Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—S.D. N.Y.: Reconsideration denied to both sides in Risperdal patient's suit against Janssen; additional briefing allowed, (Oct. 26, 2017)

Products Liability Law Daily Wrap Up

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By Jordan A. Silver, J.D.

In a products liability action brought against Janssen Pharmaceuticals by a patient who developed gynecomastia after taking Risperdal, both parties' motions for reconsideration were denied by a federal district court in New York, finding that summary judgment had been properly granted on the patient's failure to warn claims and properly denied on the patient's implied warranty claim, as well as other claims which the pharmaceutical company had failed to brief. However, the court allowed for additional briefing based on new evidence Janssen presented, which undermined the patient's fraud and misrepresentation and design defect claims (*Adeghe v. Janssen Pharmaceuticals, Inc.*, October 24, 2017, Schofield, L.).

Failure to warn. The patient's argument that he was entitled to a "heeding presumption" that a user would have heeded warnings had they been provided and that the injury would not have occurred previously was rejected [see Products Liability Law Daily's August 31, 2017 analysis] when the patient first opposed summary judgment. The court had found that a plaintiff bears the burden of proving that the defendant's failure to warn was the proximate cause of injury, including by adducing proof that the user of a product would have read and heeded a warning had one been given. Based on the record, the court had found that no reasonable jury could conclude that any failure to warn caused the patient's injuries. Likewise, the court rejected another previously presented argument by the patient that there was evidence suggesting that a physician balancing the risks of Risperdal-induced gynecomastia against the benefits of Risperdal would conclude that Risperdal should not have been prescribed, based on expert testimony of the drug carrying greater risks of this side effect than other medications. As the court reiterated, this was not new evidence but instead "mere speculation" as to how a physician might have acted with enhanced warnings. Finally, the court was not persuaded by the patient's suggestion that prior to the adoption of a stronger warning in 2006, the medical community was not adequately ware of the extent of the risk associated with Risperdal. Once again, the court echoed its earlier opinion, in which the court had granted summary judgment without offering any opinion as to whether there was a factual dispute as to the adequacy of the label, making such evidence irrelevant to its decision.

Pharmaceutical company's motion for reconsideration. While denying reconsideration on claims that the company had failed to contest initially, t court conceded that the company's new arguments presented "serious issues" which deserved full consideration before trial in the interest of judicial economy. Specifically, the pharmaceutical company pointed to the fact that the patient's fraud and misrepresentation claims contained elements of causation and reliance. However, given the lack of evidence of inadequate labeling causing patient's physicians to prescribe Risperdal, those claims could not survive summary judgment under those theories. Moreover, the pharmaceutical company argued that the patient failed to establish a case for any of his claims under a design defect theory and that theory was preempted.

The pharmaceutical company initially sought summary judgment on the patient's breach of implied warranty, breach of express warranty, and failure to warn claims, in which summary judgment was denied on the first and granted on the second and third. The pharmaceutical company made no particularized arguments as to the patient's other claims- negligence, strict products liability, manufacturing defect, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, fraud and deceit, and violation of New York General Business law. Instead, the company unsuccessfully moved to preclude the patient's causation expert for testifying, arguing that because the patient lacked admissible expert testimony to support his allegation that

Risperdal caused his gynecomastia, the company was entitled to summary judgment on all of those claims. Instead, the court found the expert's testimony admissible, and denied summary judgment on all of the claims the company failed to contest. Because the pharmaceutical company had previously neglected to specifically address those claims in its initial briefing, the court refused to allow the company to present additional arguments on these issues. To do otherwise, the court noted would be tantamount to allowing a "second bite at the apple" by permitting the company to improperly secure a rehearing on the merits.

The case is No. 16 Civ. 2235 (LGS).

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Companies: Janssen Pharmaceuticals, Inc. a/k/a Orthormcneil Janssen Pharmaceuticals, Inc.; Johnson & Johnson

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