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Prenatal Safety

Birth Defects, Prescription and Over-the-Counter Drugs

CONTENTS

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Drugs, both prescription and over-the-counter, have little to no information on the label or packaging about how pregnant women or their fetus/baby will be affected. Pregnant women are vaguely directed to check with their doctor.

CAN BIRTH DEFECTS BE PREVENTED?

Doctors don't usually have an answer because part of the problem is there have been no clinical trials or testing on pregnant women; that would be highly unethical. Another problem is that women who take prescription and over-the-counter drugs don't immediately know they are pregnant.

Genetic birth defects may not be preventable but prescription and over the counter drug inducing birth defects could be prevented with more up front information.

Medications that a pregnant woman takes can cross the placenta and affect her unborn child. The harsh reality is newborns are suffering from cleft palate, cleft lip, spina bifida, congenital heart defects, and more. Where's the warning?

BACKGROUND ON BIRTH DEFECTS: CLEFT PALATE, CLEFT LIP, SPINA BIFIDA, HEART DEFECTS

First, let's explain what these major birth defects are:

CLEFT PALATE is a condition in which the two plates of the skull that form the roof of the mouth are not completely joined.

CLEFT LIP is formed in the top of the lip as either a small gap or an indentation in the lip as a partial cleft or continues into the nose as a complete cleft. Cleft lip can occur as one sided or two sided. A cleft lip almost always accompanies a cleft palate. Cleft lip was formerly known as harelip.

Treating cleft oral birth defects takes time, patience, and good medical coverage. Health problems may include breathing and feeding difficulties, speech improvement, infections of the middle ear and hearing loss. Psychologically, a child may be tormented by societal cruelty for being different.

SPINA BIFIDA is caused by the failure of the neural tube to close during the first month of embryonic development even before a mother knows she is pregnant. Spina bifida is one of the most common birth defects, with an average incidence of 0.7 per 1,000 births in the United States. Caucasian women have the greatest risk. It is also known as cleft spine.

There is no known cure for nerve damage due to spina bifida. To prevent infection, pediatric neurosurgeons close the opening on the back. During the operation for spina bifida, the spinal cord and its nerve roots are put back inside the spine and covered with meninges.

Depending on severity, affected people will need to use braces, crutches, walkers, or wheelchairs to maximize their mobility. Sometimes paralysis occurs and sometimes not. Some will need urinary and bowel management.

HEART DEFECTS Congenital heart defects are the most common type of birth defect. They affect 8 out of every 1,000 newborns. Each year, more than 40,000 babies in the United States are born with congenital heart defects. Congenital heart defects are problems with the heart's structure that are present at birth. These defects can involve the interior walls of the heart, the valves inside the heart, or the arteries and veins that carry blood to the heart or out to the body. Congenital heart defects change the normal flow of blood through the heart.

Severe heart defects generally are found during pregnancy or soon after birth.

5 common congenital heart defects include:

- Ventricular septal defect
- Transposition of the great vessels
- Coarctation of aorta
- Tetralogy of Fallot
- Hypoplastic left heart syndrome

OTHER BIRTH DEFECTS:

- Hydrocephaly (build up of fluid in the brain)
- Glaucoma (an eye defect)
- Gastroschisis (a defect of the abdominal wall)
- Hypoplastic left heart syndrome (one of the most critical heart defects)
- Hypospadia (a condition in male babies that causes the opening of the urethra to occur in the wrong place)
- Craniofacial defects
- Cardiovascular malformations
- Cleft Lip
- Cleft Palate
- Congenital Heart Defects
- Mental Deficiencies
- Anencephaly (open cranium with the absence of a brain)
- Esophageal atresia (closed esophagus)
- Omphalocele (protrusion of part of the intestine through the abdominal wall)
- Craniosynostosis (premature fusion of the skill bones)
- Dandy Walker malformation (defect of the brain)
- Cloacal extrophy (involves multiple abnormalities of the gastrointestinal and genitourinary tracts)
- Autism spectrum disorder
- Penoscrotal hypospadia
- Down's Syndrome
- Club foot
- Undescended testes in males
- Blindness
- Hernia

FDA DRUG RATINGS FOR PREGNANT WOMEN

In 1979 the Food & Drug Administration set up a system—A, B, C, D, and X, to rate drug safety while pregnant. Category A means that well-documented drug studies demonstrate safety for human fetuses. Category B is deemed also safe but there is less evidence. Category C has no harm to humans but there are no studies on pregnant women. The majority of drugs are in Category C. Category D poses some harm to human fetuses, but the potential benefits may outweigh to risks. Category X has clear risk or is of little benefit to pregnant women.

The rating list has many flaws and criticisms and is being updated.

TOPAMAX

Topamax (generic topiramate) is a drug used for anti seizures or to prevent migraine headaches. It may also have other off label uses such as neuropathic pain, anger control, post-traumatic stress disorder (PTSD) associated nightmares, metabolic diseases like adiposopathy, self injurious skin pricking, essential tremor, cluster headaches, and alcoholism.

In March 2011, the FDA announced the dangerous relationship between taking Topamax during the first trimester and cleft birth defects.

For women who are of child bearing ages or who want to get pregnant, taking Topamax during the first trimester is dangerous to newborns.

Topamax raises the risks of cleft birth defects.

DEPAKOTE

Depakote, Depakote ER, Depakene, Depacon, and Depakine are the brand names for Valproic acid (VPA), a chemical compound that is used as an anticonvulsant and mood-stabilizing drug, primarily in the treatment of epilepsy, bipolar disorder, and, less commonly, major depression. It is also used to treat migraine headaches and schizophrenia.

The most dangerous Depakote side effects involve damage to the unborn fetus. Consequently, women who are pregnant, likely to become pregnant or want to get pregnant or are of childbearing age, or are nursing should not take Depakote because it may cause the following conditions:

- Spina bifida
- Cleft palate
- Hand malformations
- Abnormally developed ribs
- Hypospadia (a condition in male babies that causes the opening of the urethra to occur in the wrong place)
- Undescended testicles

According to data reported by the FDA from the North American Antiepileptic Drug Pregnancy Registry, use of about 1 g/day of Depakote during the first trimester of pregnancy is linked to a four-fold increased risk for congenital malformations compared with other anti-epileptic drugs.

PAINKILLERS

Oxycodone (brand name Oxycotin), hydrocodone (brand name Vicodin), and codeine are common drugs or analgesic painkillers known as opioids. These are among the world's oldest known drugs as the use of the opium poppy and its therapeutic benefits predate recorded history. An opioid is a chemical that works by binding to opioid receptors, which are found principally in the central and peripheral nervous system and the gastrointestinal tract.

The National Birth Defects Prevention Study (from 1997 through 2005) was an ongoing population-based case-control study.

Therapeutic opioid use was reported by 2.6% of 17,449 case mothers and 2% of 6,701 control mothers. Researchers found that 2 to 3% of the mothers interviewed were treated with prescription opioid pain killers, or analgesics, just before or during early pregnancy. Codeine and Vicodin (generic hydrocodone) were the most frequently reported medications, representing 69% of all reported opioid analgesics used.

The following birth defects were linked with painkillers:

- Spina bifida
- Congenital heart defects
- Hydrocephaly
- Glaucoma
- Gastroschisis

The study found that women who took prescription opioid painkiller medications just before or during early pregnancy had about two times the risk for having a baby with hypoplastic left heart syndrome vs. women who were not treated with these opioid medications.

OXYCONTIN (GENERIC OXYCODONE) is a Schedule II controlled substance with an abuse potential similar to morphine. Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids.

Recently, the Centers for Disease Control and Prevention warned that taking pain relievers containing opioids, such as Vicodin, OxyContin and Tylenol with codeine, just before or in early pregnancy increased the risk of congenital heart defects, glaucoma and other problems.

HYDROCODONE—(BRANDS: VICODIN, LORCET, LORTAB, NORCO, ANEXSIA, ZYDONE) Hydrocodone is an opioid used to treat moderate to severe pain. In the United States hydrocodone is only available in combination with other therapeutic drugs generally acetaminophen or Ibuprofen. Hydrocodone containing products with 10 mg of hydrocodone are available with acetaminophen 300 mg, 325 mg, 400 mg, 500 mg, 650 mg, 660 mg, or 750 mg, and Ibuprofen 200mg. These combination products are among the most commonly prescribed pain medications in the USA. Hydrocodone products are Schedule 3 controlled substances.

Hydrocodone crosses the placenta and reaches the fetal circulation. This means that each dose taken by the mother also delivers a dose to the developing fetus.

CODEINE Codeine is present in many migraine treatments. Case control studies and case reports have suggested that defects such as cardiac and respiratory system defects, inguinal hernia, clefting and dislocated hips occur more frequently in babies born to mothers who consumed codeine during pregnancy. Codeine exposure in third trimester has been associated with an increased risk for transient neonatal withdrawal symptoms.

CLOMID Clomid is an orally administered non-steroidal fertility treatment used to induce ovulation in women who have difficulty conceiving. If Clomid is taken during pregnancy, the risks of the following birth defects increase:

- Congenital heart lesions
- Down's syndrome
- Club foot
- Cleft lip and/or cleft palate
- Undescended testes in males
- Blindness
- Spina bifida
- Hernia
- Malformations
- Lifelong disability
- Death

Clomid is in category X as to drug safety while pregnant.

RESOURCE

Medications & Pregnancy

Use this Food & Drug Administration guide and talk to your doctor, nurse, or pharmacist about keeping you and your baby safe.

BIRTH DEFECT LAWSUITS

Drug makers have a responsibility to ensure that the drugs they make don't cause harm especially long-term harm like birth defects. While the FDA plays a regulatory role in approving and monitoring drug safety, the drug maker is liable for any injuries from their medications.

Many of the above birth defects happen only rarely. The odds are in your favor that you will have a perfectly healthy baby.

However, when newborns suffer birth defects the matter becomes quite personal. Numbers and percentages are meaningless. All that matters is your baby's health.

If you're the mother of a baby born with a preventable birth defect caused by a negligent drug maker—it's time to find out what your legal options are.

People may worry that they cannot afford a lawsuit against a drug company. Not to worry because if you agree to retain Anapol Schwartz and they think your situation is the right fit for their unsafe drug litigators and agree to be retained; you both sign an agreement. As the plaintiff, you have no out-of-pocket expenses. Anapol Schwartz law firm would take your case on a contingency fee basis.

CLEFT LIP AND PALATE SUPPORT NETWORK

The Cleft Lip and Palate Foundation of Smiles

Join the network of parents at The Cleft Lip and Palate Foundation of Smiles to "Get Support, Meet Families, Build Relationships, Ask Questions and Get Answers!"