FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women

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Safety Announcement

The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains.

Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

To better inform the public about this potential risk, we are requiring warnings to be added to the labels of general anesthetic and sedation drugs (see List of General Anesthetic and Sedation Drugs Affected by this Label Change). We will continue to monitor the use of these drugs in children and pregnant women and will update the public if additional information becomes available.

Anesthetic and sedation drugs are necessary for infants, children, and pregnant women who require surgery or other painful and stressful procedures, especially when they face life-threatening conditions requiring surgery that should not be delayed. In addition, untreated pain can be harmful to children and their developing nervous systems.

Health care professionals should balance the benefits of appropriate anesthesia in young children and pregnant women against the potential risks, especially for procedures that may last longer than 3 hours or if multiple procedures are required in children under 3 years. Discuss with parents, caregivers, and pregnant women the benefits, risks, and appropriate timing of surgery or procedures requiring anesthetic and sedation drugs.

Parents and caregivers should discuss with their child's health care professional the potential adverse effects of anesthesia on brain development, as well as the appropriate timing of procedures that can be delayed without jeopardizing their child's health. Pregnant women should have similar conversations with their health care professionals. Also talk with them about any questions or concerns.

Published studies in pregnant animals and young animals have shown the use of general anesthetic and sedation drugs for more than 3 hours caused widespread loss of nerve cells in the brain. Studies in young animals suggest these changes result in long-term effects on the animals' behavior or learning (see Data Summary).\(^1\)\(^-\)\(^20\) Studies have also been conducted in children,\(^21\)\(^-\)\(^43\) some of which support findings from previous animal studies, particularly after repeated or prolonged exposure to these drugs early in life. All the
studies in children had limitations, and it is unclear whether any negative effects seen in children's learning or behavior were due to the drugs or to other factors, such as the underlying medical condition that led to the need for the surgery or procedure.

FDA has been investigating the potential adverse effects of general anesthetic and sedation drugs on children's brain development since the first animal study on this topic was published in 1999.\(^9\) We held advisory committee meetings in 2007 ([http://www.fda.gov/ohrms/dockets/ac/der07.htm#AnestheticLifeSupport](http://www.fda.gov/ohrms/dockets/ac/der07.htm#AnestheticLifeSupport)), 2011 ([AdvisoryCommittees/Calendar/ucm238440.htm](http://www.fda.gov/AdvisoryCommittees/Calendar/ucm238440.htm)), and 2014 ([AdvisoryCommittees/Calendar/ucm418045.htm](http://www.fda.gov/AdvisoryCommittees/Calendar/ucm418045.htm)). To coordinate and fund research in this area, we also formed a partnership with the International Anesthesia Research Society (IARS) called SmartTots (Strategies for Mitigating Anesthesia-Related neuroToxicity in Tots) ([http://smarttots.org/](http://smarttots.org/)). More research is still needed to provide additional information about the safe use of these drugs in young children and pregnant women.

We urge health care professionals, patients, parents, and caregivers to report side effects involving anesthetic and sedation drugs or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

**List of General Anesthetic and Sedation Drugs Affected by this Label Change**

**Facts about General Anesthetics and Sedation Drugs**

**Additional Information for Parents, Caregivers, and Patients**

**Additional Information for Health Care Professionals**

**Data Summary**

**References**


**Drug Safety Communication** ([PDF - 100KB](http://downloads/drugs/drugsafety/UCM533197.pdf))

**Related Information**

- [FDA Statement from Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, on new safety information on anesthesia use in young children and pregnant women ([NewsEvents/Newsroom/PressAnnouncements/ucm533346.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533346.htm))](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533346.htm)
- [SmartTots (Strategies for Mitigating Anesthesia-Related neuroToxicity in Tots) ([AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm))](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- [The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective ([Drugs/ResourcesForYou/Consumers/ucm143534.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm))](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm)
- [Think It Through: Managing the Benefits and Risks of Medicines ([Drugs/ResourcesForYou/Consumers/ucm143568.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143568.htm))](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143568.htm)