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## \$2.5M Verdict Awarded in First Phila. Risperdal Trial

**BY P.J. D'ANNUNZIO**

*Of the Legal staff*

A Philadelphia jury has awarded \$2.5 million to the plaintiff in the first of roughly 1,250 Risperdal mass-tort cases in the city's courts.

After roughly a day-and-a-half of deliberations, the 12-member jury in Pledger v. Janssen Pharmaceuticals handed down the verdict in Philadelphia Court of Common Pleas Judge Ramy I. Djerassi's courtroom Tuesday afternoon. The verdict, agreed upon by 11 of the jurors, brought an end to the month-long trial.

The jury found defendant Janssen Pharmaceuticals negligent in having failed to warn of the potential for Risperdal to cause gynecomastia, a condition in which males grow enlarged breasts. The plaintiff in the case, Austin Pledger, took Risperdal to assist with behavioral symptoms related to autism and claimed to have developed gynecomastia from taking the drug.

**Kline & Specter co-founder Thomas R. Kline** said the verdict set the stage for the rest of the Risperdal cases set to go to trial.

He also remarked that, in 37 years of trying drug cases, "I have

never seen a worse case of corporate misconduct than I have seen here."

That misconduct, Kline said, was exemplified by Janssen's failure to turn over information to the U.S. Food and Drug Administration about Risperdal's ability to elevate levels of prolactin, the hormone that causes gynecomastia.

"The documents now in the public domain, including the statistically significant association between elevated prolactin levels and gynecomastia, which was never turned over to the FDA, was seen by the jury for what it was," Kline said.

As for whether the amount of the verdict met his expectations, Kline said, "The amount of the verdict speaks to the reaction of the jury, not only to the evidence against Janssen—which was damning—but to the injury caused to the most vulnerable members of our society."

In a Janssen statement issued in response to the verdict, a company spokeswoman said, "We are disappointed and will consider all of our options going forward, including appeals. We firmly believe this verdict should be overturned."

The spokeswoman continued, "During the trial, Janssen present-

ed abundant evidence showing that the FDA-approved label properly warned of the medication's potential side effects and the plaintiff's physician was aware of those side effects. The evidence also showed that Mr. Pledger was not harmed by using Risperdal and, in fact, his quality of life was significantly improved during the time he was taking Risperdal."

The atmosphere of the trial itself was often combative, with counsel for both parties verbally sparring with each other. Frequent objections were commonplace as well as informal criticisms of expert witnesses tossed around in open court.

Closing arguments in the case encapsulated the contentious nature of the trial.

Weil, Gotshal & Manges attorney Diane Sullivan, who represented Janssen, noted how much the plaintiff's experts, Dr. Mark P. Solomon and former FDA commissioner Dr. David Kessler, earned as testifying witnesses, and said the plaintiff had failed to bring a specialist in endocrinology, which Sullivan argued would be the medical field most directly related to the plaintiff's allegations.

Sullivan also referred to Solomon, who is a plastic surgeon, as "the Tom Brady of penile enlargement surgery," and said that

as an expert, Kessler "hasn't met a warning label he liked yet."

However, Kline, during the rebuttal portion of his argument, referred to Sullivan's portrayal of Solomon as "disgusting crap," and noted the defendants did not call a pediatric endocrinologist.

"I brought in a commissioner of the FDA," Kline said, before turning to Sullivan. "Where's your commissioner of the FDA?"

Pledger, a 20-year-old from Alabama, claimed he grew large breasts as a result of taking Risperdal when he was 8 years old, and that—barring a mastectomy—the condition is permanent. Kline alleged that Janssen knew about the increased risk of gynecomastia associated with Risperdal relative to similar drugs, but was not forthcoming in disclosing that information.

Pledger had used Risperdal beginning in 2002, but stopped after the FDA provided a new warning label in 2006 outlining the risks associated with gynecomastia.