



## Risperdal Judge Won't Reconsider Punitive Damages Ruling

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A Philadelphia judge has declined to reconsider his decision denying hundreds of plaintiffs in the Risperdal mass tort litigation the ability to seek punitive damages.

In a one-paragraph order July 18, Philadelphia Court of Common Pleas Judge Arnold L. New denied the plaintiffs' motion for reconsideration in *In re Risperdal Litigation* and denied their request for him to certify the question for an immediate appeal to the state Superior Court.

The cases are still awaiting a ruling from New on the remaining motions for summary judgment.

The plaintiffs are represented by attorneys at Kline & Specter and Sheller P.C.

Thomas R. Kline of Kline & Specter said in a statement that Janssen Pharmaceuticals' conduct as it relates to Risperdal was "abhorrent."

"This global ruling by Judge New will now need to be applied in individual cases, which will undoubtedly result in appellate review at the appropriate juncture as the first of individual cases are tried," Kline said in a statement. "We respectfully do not believe New Jersey law applies to the issue of punitive damages, or that New Jersey law, if applied, in these individual cases prohibits punitive damages recovery given Janssen's misconduct—including off-label marketing of a drug to children which caused them harm."

Kline said Pennsylvania's policy is to allow the imposition of punitive damages when the conduct warrants it. He said that is the case in the Risperdal litigation.

A call to Kenneth Murphy of Drinker Biddle & Reath, the attorney for defendant Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, was not immediately returned.

In a May 2 order, New said in a footnote that New Jersey law applies to the plaintiffs' claims alleging Janssen engaged in off-label marketing of Risperdal to children that resulted in alleged damages that included boys developing breasts as a result of taking the drug.

In granting Janssen's motion for partial summary judgment as to punitive damages, New had said the New Jersey Product Liability Act and controlling New Jersey case law do not permit the recovery of punitive damages in these cases.

"Here, the court should reconsider and vacate its May 2 order because neither choice-of-law nor the availability of punitive damages are matters that can be decided in Risperdal litigation on a global basis,"

the plaintiffs had said in their motion for reconsideration. "Each analysis involves case-specific considerations that can be assessed properly only within the context of an individual case."

The plaintiffs had argued applying a bar on punitive damages across all of the cases would be the first time a court has precluded punitive damages in such a way.

The New Jersey Product Liability Act bars the recovery of punitive damages in claims involving a U.S. Food and Drug Administration-approved drug unless there is evidence the defendant committed fraud on the FDA, according to the motion. The plaintiffs noted that, in cases where a drug was not approved by the FDA for the use prescribed to the plaintiffs, claims for punitive damages were allowed to proceed.

In the Risperdal litigation, most of the cases involve the use of the drug in children, according to the motion. The plaintiffs said Risperdal wasn't approved by the FDA for pediatric use until Oct. 30, 2006. Many of the cases in the mass tort litigation involve the use of the drug by children before October 2006. That issue alone, the plaintiffs said, requires a case-by-case assessment of whether punitive damages can apply.

"Even if the ingestion occurred after the 2006 approval, it does not follow that the bar on punitive damages applies," the plaintiffs said. "There was still off-label marketing by Janssen during this period for uses that were not within the strict criteria of the label."

Not only is a case-by-case analysis required to determine whether punitive damages should be available, but it also should apply to determine which state law applies, the plaintiffs argued. The plaintiffs said New should reconsider his decision that New Jersey law applies. They said the state where a plaintiff was prescribed and took the drug may have a greater interest than New Jersey in seeing its laws on punitive damages applied.

In its response to the plaintiffs' motion, Janssen had said the plaintiffs were belatedly changing their legal argument in an effort to sway the judge into reconsidering his ruling.

"After strenuously (and repeatedly) arguing that Pennsylvania law should govern the issue of punitive damages (based on the strategic decision that Pennsylvania does not have a statutory cap on punitive damages), plaintiffs now maintain that the court should determine the availability of punitive damages on a 'case-by-case basis,'" Janssen said in its opposition to the plaintiffs' motion for reconsideration.

Janssen further argued these cases are about Risperdal's warning label and not about what the plaintiffs asserted was the company's off-label marketing of the drug to children. Janssen said there has been no evidence to show its business decisions about the creation of Risperdal's warning label occurred anywhere other than New Jersey.

By focusing on the multistate marketing campaign of Risperdal, the plaintiffs are moving the relevant punitive damages inquiry from the place where corporate decisions are made to individual state activities, the company argued.

Janssen also took issue with the plaintiffs' argument that some of their claims for punitive damages could survive if they were prescribed the drug before it was FDA-approved for certain off-label uses.

"Consistent with the plain text of the statute, courts consistently have found that the punitive damages bar applies whenever the FDA has approved the medicine at issue," Janssen countered in its opposition brief.

Janssen said the plaintiffs' arguments didn't fall within the proper grounds for granting a motion for reconsideration. Janssen said there was no new evidence presented, nor was there any change in controlling law. The company also argued against the plaintiffs' request for a determination that New's May 2 order granting partial summary judgment as to punitive damages was either a final order that could be appealed or an interlocutory order that could be certified for appeal.

"There is no compelling reason that the single issue of punitive damages should delay this mass tort litigation," Janssen argued.