Zofran® Prescribed for Morning Sickness Linked to Possible Birth Defects

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Janice Smith, of Alexandria, and her husband Peter celebrated when they learned Janice was pregnant with their first child. So did Annie Rogers, of Annandale, and her husband Jack and Megan Henderson, of Fairfax, and her husband, Paul. Each gave birth to a baby with serious birth defects. Justin Smith was born with a hole in his heart, Richard Rogers was born with a cleft palate and Ronald Henderson was born with a club foot. What did all three pregnant women have in common? Each had morning sickness during their first trimester of pregnancy and were prescribed Zofran® to alleviate it.

What is Zofran® & Who Makes It?

Zofran® (odansetron) is a prescription drug manufactured by one of the largest drug companies in the world -- GlaskoSmithKline, known as GSK. Zofran® was approved by the FDA 24 years ago to treat only nausea and vomiting in three specific instances: 1) from chemotherapy; 2) from radiation therapy; and 3) following surgery. Zofran® has never been approved by the FDA to treat the morning sickness of pregnancy. Yet, Zofran® is still being promoted today "off label" by GSK for morning sickness, even though it has been linked to an increased risk for birth defects and lawsuits have been filed against GSK.

Zofran® is what pharmacists call a "5HT3 receptor antagonist" – a big word for a cell blocker. Biological activity in our bodies occurs at the cellular level. Cells have a receptor on the outside surface where natural body chemicals, like hormones, fit. Once attached, the natural chemical influences activity within the cell. Serotonin, a natural body chemical, when attached to certain cells causes vomiting. Zofran® blocks (antagonizes) the effect of Serotonin by taking up the space on the cell's 5HT3 receptor that Serotonin would occupy. Hence, the big pharmacologic name for Zofran® – "a 5HT3 receptor antagonist".

Morning Sickness & the First Trimester of Pregnancy

Three quarters of pregnant women experience morning sickness during their first trimester of pregnancy. Generally, nausea begins from the 4th-6th week of pregnancy and ends during the 14th week. Fetal development begins during the first trimester of pregnancy and follows an expected course. The embryonic period begins during the 5th week when the baby's heart, organs, brain and spinal cord begin to develop. It is during this vulnerable first trimester of pregnancy that morning sickness begins and Zofran® is promoted and prescribed.

Court documents filed against GSK report that over 25 years ago, GSK performed studies in mammals that showed Zofran® crossed the placental barrier, exposing the fetus to Zofran®. These court documents further report that a later study, conducted on humans, confirmed that Zofran® passed through the placental barrier exposing a fetus to the drug and GSK failed to disclose this information to pregnant women and their doctors.

Did GSK Know that Zofran® Posed a Risk of Birth Defects to Pregnant Women? Court documents, filed against GSK, show that GSK received at least 32 reports of birth defects by the year 2000 and more than 200 reports of birth defects by February, 2015 in babies born to pregnant women who were prescribed Zofran® during their first trimester of pregnancy and that GSK failed to disclose this to pregnant women and their doctors.

In addition, large, independent scientific studies have been done on the incidence and prevalence of birth defects in pregnant women taking Zofran® during their first trimester of pregnancy. These studies showed an increased risk for birth defects. Court documents, filed against GSK, report that GSK has not disclosed the results of these studies to pregnant women or their physicians, but instead promoted Zofran® as a morning sickness drug during the first trimester of pregnancy.

Even today, in its "prescribing information" for Zofran®, in the section on "warnings", "precautions", and "adverse reactions", GSK fails to disclose an increased risk of birth defects from Zofran ® when prescribed for pregnant women in their first trimester of pregnancy.

The FDA never approved Zofran® for use in pregnant women – only for patients experiencing terrible nausea and vomiting from chemotherapy, radiation therapy and post-surgery. By promoting Zofran® as a morning sickness drug -- way beyond the limited uses approved by the FDA, GSK transformed Zofran® into a multibillion dollar block buster drug.

US Justice Department Charges GSK with Fraud and Illegal Promotion of Zofran® and Other Drugs. In 2012, GSK pled guilty to charges by the US Government of fraud and unlawfully promoting Zofran® and other drugs. GSK agreed to plead guilty and pay 3 billion dollars to settle criminal and civil charges. The Justice Department on July 2, 2012, in its "Justice News," reported "the resolution is the largest healthcare fraud settlement in US history and the largest payment ever made by a drug company."

Lawsuits against GSK by mothers and fathers of babies born with birth defects are beginning to be filed, as they may be eligible for compensation against GSK.

Gerald A. Schwartz *has more than 30 years experience specializing in Virginia personal injury and wrongful death law. Schwartz is a member of the VA and DC Bars and works in association with other lawyers on Zofran® cases. A leader among Virginia personal injury and wrongful death lawyers, Schwartz is recognized as one of the "Top 100 Trial Lawyers in Virginia". A Past President of the Virginia Trial Lawyers Association, Schwartz is also a faculty and board member of the Virginia College of Trial Advocacy and has been named to Virginia Super Lawyers since 2007. Schwartz is often invited to teach other lawyers how to Maximize Recovery for their clients.*