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## Phila. Court Cues Up Appeal Over Risperdal Punitive Damages Issue

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Of the Legal staff

A Philadelphia judge has urged the state Superior Court to affirm a \$500,000 verdict awarded last year to a man who allegedly suffered excess growth of breast -tissue as a result of taking the -antipsychotic drug Risperdal.

The case presents the first chance for a state appeals court to address whether punitive damages claims should be allowed in the Risperdal trials

Philadelphia Court of Common Pleas Judge Kenneth J. Powell Jr. issued an opinion Monday in Stange v. JanssenPharmaceuticals, which came to a verdict late last year. The opinion outlined the post-trial arguments from both sides, and asked the Superior Court to affirm the jury's findings that Janssen Pharmaceuticals failed to warn about Risperdal's link to excess growth of breast tissue and that its negligence caused plaintiff Timothy Stange's injuries.

Although Powell rejected the plaintiff's bid to overturn a prior ruling from the supervising judge of the Risperdal mass tort that had

barred punitive damages in the litigation, he also said Janssen's claims that there was not enough evidence to support the verdict were meritless.

"They lost a fair trial and now they must pay a fair price," Powell said.

According to court documents, Stange had taken Risperdal from 2006 to 2009 to control his Tourette syndrome symptoms. He argued that Janssen had been aware of the risks of the drug to cause excess breast tissue growth, which is a condition known as gynecomastia, but the company hid that information.

Attorney Thomas R. Kline of Kline & Specter, who tried the case for Stange, said the ruling rejects arguments Janssen made not only in Stange, but also in other cases in the Risperdal mass tort.

"The ruling serves as a strong repudiation of many of the arguments made by Janssen in the litigation and we are hopeful to obtain an affirmance in the Superior Court." Kline said.

A spokeswoman for Janssen said in an emailed statement that the company was disappointed by the opinion. "We are disappointed that the court did not grant our motion. We continue to believe this verdict should be overturned, and we will appeal," spokeswoman Robyn Frenze said in the statement.

The Stange trial was one of four held last year over claims that Risperdal caused gynecomastia. The other cases resulted in a \$2.5 million verdict, a \$1.75 million verdict, and a finding that, although Janssen negligently failed to warn about the risks of the medication, Risperdal did not cause the plaintiff's breast growth.

After the verdicts, the Stange award was increased by \$35,106 due to delay damages, and the \$1.75 million award was reduced to \$680,000 when the judge granted a motion for remittitur.

In the wake of the trials, the appellate dockets in the cases have been active. The Stange case is the first in line for appellate review, and it is expected to be the case in which the Superior Court rules on whether plaintiffs in the global Risperdal litigation can seek punitive damages

"This is the vehicle in which the punitive damages issue will be ripe and decided at the appellate level," Kline said Stange's trial went from Oct. 15 until Dec. 11.

On appeal, Janssen argued that the evidence was insufficient to prove causation, that Stange's treating doctor knew of the risks of Risperdal, and that the jury charges were improper. Powell dismissed the arguments as meritless.

As part of its argument, Janssen contended that Stange could not prove his claim because he never tested his levels of prolactin, which is a hormone related to gynecomastia, while taking the drug. But Powell said Stange's failure to test for the hormone was Janssen's fault.

"The defendants knew that Risperdal elevated prolactin and chose not to recommend that prescribing doctors monitor prolactin levels of patients taking their medication. In fact, they hid evidence association the between Risperdal use and elevated prolactin levels," Powell said. "The defendants themselves are to blame for the fact that the plaintiff's prolactin levels were not carefully monitored during the period in which he was prescribed Risperdal. Now the defendants wish to benefit from their own concealment."

According to court documents, Stange started taking the drug when he was 11 years old.

During trial, Kline told the jury that Risperdal was marketed for off-label use in children, despite the fact that it was not indicated by the U.S. Food and Drug Administration for that purpose.

He further maintained that Janssen hid from the FDA information on the alleged increased prolactin levels associated with Risperdal. And on the Risperdal label, Kline said, Janssen noted the incidence of increased prolactin levels was rare (one case of gynecomastia in 1,000) when it was actually closer to five in 100.

During closing arguments, McCarter & English attorney Michael Kelly, who represented Janssen, told the jury that the plaintiff's arguments had been "a lot of noise," and the plaintiff never provided any evidence linking the drug to gynecomastia.

Specifically, Kelly said the timeline of when Stange said he began noticing excessive breast growth did not match up with the time he took Risperdal, and none of the doctors were able to prove Stange's gynecomastia was a result of the drug.

According to Kelly, doctors agree that most gynecomastia is caused by puberty, and 10 to 20 percent of those instances result in the creation of permanent tissue.