



AMERICAN SOCIETY OF ANESTHESIOLOGISTS

Office of Governmental Affairs

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March 15, 2007

Cathy A. Groupe, RN, BSN
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Anesthetic and Life Support Drugs Advisory Committee Meeting, March 29, 2007
72 Fed. Reg. 5723 (February 7, 2007)

Dear Ms. Groupe and Members of the Committee:

The American Society of Anesthesiologists, the Society for Pediatric Anesthesia, and the American Academy of Pediatrics, through its Section on Anesthesiology and Pain Medicine thank the FDA Anesthetic and Life Support Drugs Advisory Committee for the opportunity to provide written comment prior to the March 29 committee meeting.

No one has a greater interest in protecting the health of children receiving anesthesia than do (pediatric) anesthesiologists; we consider this the essence of our responsibilities. We share the concerns raised by Drs. Mellon, Simone, and Rappaport in their excellent summary of the issues related to neurodegeneration in the developing brain of animals exposed to commonly used sedatives and anesthetics in the March 2007 Anesthesia and Analgesia. These findings and the question of whether or not this research has applicability to anesthetic exposure during human development has been the subject of investigation and intense inquiry within our profession.

We believe that developing a strategy to assess the safety and effects of anesthetics in neonates and young children is warranted. We echo the statement that, "there are many issues to be resolved before a definitive assessment of the risk posed by anesthetics to the developing brain can be made." We support the research effort that is outlined in this paper and note that anesthesiologists have been and will continue to be important contributors to this field. Our professional organizations are working to support these efforts.

The problems related to determining the safety of pharmaceutical use in children are well known to us. Far too few of the drugs we use in everyday practice have been approved for use in children. We appreciate the work the FDA has done in rectifying this problem as well as the efforts of the NICHD under the Best Pharmaceuticals for Children Act.

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The American Society of Anesthesiologists, the Society for Pediatric Anesthesia, and the American Academy of Pediatrics Section on Anesthesiology and Pain Medicine stand ready to assist the Advisory Committee and the FDA in these activities. We recognize the difficulty the FDA faces when it balances the potential for toxic effects against the need for drugs which have a proven benefit and for which there may not be a ready substitute. With regard to anesthetic agents, we know that failure to provide adequate analgesia and amelioration of the stress response is associated with both short and long term adverse effects in newborns. We hope the questions that have led to this Advisory Committee hearing result in more research into these relatively old and commonly used drugs, and at the same time, not deter the research and development of newer agents in this class.

As pointed out in the Mellon, Simone and Rappaport article, "there are no clinical data providing evidence suggesting that the use of anesthetics in the neonate or young child is associated with signs of developmental neurotoxicity." It is unknown if the "findings for ketamine and other anesthetics in rodent models of anesthetic toxicity are applicable to humans." Therefore, we believe that no change is necessary in the labeling of anesthetic drugs at this time. We will provide additional comment should the FDA and the Advisory Committee determine that changes to labeling may be necessary once the results of the studies currently underway are available.

Thank you very much for your consideration. Please contact Karin Bierstein, JD, MPH in ASA's Washington Office (k.bierstein@asawash.org, 202.289.2222) if you have any questions for us.

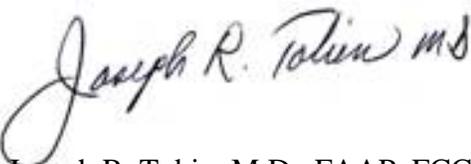
Sincerely,



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