



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

December 3, 2014

New FDA Ruling Means More Medication Risk Information For Pregnant Women; MotherToBaby To Offer Additional Support

Brentwood, TN – In a move that was several decades in the making, the U.S. Food and Drug Administration (FDA) has published a final rule that requires prescription drugs and biological products include more detailed labeling about their risks during pregnancy and breastfeeding. The Organization of Teratology Information Specialists (OTIS), the professional society that provides the MotherToBaby service and conducts observational research about exposures during pregnancy and breastfeeding, will provide additional support as health care providers and the public look to understand the new labels.

Up until the ruling announcement today, drug companies were required to use a category system to communicate risk of drugs or biological products during pregnancy. Since the implementation of this category system, the FDA has researched the system's impact, concluding it to be overly simplistic and confusing. The category system will begin to be phased out and pharmaceutical companies will be required to provide detailed risk information about the drugs, as well as relevant research, specific to pregnancy and breastfeeding.

“We know well that there is a plethora of information out there about these drugs and companies have chosen to not include that information for whatever reason. Now, they have to,” said Sandra Kweder, M.D., deputy director of the FDA's Office of New Drugs in the Center for Drug Evaluation and Research (CDER), during today's announcement.

The impact of a drug on breast milk will also have a dedicated section on the new labels, including whether medication gets into breast milk and whether it might affect the infant or not. In addition, the new labeling will include a section describing a medication's potential impact on fertility, birth control and any relevant pregnancy registry information.

“There will be a steep learning curve for clinicians and patients to feel comfortable with more detailed information as opposed to the simple letter category,” said Christina Chambers, PHD, MPH, OTIS member and director of UC San Diego's Center for the Promotion of Maternal Health and Infant Development, the hub of where MotherToBaby pregnancy studies conducted by OTIS is located. “The MotherToBaby toll-free service can help,” she added.

According to the FDA, there are 6 million pregnancies in the U.S. each year. In addition, pregnant women take an average of three to five prescription drugs during pregnancy. Those with pre-existing and chronic conditions, such as asthma or autoimmune diseases, often need to continue their medications during pregnancy or while breastfeeding. “Our hope is that the new labeling will help health care providers better understand the risks and benefits of these drugs so they can discuss the options with their pregnant and breastfeeding patients,” said Chambers. “This is a huge step forward -- and will make even clearer how critical the need is for more human pregnancy data for all medications likely to be used by women of reproductive age.”

Chambers has also acted as a consultant for the FDA on issues related to communication of risk both to patients and providers. “Through the MotherToBaby service that OTIS provides, we’re hoping to help the public understand the information provided on the new labels, as well as enroll participants into various observational research studies, the results of which will add even more useful information to the data.”

Kweder echoed this importance. “Organizations like OTIS need to continue making sure its research gets published,” she said.

MotherToBaby and OTIS are also suggested resources by many agencies including the Centers for Disease Control and Prevention (CDC). They are dedicated to providing evidence-based information to mothers, health care professionals, and the general public about medications and other exposures during pregnancy and while breastfeeding. Anyone wishing to receive a personalized risk assessment of drugs or other exposures can be connected with a MotherToBaby expert toll-FREE via its phone counseling service (866) 626-6847 or online at MotherToBaby.org.

MotherToBaby is currently conducting various research studies during pregnancy, including asthma, autoimmune diseases, and vaccines. To learn more, volunteer for a study, or refer a patient, please call (866) 626-6847 or visit MotherToBaby.org and click on the “Research” tab.

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