

**EMBARGOED UNTIL OCTOBER 13, 2015**

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**SmartTots Releases Updated Consensus Statement  
Regarding Anesthesia Safety in Young Children**

*Health experts say growing evidence points to need for  
more research; urge caution but not alarm*

San Francisco – October 13, 2015 – SmartTots today released an updated consensus statement that emphasizes a need for more research into the safety of anesthetics and sedatives administered to infants and young children under the age of 4. The statement was endorsed by 19 leading U.S. and global health organizations, including the American Academy of Pediatrics, the American Society of Anesthesiologists, and the Society for Pediatric Anesthesia.

The consensus statement was developed by a working group of experts in anesthesia, pediatric medicine and neuroscience that was convened by SmartTots, a public-private partnership of the International Anesthesia Research Society and the U.S. Food and Drug Administration. The new statement follows one released in January 2013, and takes into account mounting evidence that exposure to anesthetics or sedatives in animals at a very young age impairs learning ability, behavior and memory, and the possibility that this risk may translate to problems in young children as well. Clinical (human) research in this age group has been mixed, with some studies indicating that similar problems may exist.

“We want to ensure that children under the age of four who have serious or life-threatening medical conditions receive the safest medications possible,” said Janet Woodcock, MD, director of the FDA’s Center for Drug Evaluation and Research. “The updated consensus statement is an important moment in our journey to identify any potential harm and, if necessary, find suitable solutions for these young children.”

While the statement does not recommend putting off needed surgery or procedures requiring anesthetics or sedatives – or conducting needed treatments without pain medication – it does urge health care providers and parents to discuss the risks, benefits and timing of any treatment. In particular, it advises weighing the benefits of any elective procedure against a potential risk. Experts also suggest exploring alternatives to anesthesia or sedation when pain management is not an issue – for example, with diagnostic tests.

Established science has shown that the human brain is still growing in the first few years of life and is more susceptible to harm when exposed to certain chemicals. However, it is unclear whether anesthetics can cause damage in the very young and if so, whether the length or number of exposures makes a difference. Also unknown is if any harm that may be detected is caused by the medication or by the underlying condition requiring surgery or a procedure in the first place. To the

extent that there might be harm, the damage may be small – for instance, a learning deficit that would result in the loss of a few IQ points – but not insignificant.

### **Growing body of evidence**

Since release of the last consensus statement, new animal research has continued to show short- and long-term learning deficits when general anesthetics are administered at an age comparable to a human under the age of 4. This growing evidence, combined with limited clinical results, has led the working group to call for more research to determine the safety of current anesthetics for young children, as well as whether there are drugs that might mitigate any harmful effects.

“While the accumulated data in young animals is very concerning, it is still unclear as to whether this means that young children are at risk,” said Constance Houck, MD, chair of the Surgical Advisory Panel with the American Academy of Pediatrics and an anesthesiologist at Boston Children’s Hospital and associate professor at Harvard Medical School. “We don’t have any alternatives to the anesthetic drugs that are currently used, so it is imperative that we have comprehensive studies of the effects of anesthetics in infants and young children.”

### **Pilot clinical trial launched; funding sought**

In an unusual move, an international team of investigators has come together to design prospective clinical trials studying the possible long-term effects of anesthetics and sedatives on the developing brain. A pilot study evaluating a potential alternative to commonly used inhalational anesthetics is already underway. Unlike most previous studies involving children, which have been *retrospective*, i.e. looking at children's medical records *after* their exposure to anesthesia – the pilot study follows children *prospectively*, starting *before* medications are administered. Depending on the outcome of the pilot study, a more definitive clinical trial may be feasible.

“These scientists would normally be competing for research funds,” said Santhanam Suresh, MD, chair of pediatric anesthesiology at Lurie Children’s Hospital in Chicago and professor at Northwestern University Feinberg School of Medicine, who co-chairs the SmartTots Steering Committee. “But they recognized the urgent need for knowledge and the benefits of working collaboratively to create the best possible study design.”

SmartTots is actively seeking funds for prospective clinical trials estimated to cost upwards of \$30 million. They also are hopeful that the U.S. National Institutes of Health might receive additional funding, which in turn could provide more support for “orphan” research such as this project.

SmartTots has created FAQ sheets for healthcare providers and for parents and caregivers to provide guidance when considering anesthetic or sedative use in infants and toddlers.

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[SmartTots](#) is a Public-Private Partnership between the U.S. Food and Drug Administration (FDA) and the International Anesthesia Research Society (IARS) designed to close research gaps related to the effects of anesthetics on the developing brain, and ensure the safety of infants and young children undergoing anesthetics in medical procedures. Findings from SmartTots research studies will determine the safety of commonly used anesthetics, establish new practice guidelines, and potentially foster the development of new, safer anesthetics and sedatives.