Fertility Drugs Clomid And Serophene Have Long Been Associated With Birth Defects

Should These Drugs Have Stronger Warning About Increased Risk Of Fetal Abnormality After Clomiphene Use?

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 7, 2011; see http://bit.ly/fFKiDh)

Clomiphene is a prescription drug used for more than thirty years, now, to induce ovulation (egg production) in women who do not produce ova (eggs) but wish to become pregnant (infertility). Clomiphene is in a class of medications called ovulatory stimulants. This so-called "fertility drug" works similarly to estrogen, a female hormone that causes eggs to develop in the ovaries and be released.

Clomid and Serophene are two popular brand names for clomiphene.

Unfortunately, these ovulation-inducing drugs Clomid and Serophene have been associated with various fetal abnormalities, congenital malformations, and birth anomalies, *i.e.*, birth defects, in clinical trials and postmarketing surveillance, both.

While the incident rate of clomiphene-related birth defects is relatively low, some have suggested that the current warnings on the package inserts, or labels, for Clomid and Serphene are not sufficient to adequately inform potential parents about this possible serious "side effect", if you will, of using Clomid and Serphene.

From the Fetal/Neonatal Anomalies and Mortality section for Clomid on the DrugLib.com Drug Information Portal:

> The following fetal abnormalities have been reported subsequent to pregnancies following ovulation induction therapy with CLOMID during clinical trials. Each of the following fetal abnormalities were reported at a rate of <1% (experiences are listed in order of decreasing frequency): Congenital heart lesions, Down syndrome, club foot, congenital gut lesions, hypospadias, microcephaly, harelip and cleft palate, congenital hip, hemangioma, undescended testicles, polydactyly, conjoined twins and teratomatous malformation, patent ductus arteriosus, amaurosis, arteriovenous fistula, inguinal hernia, umbilical hernia, syndactyly, pectus excavatum, myopathy, dermoid cyst of scalp, omphalocele, spina bifida occulta, ichthyosis, and persistent lingual frenulum. Neonatal death and fetal death/stillbirth in infants with birth defects have also been reported at a rate of <1%.

And from the Fetal/Neonatal Anomalies section for Clomid at that same online resource:

> The following fetal abnormalities have also been reported during postmarketing surveillance: delayed development; abnormal bone development including skeletal malformations of the skull, face, nasal passages, jaw, hand, limb (ectromelia including amelia, hemimelia, and phocomelia), foot, and joints; tissue malformations including imperforate anus, tracheoesophageal fistula, diaphragmatic hernia, renal agenesis and dysgenesis, and malformations of the eye and lens (cataract), ear, lung, heart (ventricular septal defect and tetralogy of Fallot), and genitalia; as well as dwarfism, deafness, mental retardation, chromosomal disorders, and neural tube defects (including anencephaly).

A recent medical journal article, "Use of clomiphene citrate and birth defects, National Birth Defects Prevention Study, 1997–2005", first published online on November 26, 2010 by *Human Reproduction*, provides us with the most current perspective on the association between Clomid and birth defects.

From the Abstract for this November 2010 *Human Reproduction* medical journal article:

> **RESULTS** [Clomiphene citrate (CC)] use was reported by 1.4% of control mothers (94/6500). Among 36 case-groups assessed, increased adjusted odds ratios (aOR) were

> found [all: aOR, 95% confidence interval (CI)] for anencephaly (2.3, 1.1–4.7), Dandy–Walker malformation (4.4, 1.7–11.6), septal heart defects (1.6, 1.1–2.2), muscular ventricular septal defect (4.9, 1.4–16.8), coarctation of aorta (1.8, 1.1–3.0), esophageal atresia (2.3, 1.3–4.0), cloacal exstrophy (5.4, 1.6–19.3), craniosynostosis (1.9, 1.2–3.0) and omphalocele (2.2, 1.1–4.5).
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> **CONCLUSIONS** Several associations between CC use and birth defects were observed. However, because of the small number of cases, inconsistency of some findings with previous reports, and the fact that we cannot assess the CC effect separately from that of the subfertility, these associations should be interpreted cautiously.

From there we go to the final two sentences in the Discussion section of this November 2010 *Human Reproduction* article (subscription required) about clomiphene citrate (CC) and birth defects:

> In the USA an estimated 1.6% of pregnancies are conceived with the use of [clomiphene citrate (CC) drugs like Clomid and Serophene], reflecting more than 67 000 exposed pregnancies per year. Although the associations we observed in this analysis are limited in magnitude and some are based on small numbers and were seen for the first time, the frequency of CC-exposed pregnancies warrants additional investigations to confirm or refute our findings.

We will continue to monitor the medical literature for reports of birth defects following the use of Clomid and Serophene as well as clomiphene, the generic version of these popular fertility drugs.

If you know of an infant or child born with birth defects after their mother used Clomid, Serophene, or a clomiphene generic product, you may want to contact me privately about the possibility of obtaining legal compensation from the responsible drug company.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com