J&J Hid Topamax Birth Defect Risks, Philly Jury Hears

By **Matt Fair**

Law360, Philadelphia (February 24, 2014, 5:55 PM ET) -- A Johnson & Johnson subsidiary failed to adequately warn parents about the risk of birth defects associated with the epilepsy and migraine drug Topamax, an attorney for the family of a 5-year-old boy born with a cleft palate told a Philadelphia jury on Monday.

Scott Love, an attorney with Clark Love & Hutson representing the family of 5-year-old Josiah Brown, told a state jury during opening arguments that the failure of J&J subsidiary Janssen Pharmaceuticals Inc. to provide information to doctors about the possibility of birth defects led Josiah's mother to continue taking Topamax to treat her migraines around the time her son was conceived in 2008.

"They hurt people, and one of the people they hurt was Josiah Brown. They didn't give Mrs. Brown … the opportunity to say no." he said. "They took that decision away from his family. We wouldn't be here today had they disclosed what they knew."

Josiah's family filed suit in the Philadelphia County Court of Common Pleas in 2008 alleging that his mother's use of Topamax around the time of the child's conception led to him developing a cleft palate that has required at least five surgeries.

His case is the fourth Topamax-related product liability case to go to trial in Philadelphia. A jury in October **returned a $4 million verdict** against Janssen in a similar suit. Another family **won $10 million in damages** after a jury returned a verdict in their favor in December. Those cases are currently on appeal before the state's Superior Court.

In 2010, Janssen **agreed to pay more than $81 million** to put to rest a U.S. Department of Justice inquiry into off-label marketing of Topamax.

Alexander Calfo, an attorney with Barnes & Thornburg LLP who is representing the defendants, told the jury that Josiah's condition was likely genetic and that the boy's mother had ceased taking Topamax weeks before his conception and the development of his palate in utero.

"Here in court you must decide the case based on facts and not on sympathy or emotion," he said. "[Josiah's condition] was caused by a genetic disorder and not by any medication that Mrs. Brown took."

He said that Josiah's treating physicians were not provided with key information that would have led them to concluded that the boy was actually suffering from a genetic condition known as CPX, and that

doctors had drawn conclusions about his condition based on only partial information.

“The evidence is going to show you that the genetics doctor was never provided with accurate family or medical history, either by Mrs. Brown or her lawyers,” Calfo said. “[The doctor] didn’t know to test for CPX.”

The trial, which is being overseen by Judge George Overton, is expected to last about three weeks.

Prior to opening arguments, attorneys for both sides spent several hours dueling over evidentiary motions.

Attorneys for the plaintiff urged Judge Overton to allow them to introduce evidence showing that Janssen changed the label for the drug in 2011 to warn that it could cause cleft palates and lips. They pointed to a 2011 decision by the state’s Superior Court in Daniel v. Wyeth Pharmaceuticals Inc. which they said permitted the introduction of labels that post-dated a plaintiff’s use of the drug.

The state’s Supreme Court in December reversed its decision to hear the Daniel case, saying that it had “improvidently granted” an appeal in the case. The justices did not expound on their rationale for jettisoning the case.

“The Superior Court decision is the law of the land,” said Eric Weitz of Messa & Associates PC, who is also representing the plaintiffs.

Judge Overton, however, found that the admissibility issue the Superior Court ruled on in the Daniel case dealt with whether the label would have altered the way a doctor recommended a drug be used. He added that the evidence was also never actually introduced in the Daniel case.

“The case is not on all fours with the situation we have here,” Judge Overton said when he denied the motion from the bench.

A motion regarding the 2011 label change has also been presented to Judge Arnold New, who is overseeing the consolidated docket in the Topamax mass tort program that’s been created in the court, but no ruling had been made as of Monday afternoon.

According to court records, Judge New barred the introduction of the label change for the purpose of imputing negligence. However, the plaintiffs say that Judge New’s order gives discretion to trial judges to allow or disallow evidence of subsequent remedial measures taken by the company to address potential side effects as they see fit.

According to court records, there are more than 130 Topamax-related cases pending in Philadelphia. Trial in a third Topamax case began two weeks ago, and jury deliberations in that case are expected to begin next week.

The plaintiffs are represented by Rosemary Pinto of Feldman & Pinto PC; Scott Love of Clark Love Hutson; and Eric Weitz of Messa & Associates.

The defendants are represented by Kenneth Murphy, Melissa Graff and Molly Flynn of Drinker Biddle & Reath LLP; Alexander Calfo of Barnes & Thornburg LLP; James Murdica ofPatterson Belknap Webb & Tyler LLP; and Adam Spicer of Butler Snow LLP.

The case is Josiah Brown v. Ortho-McNeil-Janssen Pharmaceuticals Inc., case number 110503417, in the Philadelphia County Court of Common Pleas.

-- Additional reporting by Kurt Orzeck and Juan Carlos Rodriguez. Editing by Emily Kokoll.