Fast Facts about
Pregnancy, Prescriptions, and Pharmacodynamics

FDA Drug Classification

In the US, all drugs that have the potential to absorbed by the fetus must be labeled according to the following classification system:

A	Controlled studies show no risk
B	No evidence of risk in humans
C	Risk cannot be ruled out
D	Positive evidence of risk in humans
X	Contraindicated in pregnancy

How widespread is the use of prescription drugs during pregnancy?

A four year study of 152,531 women in the U.S. determined that 64% of the participants were prescribed drugs other than vitamin or mineral supplements during pregnancy.[1] The study also provided a breakdown of prescribed drugs by FDA class:

CLASS	# OF WOMEN	% OF TOTAL
A	3,595	2.4
B	76,292	50
C	57,604	37.8
D	7,333	4.8
X	6,976	4.6

What about the use of over-the-counter medications?

- Over-the-counter (OTC) medications are not required to have an FDA classification letter.[2]
- OTC drugs account for 60% of the medications used in the US.[2]
- 30% of the OTC drugs marketed between 1975 and 1994 were originally sold as prescription medications.[2]
- It is estimated that 10% of birth defects are a result of fetal exposures to OTC drugs during pregnancy.[2]

How well is the FDA classification system protecting pregnant women?

The FDA drug classification system is the subject of considerable controversy and is currently under review because many experts believe that it:

- Gives the false impression of a linear progression of risk (i.e. the increase in risk is consistent as you move up the scale from A to B, B to C, etc.);
- Does not accurately portray the complexity of clinical decision making;
- May incorrectly convey that different drugs within the same category have similar associated risks;
- Uses a system that does not acknowledge the statistical significance of findings or data quality used in the studies.

How are pregnant women currently protected?

According to federal regulations, pregnant women are one of three populations (along with prisoners and children) that are given additional protections in scientific research studies.[3] Pregnant women or fetuses may be involved in research only if additional human subjects criteria are met. These criteria seek to balance risks with direct benefits to both the pregnant woman and the fetus. They also address issues of informed and paternal consent, as well as desision making and advice regarding terminating a pregnancy. These protections largely resulted from two landmark cases:

- **Thalidomide** was a new drug sold to pregnant women in 50 countries between the late 1950s and early 1960s as an antiemetic (anti-nausea and vomiting) drug to combat morning sickness. However, the drug was found to cause severe birth defects in children born to women who took the drug while pregnant. Approximately 10,000 infants were affected. Only 17 children were born with Thalidomide-caused birth defects in the United States because the FDA refused to approve the drug until more trials had been completed.[4]

- **Diethylstilbestrol (DES)** was a synthetic estrogen prescribed to pregnant women between 1938 and 1971 in order to prevent miscarriages and avoid other pregnancy complications. However, a study published in 1971 demonstrated that the drug caused a rare form of vaginal cancer in young women exposed to the drug in utero. In addition, young women exposed to DES in utero have a higher probability of experiencing other cancers and pregnancy complications.[5]

Where can I go to learn more?

CARE NW is a phone consultation service that provides pregnant and nursing mothers and their physicians with information about the possible adverse effects of drugs, chemicals, and other agents. The service is free and is available by calling **1-888-616-8484**.

The Organization of Teratology Information Services (OTIS) provides information to healthcare providers and pregnant women about the risks of certain medications – http://www.otispregnancy.org.

Fast facts about medication use during pregnancy and while breastfeeding are available at http://www.cdc.gov/ncbddd/meds/fast.htm.

Pregnancy registries are used to monitor the potential effects of approved prescription drugs by comparing children born to women who have used those drugs to children born to mothers who have not used such medications. A list of current registries and information on how to enroll is at http://www.fda.gov/womens/registries/registries.html.

Funded by the CDC, **The National Birth Defects Prevention Study** is the largest ongoing, population-based study of its kind – http://www.cdc.gov/ncbddd/bd/centers.htm.

References

1. Andrade SE, et al. Prescription drug use in pregnancy. Am J Obstet Gynecol August 2004; 191:398-407.
2. Black RA, and Hill DA. Over-the-Counter Medications in Pregnancy. (2003). American Family Physician 67 (12): 2517-2524.)
3. Code of Federal Regulations Title 45, Part 46, Subpart B, Section 46.204.
4. von Moos R., Stolz R., Thomas C., Cerny, and Gillessen S. Thalidomide: from Tragedy to Promise (2003). Swiss Med Weekly. 133:77-78.
5. DES update (http://www.cdc.gov/DES/).

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