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GSK Faces Wave Of Zofran Birth Defect Suits

By **Jeff Overley**

Law360, New York (July 23, 2015, 6:31 PM ET) -- GlaxoSmithKline LLC on Wednesday was hit with a complaint in California federal court tying alleged off-label promotion of anti-nausea drug Zofran to birth defects, adding to a number of similar lawsuits that have emerged this year and appear headed for multidistrict litigation.

In the complaint, California resident Melisa Arellanes says she was prescribed Zofran for morning sickness during the first trimester of her pregnancy despite the drug not being cleared for such use. Her daughter was born in 2002 with "birth defects, including but not limited to kidney problems," for which there are no known genetic causes or family history, according to the suit.

Arellanes' complaint directed strong words at GSK, saying it aggressively promoted Zofran as a "wonder drug" for morning sickness despite lacking any evidence of safety in pregnant women and only having U.S. Food and Drug Administration approval for nausea related to cancer and surgery.

"GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs," the complaint charged, adding that Zofran eventually became the most prescribed drug for morning sickness in the U.S.

According to the complaint, GSK has received more than 200 complaints of birth defects associated with Zofran but hasn't updated the product's warning label. That label currently says that studies of Zofran, or ondansetron, in pregnant rats and rabbits "revealed no evidence of … harm to the fetus." But it also cautions that data for pregnant women is lacking and that as a result, "this drug should be used during pregnancy only if clearly needed."

GSK paid $3 billion in 2012 to settle allegations of off-label promotion involving several drugs, including Zofran, which the U.S. Department of Justice said had been illicitly promoted for morning sickness from 2002 through 2004.

Arellanes' suit joins many others that have been lodged in recent months. For example, a case called LeClair v. GlaxoSmithKline was filed in February in Massachusetts federal court and blames Zofran for causing congenital heart defects and "developmental delays" in the plaintiff's daughter. Another case, Hunter v. GlaxoSmithKline, was filed in April in Alabama federal court and blames Zofran for causing glaucoma, a seizure disorder and other problems in the plaintiff's son.

GSK had no immediate comment on Thursday.

The U.K.-based drugmaker filed a motion earlier this month with the Judicial Panel on Multidistrict Litigation stating that 12 suits involving similar allegations had been filed in 10 districts. The company asked that those suits and any comparable ensuing cases be

transferred for coordinated or consolidated pretrial proceedings in the Eastern District of Pennsylvania, and it predicted that the JPML would consider the motion in October.

Arellanes is represented by T. Christopher Pinedo, Robert C. Hilliard, Catherine Tobin, John Martinez and Marion Reilly of Hilliard Munoz Gonzales LLP.

Counsel information for GSK was not immediately available.

The case is Melisa Arellanes v. GlaxoSmithKline LLC, case number 2:15-cv-05544, in the U.S. District Court for the Central District of California.

--Editing by Mark Lebetkin.