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## Paxil Litigation Over Birth Defects Shifts to Settlement

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Drugmaker GlaxoSmithKline has agreed to settle almost 200 cases in which plaintiffs allege the use of the antidepressant Paxil caused birth defects.

Only one case in Philadelphia's mass tort Paxil program has gone to trial.

GSK has settled every other case scheduled for trial in the eight months since a Philadelphia **jury awarded a \$2.5 million plaintiffs verdict in the first Philadelphia Paxil test case to go to trial.**

GSK started to appeal that plaintiffs verdict from October. The jury awarded only compensatory damages and no punitive damages. But GSK then decided to settle *Kilker v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline* along with another 190 cases, according to an order signed by Philadelphia Common Pleas Judge Sandra Mazer Moss last week.

The cases have settled for confidential amounts, said Jamie Sheller of the **Sheller firm** and local plaintiffs liaison counsel for the Paxil pregnancy mass tort program. GSK confirmed the settlements but said in a spokeswoman's statement that the terms of the settlements are confidential.

Sheller estimates that up to another 100 cases, including cases that have not yet been filed, have settled. The litigation is two-thirds over, Moss and Sheller said.

The *Kilker* case was viewed by the plaintiffs mass torts bar as a leading indicator of the strength of more than 600 similar cases.

"When you're dealing with children with birth defects that's a concern for any company," Sheller said. "GSK gave it their all at that trial. ... Despite that, the plaintiffs were successful in the case and that set a tone for their analysis. Even though they mounted an excellent and strong defense they weren't able to overcome the plaintiffs' position."

The next cases in the litigation are scheduled for trial in the fall.

GSK spokeswoman Sarah Alspach said in an e-mail statement that GSK has agreed to settle some cases involving the use of Paxil during pregnancy "despite its litigation defenses, in order to avoid the costs, burdens and uncertainties of ongoing litigation."

Moss, the coordinating judge of Philadelphia's mass tort program, the Complex Litigation Center, said the philosophy of GSK "is to try and settle what they can and to settle in groups."

Moss also said the Paxil litigation has been resolving successfully in the last few months because of the cooperation between the plaintiffs and the defense bars and because GSK has not taken a stance that they're "not offering a penny."

"I think there is a great deal of cooperation between the plaintiffs and defendants," Moss said. "They actually work well together. There is not a lot of animosity."

Moss has been meeting monthly with the Paxil plaintiffs lawyers and the Paxil defense team, Sheller said.

Michael T. Scott, a defense attorney with Reed Smith's life sciences health industry group, said that settling a case is not an admission that the company did anything wrong and does not mean that all cases are going to settle. Scott said his firm represents GSK in some matters, but not in cases involving Paxil.

Tom Kline, a plaintiffs attorney with Kline & Specter, said that it appears that the *Kilker* trial was a "cathartic event" that influenced the course of the litigation.

Pharmaceutical companies have "economic and reputational incentives" to turn away from litigation, Kline said.

Pharmaceutical companies think in terms of billions of dollars, Kline said, and settling cases en masse doesn't break their bottom line and must be weighed against the impact on their reputation with the public -- including the federal Food and Drug Administration and health care professionals -- with every case that goes to trial, Kline said.

Moss said a mediator paid for by the defendants and the plaintiffs also was very helpful in settling the cases.

More of the cases that are settling involve cardiac defects, but there are other minor plaintiffs alleging defects because of their mothers' use of Paxil, Sheller said.

Because the cases involve minors, Orphans' Court approval is necessary, Moss said.

Moss said because the cases involve many out-of-state plaintiffs, she is working with Judge Joseph D. O'Keefe, administrative judge of Orphans' Court, on how to handle settlements for out-of-state minor plaintiffs.

Moss said it is contemplated that out-of-state minor plaintiffs can have approval for their settlements given by the state court jurisdictions in which the plaintiffs live. However, cases will come back to Philadelphia Orphans' Court if there is any reason that approval by judges in other states doesn't happen, Moss said.

O'Keefe said last week the Orphans' Court has not yet started to receive any Paxil cases.

Despite settling many of the Paxil cases, GSK continues to argue it acted appropriately regarding the drug.

"GSK believes it acted properly and responsibly in conducting its clinical trial program for Paxil, in marketing the medicine, in monitoring its safety once it was approved for use and in updating pregnancy information in the medicine's label as new information became available," Alspach said.

In post-trial motions seeking judgment notwithstanding the verdict or a new trial in *Kilker*, GSK said that 65 percent of all birth defects have no known cause and less than 1 percent of all birth defects are attributable to a mother's exposure to medication during pregnancy.

Plaintiff Lyam Kilker has three congenital defects in his heart: a defect between the upper two chambers of his heart, a defect between the lower two chambers of his heart and a defect that has left a hole in the wall of his heart that separates the two pumping chambers of the heart as well as preventing the heart's aorta from forming a complete "tube," according to court papers.

The last of Kilker's heart defects, called an interrupted aortic arch, is a defect that GSK argued has not been found in research to be associated with the use of Paxil by pregnant mothers and the cause of this type of heart defect is generally considered to be unknown.

"There is no established -- or even speculative -- link between Paxil and interrupted aortic arch," GSK said in its post-trial motions.

Sheller said last fall that GSK thought it could win on Kilker's more rare defect, which is why they took Kilker to trial and settled other cases.

Prior to *Kilker*, three other bellwether cases settled for confidential amounts.

Joseph O'Neil of Philadelphia's Lavin O'Neil Ricci Cedrone & DiSipio is the local defense liaison counsel for the Paxil pregnancy program.

The main plaintiffs firms include Clark Burnett Love & Lee in Houston, the Tracey Law Firm in Houston and **Robinson Calcagnie & Robinson** in Newport Beach, Calif., Sheller said.

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