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Third Risperdal Trial Against J&J Begins in Philadelphia

BY P.J. D'ANNUNZIO

Of the Legal Staff

Lawyers in the third Risperdal gynecostasia trial against Johnson & Johnson subsidiary Janssen Pharmaceuticals in the Philadelphia Court of Common Pleas on Thursday painted starkly different pictures to the jury on what caused a young boy to grow enlarged breasts.

Plaintiff Tim Stange's case will be the tie-breaker in the litigation, as the first and second trials resulted in victories for the plaintiff and defendants, respectively. On Feb. 25, a jury awarded \$2.5 million to plaintiff Austin Pledger, while on March 20, the jury in plaintiff William Cirba's case came back in favor of Janssen.

Stange, like the other plaintiffs, alleged his use of the antipsychotic drug Risperdal caused him to develop enlarged breasts. Stange took Risperdal from 2006 to 2009 to control his Tourette syndrome symptoms.



Photo by Diego M. Radzinski

KELLY



KLINE

Before the jury in Philadelphia Court of Common Pleas Judge Kenneth Powell's courtroom, Thomas R. Kline of Kline & Specter, representing Stange, repeated allegations made by plaintiffs in the other cases that Janssen failed to warn doctors of the increased risk of breast development in young males associated with taking Risperdal.

Stange started taking the drug when he was 11 years old, and according to Kline, "a

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year after the prescription of the drug, he had grown female breasts.”

Kline said Stange had surgery to remove the excess breast tissue when he was 18, but the emotional damage that came from his peers’ taunts is not so easily repaired.

He added the drug caused Stange to gain 60 pounds, initially masking the breast growth. The gynecomastia, Kline argued, was not revealed until Stange had lost weight after ending his use of the drug. Stange also complained of stabbing pains in his left nipple while on the drug.

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.

“The drug was never, ever approved for children with Tourette’s, but Janssen Pharmaceuticals had different ideas, and that affected what they were willing to tell doctors about the drug and what its real risks were,” Kline said.

He further maintained that Janssen hid information on the alleged increased prolactin levels—the hormone that causes breast growth—associated with Risperdal from the FDA. 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.

McCarter & English chairman Michael Kelly went up to bat for Janssen after Kline had concluded his opening remarks.

Kelly said Stange didn’t complain of gynecomastia until after he had been off the drug for a year.

“If you’re going to see something, you’re going to see it while he’s taking the drug,” Kelly explained to the jury.

Kelly went on to answer Kline’s claims that Stange was teased for his enlarged breasts by pointing out that he was also teased for his Tourette syndrome, a condition that Risperdal helped to improve.

He also asked the jury that if Risperdal was such a bad drug, why did Stange’s doctor keep prescribing it to him for four years before switching to a generic? Kelly said the doctor was aware of the risks and benefits.

Additionally, Kelly said puberty is the main cause of gynecomastia, and Stange took Risperdal right in the middle of it. He also said 50 to 75 percent of boys going through

puberty experience breast growth; for some, it diminishes afterward and for others, it remains.

He told the jury that Stange was never tested to see if his prolactin levels had increased while on the drug.

Kelly added Stange’s weight gain could also be attributed to other drugs he was taking, along with his normal pubescent growth spurt.

Lastly, Kelly said the warning labels on Risperdal were adequate in informing physicians of the potential risks.

“Even the earliest label mentions prolactin,” Kelly said, and as more testing was done down the road, the warnings were updated.

P.J. D’Annunzio can be contacted at 215-557-2315 or pdannunzio@alm.com. Follow him on Twitter @PJDannunzioTLI. •