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Zofran and the Devastating Risk of Birth Defects

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Zofran is a prescription drug developed and manufactured by Glaxo Smith Kline (GSK) to treat nausea and vomiting symptoms experienced by patients after surgery, and those receiving chemotherapy and radiation therapy. Zofran is part of a class of drugs called selective serotonin receptor antagonists. This class of drugs antagonizes, or inhibits, the body's serotonin activity which reduces nausea and vomiting symptoms. Zofran was first approved by the FDA in 1991 as an injectable solution but is currently available in various forms, including oral tablets.

Shortly after its approval, GSK began to market Zofran off label to pregnant women for the treatment of severe morning sickness. The term 'off label' relates to the prescription of a drug or condition other than that for which it has officially been approved. In this case, Zofran was prescribed off label because the FDA had not approved it for use during pregnancy. GSK had not proved the drug was effective at treating morning sickness, and more importantly, safe to the mother and her unborn child. In fact, the research indicated just the opposite.

GSK's early clinical testing of Zofran revealed that animals exposed to the drug during pregnancy exhibited increased maternal weight loss, an increase in the number of intra-uterine deaths, and developmental retardation in off-spring and fetuses. To counter its own research, GSK included a disclaimer in Zofran's prescribing information which states that "animal reproduction studies are not always predictive of human response." Based upon this technically true statement, and without performing any human studies designed to assess the risk of birth defects, GSK concluded that Zofran was safe to market off label to doctors and their patients as a treatment for morning sickness.

By as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran in pregnant women. From 1992 to present, GSK received

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at least 200 reports of birth defects in children who were exposed to Zofran during pregnancy. The most common birth defect reported to GSK was congenital heart defects, though other defects including cleft lip and palate, intrauterine death, still birth, and severe malformations were also reported. In addition, at least 4 peer reviewed studies have been published since 2004 confirming the link between Zofran and birth defects.

In the United States, the FDA requires drug manufacturers to revise a drug's labeling to include a warning as soon as there is reasonable evidence of a serious hazard associated with the drug. Clearly, GSK knew of the association between Zofran and birth defects soon after it introduced the drug to the market yet failed to update the warnings on its label, choosing instead to put profits ahead of patient safety. GSK's inaction exposed untold thousands of mothers and their babies to the devastating risk of birth defects. As a result, numerous lawsuits have been filed against GSK seeking to hold it responsible for birth defects associated with Zofran use.

Our office is currently investigating these types of cases. If you or a loved one took Zofran during pregnancy and had a child who was born with a birth defect, please contact our office for a free and confidential consultation.

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