Response to the FDA Med Watch December 16, 2016

On Wednesday, December 14, the United States Food and Drug Administration (FDA) released a Drug Safety Communication warning that; “repeated or lengthy use of general anesthetic or sedation drugs during surgeries or procedures in children younger than three years of age or in pregnant women during the final trimester may affect development of children’s brains”. The FDA defined lengthy as greater than three hours of exposure.

While there is abundant animal data concerning suspected toxicities in prolonged and multiple anesthetics, the accumulated human data suggest that one brief anesthetic is not associated with cognitive or behavioral abnormalities in children. Most but not all studies in children do however suggest an association between repeated and or prolonged exposure and subsequent difficulties with learning or behavior. It is not yet known whether the anesthetic drug or some other factor is responsible for these findings. Rigorous research to further characterize any possible associations is ongoing.

The data reviewed by the FDA in making the decision to issue this labelling changehave accumulated over more than a decade and has been discussed at three separate FDA advisory

committee meetings since 2007. This warning appears to have been issued to raise awareness among practitioners and the public to ensure the information needed to make informed judgments about the risks and benefits of anesthesia and sedation in young children and pregnant women is widely available.

The potential risk of negative cognitive or behavioral effects of anesthetic agents remains uncertain and must be placed in the context of the known risks and benefits of both the anesthetic and the related surgical or diagnostic procedure for which the anesthetic is required. Clinicians and parents are cautioned against the possible risk of delaying needed surgical or diagnostic procedures. Until additional information is available from ongoing studies, parents and providersshould carefully weigh the risk and benefit of each contemplated procedure before proceeding.

The complete FDA statement can be found at:

http://www.fda.gov/Drugs/DrugSafety/ucm532356.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Additional information may also be found at the following web site: www.smarttots.org. SmartTots is a public private partnership between the FDA and the International Anesthesia Research Society. The above statement represents a consensus of each of the following organizations all of which share a commitment to health and safety of children and pregnant women.