



Drug Labels May Revise Pregnancy Risks

FDA Proposes Changing Physician Labeling on Prescription Drugs' Risk During Pregnancy or Breastfeeding

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May 28, 2008 -- The FDA today proposed major changes in how prescription drug labels inform doctors about drug risks during pregnancy and breastfeeding .

The proposal ditches FDA's nearly 30-year-old pregnancy category system for prescription drugs to help doctors prescribe drugs and counsel women who are pregnant, lactating, or of childbearing age.

"As a physician, a husband, a father, and even a grandfather, I'm well aware that the most important question a woman asks when taking a drug when she finds out that she's pregnant is the question, 'Will this hurt my baby ?' FDA wants to provide the right information and in the right way to appropriately address that question," FDA Commissioner Andrew C. von Eschenbach, MD, told reporters in a news conference.

There are about 6 million pregnancies per year in the U.S. Pregnant women take, on average, three to five prescription drugs, according to the FDA. That includes drugs to treat chronic and pregnancy-related conditions.

Pregnancy Category System to Go

In 1979, the FDA began grouping prescription drugs into five pregnancy categories -- A, B, C, D, and X -- to describe drugs' risks when used during pregnancy.

The system, which hasn't changed since it was established, "has led to an inaccurate and overly simplified view of prescribing in pregnancy and the attendant risks," says Rear Admiral Sandra Kweder, MD, deputy director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research.

Kweder says the pregnancy category system has also "by its very nature, made it very difficult to update labeling as new information becomes available."

The FDA proposes eliminating that system and summarizing what's known about drugs' risks during pregnancy and lactation.

Under the FDA's proposal, the pregnancy section of drugs' physician labeling would include three subsections:

Fetal Risk Summary: What's known about the effects on the fetus

Clinical Considerations, such as dosing, risks of not treating conditions, and complications

Data: More details on the data used to write the fetal risk summary and clinical considerations

The proposal also requires labels to address "the risk that any developing baby has of being born with a birth defect ," regardless of drug use, to put the drug information in context, Kweder says.

Proposed Lactation Label Change

The FDA's proposed label changes don't end with pregnancy; they also address drug use during breastfeeding.

The proposed lactation labeling would cover topics including whether the drug can be found in human breast milk, what effect that might have on a breastfed baby, and how those risks compare to breastfeeding's known benefits.

The FDA will take comments on its proposal for 90 days. When finalized, all new drugs would use the new pregnancy labeling format, and previously approved drugs would transition to the new format over "a number of years," Kweder says.

SOURCES: News release, FDA. FDA: "Content and Format of Labeling for Human Prescription Drug and Biologic Products; Requirements for Pregnancy and Lactation Labeling." Andrew C. von Eschenbach, MD, commissioner, FDA. Rear Admiral Sandra Kweder, MD, deputy director, Office of New Drugs, Center for Drug Evaluation and Research, FDA.

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