

Products Liability Law Daily Wrap Up

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By Georgia D. Koutouzos, J.D.

An Illinois federal court has refused to set aside a $3-million jury award to the widow of a man who killed himself while taking the generic version of the prescription anti-depressant Paxil. Denying a motion for judgment as a matter of law or for a new trial by the medication's manufacturer, the court found that despite the drug-maker's various objections to the jury instructions, expert testimony, and cross-examination/rebuttal testimony, both sides had presented evidence from which the jury could have found for either side on the cause-of-death issue and there was no basis to set aside the jury's finding that the decedent's death had been caused by his ingestion of a generic formulation of the drug (*Dolin v. GlaxoSmithKline LLC*, September 14, 2017, Hart, W.).

The widow of a 57-year-old attorney who had leapt in front of a Chicago elevated train and committed suicide while taking the prescription medication paroxetine—the generic form of the anti-depressant Paxil—sued the drug's developer-manufacturer, GlaxoSmithKline LLC (GSK), seeking damages for her husband's death. The case went to trial on the claim that GSK negligently had failed to include a warning in the label that the medication can be a cause of adult suicide despite being aware of a significant risk of suicide in adults taking the drug.

The widow alleged that GSK had allowed an affirmative misrepresentation to exist in the label that there was no risk of suicide beyond the age of 24 years. She also asserted that the label did not warn of the association of akathisia (a psychomotor agitation disorder from which her husband allegedly suffered due to taking paroxetine) with suicidal behavior. The widow contended that the company had negligently misled the medical profession, including her husband's doctor and the U.S. Food and Drug Administration, by concealing and misrepresenting adult-suicide-risk data related to paroxetine usage.

The drug maker moved for summary judgment three times, two of which argued that any state-law claim was preempted because FDA had rejected the drug maker's efforts to place certain warnings on the label (see *Products Liability Law Daily's* February 17, 2016 analysis). The company maintained that the decedent's physician was aware of the risks of adult suicide associated with paroxetine and that the warning label was adequate as a matter of law. The widow's strict liability claims of design defect and failure to warn were dismissed, and the case ultimately went to trial on a negligence claim only.

The jury was instructed that GSK was responsible for the content of paroxetine's label and, as such, was charged both with crafting an adequate label and ensuring that the warnings remain adequate so long as the drug is on the market. Under FDA regulations, a drug manufacturer is required to revise and update its label to include a warning as soon as there is "reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved."

In addition, the jury was told that FDA regulations permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning to the agency for review and approval. In recognition of the learned intermediary doctrine, the jury was told that GSK had a duty to warn only the prescribing physician of the risks of which it knew, or in the exercise of ordinary care, should have known.

The jury returned a $3-million award for the widow (see *Products Liability Law Daily's* April 26, 2017 analysis), after which GSK moved for judgment as a matter of law or for a new trial, arguing that: (1) the jury instructions

were improper; (2) the widow's experts testified to undisclosed opinions; (3) the court improperly limited cross-examination; and (4) the court permitted improper rebuttal testimony.

Jury instructions. Contrary to the drug maker's contention that the Causation instruction was improper because the jury had been misled into believing that GSK had manufactured the generic paroxetine ingested by the decedent, both the court and the parties made that distinction clear. Therefore, GSK's proposed instructions explaining distinctions between "cause-in-fact" and "legal cause" were unnecessary and were likely to cause confusion, the court found, noting that the company's proposed instructions also contained argument and did not explain that voluntary suicide following a tortious act only breaks a chain of causation if it appears that the suicide could not be foreseen, which was not the circumstance here. Additionally, other instructions proposed by the drug maker were deemed unnecessary and very argumentative. The parties were permitted full opening and final arguments, which included references to many demonstrative exhibits. As such, the company's defense had been fully explored before the jury.

Expert testimony. GSK also claimed that the court committed error by allowing the widow's experts to testify to opinions or matters that had not been previously disclosed in discovery. However, the widow's experts provided detailed reports and gave lengthy depositions, after which the company's experts responded in detail. The issues tried in the case were the subject of previous litigation presented by some of the same attorneys, some of the same experts, and included many of the same documents. Consequently, surprise was not a factor in the instant case.

Cross-examination and rebuttal testimony. As for the drug maker's contention that the court had improperly limited the company's case by excluding two additional experts from testifying about suicide statistics, excluding the testimony of an expert on the nature of international law firms, refusing cross-examination of expert witnesses concerning fees paid to them in other cases, and refusing cross-examination in order to show bias of the widow's expert about his research and views with respect to drugs other than Paxil, the court found that GSK's experts had testified on the subject of suicide rates and additional suicide statistical studies would not have assisted the jury.

Furthermore, there was direct testimony from several lawyers in the decedent's law firm about structure and management such that the jury would not have been helped by hearing an expert on law firm structure, procedures, and stressors. In sum, both sides had presented evidence from which the jury could have found for either the plaintiff or the defendant on the issue of cause of death, and there was no basis to set aside the jury's finding that the decedent's death had been caused by his ingestion of paroxetine. Accordingly, GSK's motion for judgment as a matter of law or for a new trial was denied.

The case is No. 12 C 6403.

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Companies: GlaxoSmithKline LLC

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