

FDA Says to Avoid Repeated or Lengthy Sedation or Anesthesia for Pregnant Women and Children Under Three

Studies on childhood brain development in children under three have found that long or repeated exposure to general anesthesia has the potential to negatively affect that growth. The Food and Drug Administration has recently issued a warning regarding the use of general anesthesia and sedation drugs for children under three and pregnant women in their third trimester to make consumers aware of the possible side effects. The list of drugs includes commonly used anesthetics like lorazepam, ketamine, and midazolam, among others.

Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research released a statement regarding the FDA's position on the new labeling requirements. "...based on the FDA's comprehensive analysis of the latest published scientific studies, we are issuing a Drug Safety Communication to inform health care providers, parents and caregivers of children younger than three years, and pregnant women in their third trimester, that the repeated or lengthy (more than three hours) use of general anesthetic and sedation drugs may adversely affect children's developing brains."

Better Safe Than Sorry

Anesthesia or sedation are medically necessary in many cases and generally considered safe. Low-risk patients see a death rate of 1 in 300,000. Common non-emergency cases of sedation or anesthesia in small children include abdominal issues; nose, ear, and throat conditions; and dental procedures. The use of general anesthesia in emergency situations cannot

always be avoided. The new warning label required by the FDA is intended to raise awareness of the potential effects of anesthesia on brain development during its crucial development years.

Obstetricians Have Objections

As of right now, no one has taken issue with the warning labels in regards to children. Extending the warning to pregnant women in their third trimester, however, has been more controversial. The American College of Obstetricians and Gynecologists (ACOG) registered their disapproval on the inclusion of pregnant women in this warning, claiming they are "...unaware of data on pregnant women that support the FDA's claims. These warnings may cause patients and providers to inappropriately reject the use of these medically indicated drugs." Both animal and human clinical trials were studied for the safety advisory, but the actual human trials were only done on children.

Developing Brains Should Avoid Unnecessary Sedation

Babies have amazing, malleable brains that are developing by leaps and bounds. It's often hard to see how much they're learning and developing until much later in life. A caution advisory like the one issued by the FDA is designed to preserve that activity. While the ACOG makes a good point considering the clinical studies did not specifically test human pregnant women, it's hard to see why exercising caution and sedating pregnant women only when necessary is such an issue.

Recommended Reading:

- *NSAIDs Warning – These Drugs Are Not Safe (Motrin, Advil, Naproxen...)*

- *Aspirin, Ibuprofen, Acetaminophen – Why They All Are Unsafe*
- *How Plumbing (Not Vaccines) Eradicated Disease*
- *Detox Cheap and Easy Without Fasting – Recipes Included*
- *How to Cure Lyme Disease, and Virtually Any Other Bacterial Infection, Naturally*

Sources:

- *Obstetricians balk at FDA warning on anesthesia in pregnant women – Reuters*
- *FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women – FDA.gov*
- *FDA warns of anesthesia risk in pregnant women, kids under 3 – CBS News*