

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1519]

**Clinical Pharmacology During Pregnancy; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

DNRB

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an FDA/National Institute for Child Health and Human Development co-sponsored meeting on "Clinical Pharmacology During Pregnancy: Addressing Clinical Needs Through Science." Experts from industry, academia, and the public have been invited to provide their perspectives on drug therapeutics during the second and third trimester of pregnancy. The goals of the meeting are: To summarize the state of knowledge regarding clinical pharmacology in pregnancy; to raise awareness among clinician researchers and leaders about the need for clinical research and collaboration in this area; and to garner support for such research from health advocacy groups and others.

**DATES:** The meeting will be held on Monday and Tuesday, December 4 and 5, 2000, from 8 a.m. to 5 p.m. The deadline for registration is November 13, 2000.

**ADDRESSES:** The location of the meeting is the Holiday Inn, Capitol room, 550 C St. SW., Washington, DC 20024, 202-479-4000. Transcripts of the meeting will be available from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at <http://www.fda.gov/ohrms/dockets>. Register on the Internet at <http://www.fda.gov/cder/audiences/women/pharmpreg2000.htm>.

**FOR FURTHER INFORMATION CONTACT:** Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD-104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-827-2185, e-mail: [kennedyd@cder.fda.gov](mailto:kennedyd@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

Most women and physicians seek to avoid the use of medications during pregnancy to protect the developing fetus from any potential adverse effects. However, medication use by pregnant women is common. A study conducted in 1994 by FDA, using several managed care data bases, found that the average number of prescriptions per patient during pregnancy (excluding prenatal vitamins, iron preparations, and medications at the time of delivery) was three. The number of prescriptions increased with maternal age. For pregnant women over the age of 35, the average number of prescriptions was five (unpublished data, FDA).

In considering the needs for clinical pharmacology data to guide drug dosing among special populations, the pregnant woman is rarely addressed. Yet, the physiology of pregnancy is dynamic and capable of influencing the pharmacokinetic profiles of many drugs. It is commonly appreciated that hormonal changes, particularly elevated estrogens and progesterone, accompany normal pregnancy, but their effects are often unappreciated.

Many women enter pregnancy with health conditions that require medications, such as neurologic and psychiatric conditions. Some health conditions tend to worsen during pregnancy, including hypertension, asthma, endocrinopathies, rheumatologic diseases, and cardiac conditions. Previously healthy women often develop illnesses during pregnancy, such as infections, diabetes, thyroid disease, thromboembolism, or cancers. Often, not using medications poses far greater risk to fetal well being and survival than the risk of a particular drug.

Most physicians seek to prescribe the lowest effective dose of any given drug to treat a pregnant woman. Their goal is to provide the best effect for the least exposure possible to the fetus. However, when deciding what the appropriate dose is for a given patient, health care practitioners usually rely on information (typically from product circulars) from studies of individuals who are not pregnant. Particularly for drugs with a narrow therapeutic window, or with marginal efficacy at the lower end of the therapeutic spectrum, this practice risks exposing

the fetus to a dose of medication with little or no benefit to the mother. The result may be that the mother's condition worsens. She may require a second course of the same treatment or a switch to a second or third drug, exposing her developing infant to multiple courses of treatment over a much longer period of time.

Pregnant women are usually excluded from clinical trials and even in situations where pregnant women require therapeutics, pharmacokinetic studies are rarely done. There are many reasons for this. Pregnancy is a temporary condition and easily forgotten in "wish lists" for data, by subspecialists who treat pregnant women with serious medical problems. Also, interested investigators may be reluctant to pursue pharmacokinetic studies in pregnant women because of their lack of knowledge related to pregnancy or fetal development. Finally, where information does exist in the medical literature about pharmacokinetics of individual drugs in pregnancy, the data have rarely appeared in product labels, creating further disincentives for conducting such clinical research. This latter reality has its own set of probable causes, but may change as FDA enhances requirements for product safety updates based on scientific literature and human experience data. Regardless of the root causes for the current paucity of information, rational prescribing for the pregnant patient must attempt to ensure that she will have the greatest likelihood of clinical benefit from a medication in exchange for the safest or least exposure of her developing baby. This can only be achieved when adequate pharmacokinetic dosing data are available.

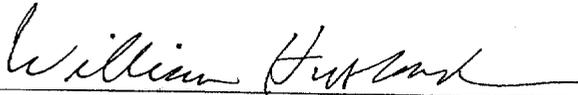
The agency hopes this meeting will help summarize the state of knowledge on clinical pharmacology in pregnancy, raise awareness among clinician researchers and leaders about the need for clinical research and collaboration in this area, and garner support for such research from health advocacy groups and others.

## **II. Registration**

There is no registration fee, however preregistration is required. Register early, as space is limited. The meeting room will hold approximately 250 people. Registration will begin with the publication of this notice. If you will need special accommodations due to a disability to attend

the meeting, please inform the contact person listed above. You may obtain information and register on the Internet at <http://www.fda.gov/cder/audiences/women/pharmpreg2000.htm>.

Dated: September 25, 2000.



William K. Hubbard  
Senior Associate  
Commissioner for Policy, Planning, and Legislation

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