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Trial Judge Says Dismissal of Risperdal Suits Should Be Affirmed

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The judge in charge of Philadelphia's Complex Litigation Center has written an opinion supporting his decision to toss 13 Risperdal cases that originated in Michigan.

Supervising Judge Arnold L. New issued an opinion earlier this month in response to an appeal to the Superior Court of 13 consolidated cases against drugmaker Janssen Pharmaceuticals explaining why he decided to apply Michigan law to the cases, all of which involve plaintiffs who were prescribed the antipsychotic Risperdal while living in Michigan. The plaintiffs have contended that the drug causes gynecomastia, a condition where men suffer from enlarged breasts.

In his decision in A.H. Jr. v. Janssen Pharmaceuticals, New determined that Pennsylvania and Michigan law conflicted as to whether the plaintiffs would be able to proceed on various products liability and negligence claims, and determined that Michigan law, which would not allow the claims, should apply.

According to New, the plaintiffs had noted that Pennsylvania has an interest in governing the conduct of its corporate citizens, but that interest is not unlimited. Among other things, he looked to the Superior Court's decision in Normann v. Johns-Manville, which involved a plaintiff who was a New York resident, and said that Michigan law should apply.

"While Michigan's products liability act may be harsh, the court should not permit this commonwealth to become a repository for cases filed by Michigan residents seeking to avoid application of the Michigan Products Liability Act," New said.

Attorneys for the plaintiffs, Stephen Sheller of Sheller P.C. and **Thomas R. Kline of Kline & Specter,** said they disagreed with New's opinion.

"Our view is he's wrong," Sheller said.

The attorneys added they plan to argue before the Superior Court that Michigan law does not bar the claims because the U.S. Food and Drug Administration never approved Risperdal for children, and the claims can also proceed under the fraud exception to the Michigan Products Liability Act.

"We understand that serious mental illnesses and neurodevelopmental conditions can have a negative impact on a person's life and on the health and stability of families, and we sympathize with those who must face those issues every day," said Robyn Frenze, a spokeswoman for Janssen, in a statement to the press. "In these cases, we believe the court acted appropriately in dismissing the lawsuits, based on case law and Michigan statutes."

Kline said the outcome of the appeal in these cases will affect 27 cases originating in Michigan that are part of the mass tort inventory. There are more than 1,400 Risperdal-related cases pending in the program.

Along with the appeal regarding the Michigan cases, Kline noted that two additional cases involving Risperdal are headed for trial later this month, and post-trial motions are also set to be argued in a Risperdal case that resulted in a $2.5 million verdict for the plaintiff. The post-trial arguments are expected to focus on trial rulings, as well as a decision barring the plaintiff from seeking punitive damages, which could affect numerous other cases in the mass tort program.

"The docket is very active both on the trial and the appellate level, and the litigation is continuing full steam ahead," Kline said.

According to New, the Michigan cases, which are all part of the mass tort program, alleged negligence, defective design, fraud, failure to warn, strict liability,

breach of warrant, violation of the Unfair Trade Practices and Consumer Protection Law, unfair and deceptive trade practices and conspiracy.

Janssen filed motions for summary judgment, arguing that Michigan's Products Liability Act applied, which would give Janssen immunity for the claims.

New granted the motion, and dismissed all the claims from the 13 plaintiffs in November 2014. The plaintiffs appealed.

In the latest decision, New looked into whether Michigan and Pennsylvania law differed, and which state had the greater interest in the case.

New noted that Michigan's statute governing products liability provides blanket immunity for drugs that are approved by the FDA, except if a drugmaker bribed an FDA official, or if information was intentionally withheld from, or misrepresented to, the FDA.

The plaintiffs noted that, when the drug was prescribed to them, the label did not say it had been approved for adolescents, and contended that Janssen intentionally withheld information from the FDA, so questions of fact existed about whether the FDA would have approved the drug with those additional findings. The plaintiffs also argued that Janssen Pharmaceuticals and Johnson & Johnson's guilty plea in November 2014 to illegally promoting Risperdal for off-label use was tantamount to a federal finding of fraud by the FDA.

New said the plaintiffs' argument that Michigan law didn't apply because the drug had not been approved for use in children and adolescents was unconvincing.

According to New, the plaintiffs would need to show that Risperdal was not approved by the FDA for safety and efficacy, or that the label did not comply with FDA guidelines to succeed on that argument. However, the plaintiffs admitted that Risperdal was approved by the FDA when it came to market in 1993.

New also noted the plaintiffs' argument that the drug was not approved for children and adolescents until 2006, but said "a physician's decision to use a pharmaceutical for an 'off-label' purpose is not only acceptable practice, but also 'an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'"

Michigan law, New said, does not address off-label usage of a drug. Since the safety and efficacy was approved in 1993 and there was no evidence that the labeling changed, Michigan law would not allow the claims, New said.

Regarding whether the exemptions to Michigan's Products Liability Law could apply to the case, New looked to whether the Federal Food, Drug and Cosmetic Act preempted Michigan's law.

New noted that Michigan courts have not addressed the issue and federal circuit courts are split; however, the crux of the issue came down to whether the FDA would have approved Risperdal without the information.

"Plaintiffs have not produced any evidence to show the FDA would not have approved Risperdal in 1993, or would have withdrawn Risperdal from the market, if the information was accurately submitted," New said. "Indeed, in response to a citizen's petition, the FDA recently declined to withdraw Risperdal from the market."