



Client Alert



Contact Attorney Regarding
This Matter:

William H. Kitchens
404.873.8644 - direct
404.873.8645 - fax
william.kitchens@agg.com

FDA Initiative to Assess Safety of Anesthetics and Sedatives in Young Children

The U.S. Food and Drug Administration recently announced agreements with five academic and clinical partners to study the effects of anesthetics and sedatives on the neurocognitive development of infants and young children. The SAFEKIDS Initiative (Safety of Key Inhaled and Intravenous Drugs in Pediatrics) will address major gaps in scientific data about the safe use of anesthetics and sedatives received by millions of children each year.

As a result of this deficiency in scientific knowledge, pediatric sedation is the subject of increasing debate and research in the medical community. It is recognized that too much of an anesthetic or sedative can harm a child, but too little does not work. Research in pain relief for children has been limited and there are no consistent records or reports to document the extent of serious reactions among children who were sedated before undergoing medical procedures or receiving anesthesia. Physicians recognize the risk is greater for young children, especially newborn and premature babies, but there are no definitive data on those risks. Consequently, the medical community cannot determine the absolute risks presented by the use of these drugs in children. Indeed, until recently there were no sedatives specifically approved by FDA for children, and currently physicians when treating children are frequently forced to rely on their own knowledge and experience in using adult drugs "off label", a practice that is legal and often necessary in pediatrics.

Previous studies conducted by the FDA's National Center for Toxicological Research (NCTR) using juvenile animal models linked memory and learning deficits and other neurodegenerative changes in the central nervous system to exposure to some anesthetics and sedatives. A more recent study at the Mayo Clinic in Rochester, Minnesota involved a population-based, retrospective birth cohort study. The researchers looked at the medical records of more than 5,000 children born in Olmsted County, Minnesota between the years of 1976 and 1982. The study results were published in the April 2009 issue of *Anesthesiology* and indicated that exposure to anesthesia is a significant risk factor for the later development of reading, written language, and math learning disabilities in children receiving multiple, but not single anesthetics before the age of four. The study authors, however, noted that there is no clear causality that it was the anesthetics that caused the learning disabilities.

It is these gaps in scientific knowledge that the FDA's SAFEKIDS Initiative will examine. The long term objective of this new study is to inform risk-benefit decisions that both anesthesiologists and parents must make when considering the choice of anesthesia and sedatives in pediatric patients.

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com



Client Alert

The FDA's research partners in the SAFEKIDS Initiative include:

- The International Anesthesia Research Society (Cleveland, Ohio), which will be responsible for leading the administrative oversight and the overarching framework for the partnership.
- Children's Hospital - Harvard University (Boston), which is conducting a long-term study of neurodevelopmental outcomes in pediatric patients administered regional or general anesthesia as neonates or infants.
- Arkansas Children's Hospital Research Institute (Little Rock, Ark.), which will research the pharmacokinetics, pharmacodynamics, and neurotoxic effects of an anesthetic agent in infants undergoing various surgical procedures.
- Columbia University (New York), which will evaluate the effects of anesthetic exposure on neurocognitive, emotional and behavioral outcomes in pediatric patients
- Mayo Clinic (Rochester, Minn.), which will study long-term cognitive development following exposure to general anesthetic agents during infancy.

In addition, NCTR will conduct non-clinical studies in non-human primates to assess the decline in mental function when young animals are exposed to anesthesia and to develop noninvasive ways of using imaging to measure structural changes in the brain.

Under the framework of the SAFEKIDS Initiative, the FDA and the International Anesthesia Research Society will develop a public-private partnership that will support additional research in this area.

The FDA expects the first results from the SAFEKIDS Initiative will be available within two years.

Arnall Golden Gregory LLP serves the business needs of growing public and private companies, helping clients turn legal challenges into business opportunities. We don't just tell you if something is possible, we show you how to make it happen. Please visit our website for more information, www.agg.com.

This alert provides a general summary of recent legal developments. It is not intended to be, and should not be relied upon as, legal advice.