

Four Studies Find Association Between Zofran & Birth Defects

May 08, 2015

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At least four epidemiological studies have demonstrated a possible link between the powerful anti-nausea drug Zofran and major birth defects.

Zofran is manufactured by GlaxoSmithKline, one of the world?s most profitable drug companies. In 1991, it was approved by the US Food & Drug Administration for the treatment of severe nausea and vomiting in patients undergoing chemotherapy, radiotherapy and surgical anesthesia. But experts have noted that physicians are also prescribing Zofran to pregnant women as a morning sickness treatment. And now that pregnancies across the world have been exposed to Zofran?s active ingredient, ondansetron, teams of researchers have begun to study the drug?s effect on fetal development.

Funded by the US Centers for Disease Control, researchers at Harvard and Boston University reviewed health records from a total of 10,383 pregnancies. While the vast majority of these women reported experiencing nausea and vomiting during the first trimester, only 15% sought medical attention to alleviate their symptoms. Comparing birth records, researchers found that women who had been prescribed Zofran or a generic equivalent were 2.37 times more likely to deliver babies with cleft palate than women who had

received no treatment for morning sickness.

Co-authored by M. Anderka, the study was published as ?Medications used to treat nausea and vomiting of pregnancy and the risk of selected birth defects? in January 2012?s edition of Birth Defects Research. Part A, Clinical & Molecular Teratology.

Researchers at the University of Western Australia investigated a total of 96,968 birth records filed between 2002 and 2005. While only 0.25% of these pregnancies were exposed to ondansetron in the first trimester, women prescribed ondansetron were found to be 20% more likely to deliver babies with a major birth defect. Specifically, the study concluded that ondansetron was linked to a six-fold increase in the rate of extremely rare kidney malformations.

Authored by Lyn Colvin and others, the study was published as ?Off-Label Use of Ondansetron in Pregnancy in Western Australia? in the 2013 volume of BioMed Research International.

Danish scientists reviewed every birth record filed in Denmark between 1997 and 2010. In total, their investigation included 903,207 pregnancies. By cross-referencing prescription and birth records, the researchers found that only 1,368 Danish women had been prescribed ondansetron during that 13 year period. Compared to unexposed women, the study found that women taking ondansetron or Zofran were 4.8 times as likely to give birth to children with a rare congenital heart defect known as ?atrioventricular septal defect.? The study found a link to other congenital heart defects as well. Women taking ondansetron were found to be 2.3 times more likely to deliver babies with ventricular septal defects and 21. times more likely to have babies with atrial septal defects.

Written by Jon Andersen et al., the study?s results were presented on August 17, 2013 at the International Society of Pharmacoepidemiology in Montreal.

A team in Sweden repeated the Danish study, using Swedish birth records that spanned from 1998 to 2012. Pregnancies exposed to ondansetron were linked to a 62% increase in the risk for congenital heart defects.

Funded by Sweden?s National Board of Health & Welfare, the study was published under the title ?Use of ondansetron during pregnancy and congenital malformations in the infant? in December 2014?s edition of Reproductive Toxicology.

In the wake of these results, multiple American families have filed lawsuits against GlaxoSmithKline, claiming that prenatal exposure to Zofran caused their children to be born with major birth defects. These parents allege that the company has been aware of Zofran?s ?unreasonable risk of harm? for more than two decades, and claim that GlaxoSmithKline failed to disclose vital safety information to the public.

In fact, they say that the company has unlawfully promoted Zofran as a treatment for morning sickness. In 2012, the US Department of Justice made similar allegations, claiming that GlaxoSmithKline had marketed Zofran to doctors as a ?safe and effective? drug during pregnancy, despite having never studied Zofran?s effects on pregnant women or their unborn babies.

Michael Monheit, Esq., a plaintiffs? lawyer who has joined with multiple attorneys to represent families across the United States in the ongoing Zofran litigation has created the website ZofranLegal.com to provide more information on this matter to parents and birth defect survivors. A detailed overview of these studies, along with information on current Zofran lawsuits, can be found at that address.

Families with questions about this press release, or those who are looking for more information on the Zofran litigation, can use the information below to contact the attorneys sponsoring ZofranLegal.com:

CONTACT DETAILS

Company Name: ZofranLegal.com

Contact Name: Michael Monheit

Phone Number: 1-877-620-8411

E-mail Address: michael@monheit.com

Mailing Address: 1368 Barrowdale Road, Rydal, PA 19046

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For more information about ZofranLegal.com, contact the company here:ZofranLegal.comMichael Monheit1-877-620-8411michael@monheit.com1368 Barrowdale Road, Rydal, PA 19046

ZofranLegal.com

Sponsored by an alliance of attorneys, ZofranLegal.com is a resource for parents, families and birth defect survivors interested in learning more about litigation surrounding the nausea drug Zofran and its link to increased risks of major birth defects.

Website: http://zofranlegal.com/

Email: michael@monheit.com

Phone: 1-877-620-8411