American Society of Anesthesiologists

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Kalyani Bhatt, BS, MS
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
WO31-2417
Silver Spring, MD 20993-0002

Re: Joint Statement from ASA, SPA and AAP, Section on Anesthesiology and Pain Medicine

The care of our smallest and most fragile patients is a crucial part of the practice of anesthesiology. It presents distinct challenges. For example, in emergency rooms, imaging suites, endoscopy units and other settings, young children routinely require sedation or anesthesia for procedures that could be performed in older children and adults without sedative medications. Advances in perinatal medicine now allow the survival of newborns with unprecedented prematurity, challenging them with a host of additional threats posed by their early birth. Every day of their continued growth is a delicate balance of risk and fortune. These babies are prone to multiple complications of prematurity that demand surgery and anesthesia, and they often have long term medical conditions that will require repeated painful procedures and surgeries throughout their lives. .

Recent studies in newborn animals show that almost all commonly used anesthetic and sedation medications cause injury to the brain with long-term behavioral consequences. Whether these effects are also seen in human infants and young children requiring anesthesia or sedation is a question of utmost importance. These medicines have been used for many years in the care of many millions of infants and young children in this country and around the world without apparent harm. Yet new studies in animals, including primates, suggest the possibility of subtle adverse effects on developing human brains, prompting the urgent need for research to more fully evaluate potential neurologic changes. Clearly this research must be a high priority for the specialty in order to provide reassurance that needed procedures can be performed as safely as possible.

Patient safety is the essence of anesthesiology. We take very seriously the faith and trust that patients and their families place in us. For each child who requires anesthesia or sedation, anesthesiologists craft a carefully considered plan using the best, most current information to minimize discomfort and maximize safety. Unfortunately, the potential for harm exists despite our best efforts and current state of knowledge. We believe that we can best protect our patients from harm by continuing to pursue the very best science that informs our practices. If anesthesia is associated with brain injury in neonates and young children, we need to understand the mechanism(s) of this injury so that we can develop ways to prevent or minimize this damage. This knowledge will help us provide the best possible guidance to our patients and families so that they can make the best choices for their children.

As anesthesiologists we care for all children as if they are our own. We urge that every effort be made to fund the research needed to ensure the continued safety of children. The membership of the American

Society of Anesthesiologists, the Society for Pediatric Anesthesia and the American Academy of Pediatrics, Section on Anesthesiology and Pain Medicine are united in our dedication to our patients. We support any and all efforts to better understand and ameliorate any risks that anesthesia and sedation may present to our youngest patients.

Sincerely,

Mark A. Warner, M.D., President, American Society of Anesthesiologists

Constance A. Houck, M.D., Chair, Section on Anesthesiology and Pain Medicine, American Academy of Pediatrics

Nancy L. Glass, MD, MBA, President-Elect, Society for Pediatric Anesthesia