Attention Docket Management:

A petition is now before the FDA that has the potential to put patient safety at unwarranted risk. On June 28, 2005, the American College of Gastroenterology (ACG) filed a petition to modify the warning label of the sedative drug, Propofol. The organization is requesting that the section pertaining to administration by individuals trained in general anesthesia be removed (see below).

In the hands of trained professionals, Propofol can be a very safe and efficient drug, but patient reactions can at times be very unpredictable during surgery. Because there are no reversal agents for this anesthetic, it is crucial that a formally educated and trained anesthesia provider, with primary and sole responsibility for advanced airway support and resuscitative support, be responsible for its administration. Experience administering this medication, as well as observing and treating common and rare untoward events, is a long process—it comes from thousands of cumulative hours spent monitoring subtle clinical clues, cardiac rhythms and observing patterns of clinical response. These comprehensive skills can not be marshaled after a two or three day program such as the NAPS (Nurse Administrated Propofol Sedation) training course. Nor are they gleaned after similar weekend seminars for gastroenterologists or other physicians who may leave with a false sense of security that they are as familiar with potent anesthetics as anesthesiologists.

There is absolutely no question that physician anesthesiologists and certified nurse anesthetists have undergone the extensive training required for administration of this anesthetic. Today's anesthesiologists complete four years of formal postgraduate training, which includes one year of clinical medicine and three years of clinical anesthesiology. Nurse anesthesia programs consist of two to three years of didactic and clinical training in the techniques of administration of anesthetics. There are several professional organizations that recognize the risks involved with Propofol:

• The American Society of Anesthesiologists' (ASA) position on Propofol is: "Whenever Propofol is used for sedation; it should be administered only by persons trained in the administration of general anesthesia who are not simultaneously involved in the surgical or diagnostic procedure. In addition, these persons must monitor patients continuously for oxygen saturation, respiration, heart rate and blood pressure."

• The American Association of Nurse Anesthetists' (AANA) issued a joint statement with the ASA, which read: "Because sedation is continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonistic medications, agents such as Propofol require special attention. Whenever Propofol is used for sedative anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in the surgical or diagnostic procedures. This restriction is concordant with specific language in the Propofol package insert and failure to follow these recommendations could put patients at increased risk of significant injury or death."

• The Joint Commission on Accreditation of Health Organizations (JCAHO) Standard PC 13.20 requires: "The person administering the medication must be qualified to manage the patient whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally." (Revised Jan.1, 2004). Further, "these standards require that individuals who administer moderate or deep sedation must also be competent to perform the rescues described in these standards," i.e. the ability to manage an airway, administer reversal agents and provide ACLS care.

• The American Association of Accreditation for Ambulatory Surgical Facilities (AAAASF) states: "Propofol is a very potent drug capable of rapidly producing a state of general anesthesia even when a state of sedation is the intended effect. If this should occur, the patient's protective reflexes- for example, control of the airway, breathing, and circulation are lost or dangerously depressed. A life-threatening condition would exist in the absence of proper supportive care. Anesthesia professionals are best qualified to provide such supportive care for the sedated or anesthetized patient.

• Boards of Nursing in 12 States (Alabama, Arizona, Connecticut, Florida, Kentucky, Louisiana, Mississippi, Missouri, South Carolina, Tennessee, Texas and Wyoming) have issued either a declaratory statement or an advisory opinion that procedural sedation administration and/or monitoring with Propofol or other anesthetic agents is beyond the scope of a non-CRNA nursing practice. IN other words, registered nurses are discouraged or prohibited from administering.

More recently, New Jersey State Supreme Court upheld regulations that even require CRNA's to be supervised by physician anesthesiologists when practicing in the office setting. The state of Pennsylvania also recognizes the potential dangers associated with administering this drug and is poised to mandate that endoscopy centers using this medication be classified as a "class-C" facility which, according to the AAAASF, requires an anesthesiologist or CRNA to administer the drug. The possible risk for bad patient outcomes in the ambulatory setting can not be ignored. Nearly 20% of all procedures occur in office-based surgical facilities and Medicare currently offers various programs that encourage the migration of appropriate surgeries to this environment. In front of this backdrop, the reality that this potent anesthetic may be administered by a registered nurse or gastroenterologist on the tenth floor of an office building—far away from the hospital ICU, ER or anesthesia work room—underscores the harrowing nature of this initiative that is predicated, according to the ACG, on pecuniary grounds.

Outpatient Surgery Magazine conducted a survey and found that 74.8% of its readers felt that RN-administered Propofol is a patient safety risk and 71.2% responded with it being outside of an RN's scope of practice

The ACG has cited a recent study which shows that nearly 100,000 patients have been anesthetized by registered nurses, under physician supervision, without any adverse outcomes. The morbidity and mortality rate for anesthesia is approximately one death per 250,000 cases. At this time, there have simply not been enough cases performed in the various surgical settings to warrant such a potentially drastic label change. We also do not know how the controlled circumstances of these study patients would be translated by gastroenterology specialists across the country—most of whom have little or no airway management training.

According to a front-page Wall Street Journal article on June 21, 2005, anesthesiologists serve as a model in healthcare of how to improve patient safety and lower insurance premium costs. The article discusses how over the last two decades anesthesiologists have advocated for devices monitors and medications that have saved lives, improved safety and lowered healthcare costs. Taking Propofol out of the hands of skilled anesthesia providers and into the hands of registered nurses and gastroenterologists does not seem to build on these accomplishments.

In the interest of patient safety and quality of care, it is my opinion that your committee denies this petition for a label change.

Respectfully Yours,

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