

Most medications OK during breast-feeding, report says

August 26 2013, by Brenda Goodman, Healthday Reporter



Mothers may be able to take needed drugs while nursing.

(HealthDay)—Most breast-feeding moms can safely take the medications and vaccines they need, without fear they'll harm a nursing infant, according to a new report from a leading group of U.S. pediatricians.

The report, from the American Academy of Pediatrics in consultation with the U.S. Food and Drug Administration, describes proposed changes to <u>drug labels</u>. The new labels would replace the current "Nursing Mothers" section with a heading called "Lactation," which would give much more detailed information about a drug's transfer to breast milk and potential to harm a breast-fed baby.

The proposed changes are part of a push by the FDA to require drug



makers to study how medications may affect breast-feeding and to better communicate that information to women and their doctors.

"Because we know that breast-feeding has both developmental and health benefits for the mom and the baby, we are encouraging research in this area so physicians can make informed decisions about how best to treat their patients," said study author Dr. Hari Cheryl Sachs, a pediatrician and leader of the pediatric and maternal health team within the FDA's Center for Drug Evaluation and Research.

Breast-feeding advocates cheered the new report, published online Aug. 26 in the journal *Pediatrics*.

"The general takeaway message—that most drugs are compatible with breast-feeding, that mothers don't have to wean to take drugs and that the labels should accurately reflect the science—is really great news and progress for breast-feeding mothers," said Diana West, a lactation consultant and spokesperson for La Leche League International.

Most drug labels now have a blanket legal statement that cautions against taking nearly any medication while pregnant, something that irks Thomas Hale, director of the InfantRisk Center at Texas Tech University Health Sciences Center in Lubbock. Hale has been doing research on the transfer of medications to breast milk for more than 30 years. He also is the author of the book *Medications and Mothers' Milk*, which has become something of a bible on the subject.

"If you pick up any package insert, you see the same language: 'There are no data available on this drug. Do not use in breast-feeding mothers,'" Hale said.

He said he was recently invited to give a presentation to the FDA committee developing the new drug labels. The first slide he put up was



a picture of the blanket caution from the label of the antidepressant drug Zoloft (sertraline).

But in the case of Zoloft and many other drugs, he said, that's not the whole story.

Hale said 60 breast-feeding mothers who were taking Zoloft and their babies have been studied. "We knew exactly how much got into milk and it was almost nothing," he said. And that's just one example.

"We now know the risk of untreated depression is far, far worse than the risk of taking a drug," he said.

The report refers women and their doctors to LactMed, a database of information on the transfer of drugs to breast milk maintained by the U.S. National Library of Medicine.

LactMed contains information on more than 450 drugs, a fraction of the roughly 3,000 unique pharmaceuticals available. That's because other medications have not been studied in breast-feeding women.

Hale said even when specific lactation studies haven't been done, doctors can still make educated guesses about whether a drug will pass into breast milk and whether it will harm a baby, based on the size of the molecule and other chemical properties of the drug.

Doctors also should consider the length of treatment—the risks of short-term therapy versus long-term therapy—when making a determination about drug use, the report said.

There are some clear cases where medications can harm nursing infants. Radioactive compounds that are used as contrast agents in imaging studies or in cancer treatments require at least a temporary cessation of



breast-feeding, according to the report. For that reason, elective imaging procedures should be delayed until a woman is no longer nursing.

Some narcotic pain relievers, including codeine, oxycodone (Oxycontin) and propoxyphene (Darvon), have caused serious problems in breast-fed infants. For that reason, the report suggests doctors steer clear of prescribing narcotic painkillers for nursing moms. Medications such as ibuprofen (Advil, Motrin), acetaminophen (Tylenol) and naproxen (Aleve) may be safer choices for pain relief.

The report also cautioned against the use of herbal products and off-label drugs—particularly metoclopramide (Reglan)—to increase <u>breast milk</u> production. Off-label drugs are medications used for an unapproved purpose.

Metoclopramide, a heartburn <u>drug</u>, boosts levels of the milk-producing hormone prolactin by blocking the brain chemical dopamine. Blocking dopamine can have a host of negative consequences for infants and new moms, including depression and thoughts of suicide.

More information: For more information on medications and breast-feeding, head to <u>LactMed</u>.

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