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Aventis Escapes Claims That Clomid Warnings Fell Short

By **Emily Field**

Law360, New York (March 17, 2016, 11:30 PM ET) -- A Utah federal judge on Wednesday tossed claims, brought by a woman whose son was born without two fingers, that the labels on Aventis' infertility drug Clomid fail to adequately warn about birth defect risks, saying the U.S. Food and Drug Administration had rejected such warnings.

U.S. District Judge Dee Benson said that the FDA twice had rejected a citizen's petition to include warnings that Clomid increases the risks of birth defects when taken by women trying to conceive. The petitions, filed by Terence Mix in 2007 and 2009, embody the same theory that Clomid has a long half-life and inhibits cholesterol biosynthesis, causing birth defects, that Victoria Cerveny does in her complaint, the judge said in granting Aventis' motion for summary judgment based on federal presumption.

"On September 8, 2009, the FDA rejected Mix's theories and, by proxy, rejected the plaintiffs' theories," Judge Benson said. "In evaluating Mix's 2007 petition, the FDA not only reviewed the scientific research submitted by Mix, the FDA also independently surveyed the literature regarding clomiphene citrate, or Clomid."

The FDA concluded that there's insufficient data, based on the scientific evidence, to demonstrate a link between taking Clomid before conception and the risk of causing birth defects, according to the opinion. And specifically, the FDA found that research showed that any half-life of Clomid isn't sufficient to cause "significant inhibition of cholesterol synthesis" even after multiple rounds of treatment, the judge said.

When a citizen petition is filed after an alleged injury and addresses the same failure to warn claim as the plaintiff's, the FDA's denial of the petition can be evidence to support a manufacturer's preemption defense, the judge said.

Cerveny had taken Clomid in 1992, according to the judge, many years before Mix's petition was denied.

"If the FDA concluded in 2009 and 2012 that Clomid is not a significant inhibitor of cholesterol, and if used as directed Clomid does not pose a risk of causing birth defects, the court cannot say the FDA would have approved a contrary warning prior to 1992," the judge said. "The FDA's denial of the plaintiffs' theories embodied in Mix's citizen petitions is clear evidence that the FDA would not have permitted Aventis to strengthen Clomid's label prior to 1992."

The judge also found it relevant that the FDA has consistently approved Clomid labeling that includes affirmative rejections of Cerverny's theories, according to the judge.

"Since 1967, Clomid's label has consistently warned about the risk to a fetus if Clomid is ingested during pregnancy," the judge said. "However, in the nearly five decades Clomid has been used to induce ovulation, the FDA has never required Clomid to carry warnings suggesting birth defects associated with Clomid use prior to pregnancy."

Cerveny took Clomid in 1992, until she discovered she was pregnant after her second round of treatment. She then gave birth to her son, Alexander, who was born without his first and fifth fingers on his left hand, according to the opinion.

Alexander was also born with "a congenital dislocation of the left radial head" on his left elbow, according to the complaint.

Cerveny had argued his birth defects were the result of Clomid still being present in her body during conception and while his organs were developing, the judge said.

Representatives for the parties didn't immediately respond to requests for comment on Thursday.

The Cervenys are represented by Eric D. Barton, Thomas P. Cartmell and Christopher L. Schnieders of Wagstaff & Cartmell LLP.

Aventis is represented by Harvey L. Kaplan and Eric A. Swan of Shook Hardy & Bacon LLP and Gary T. Wight of Kipp & Christian.

The case is Cerveny et al v. Sanofi et al., case number 2:14-cv-00545, in the U.S. District Court for the District of Utah.

--Editing by Bruce Goldman.