



January 18, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: docket number 2005P-0267/CP 1 filed on June 28, 2005

Ladies and Gentlemen:

The American College of Gastroenterology has petitioned the FDA to remove the drug warning label restricting the use of Propofol to persons trained in the administration of general anesthesia. **I urge you to approve their petition.** This warning is now out of date, as medical practitioners around the country have documented the safe utilization of the drug as a sedative instead of a general anesthetic. An overwhelming body of scientific evidence supports the safe use of this drug as a sedative when administered by personnel who do not routinely administer general anesthetics. Peer reviewed scientific literature confirms that this drug, like others used for sedation can be safely and predictably administered to patients by licensed Registered Nurses under supervision of trained physicians, by trained physicians using licensed nurses and/or other trained monitoring personnel and by Oral and Maxillo-Facial Surgeons trained in its use.

As a result of the current warning language that restricts the administration of the drug to practitioners trained in the administration of general anesthesia, regulatory bodies throughout the country have restricted the use of this drug for safety concerns and fear of liability. Anesthesiologists, CRNAs, Registered Nurses and others who may be unfamiliar with the highly successful utilization of this drug as a sedative when administered by trained physicians or a doctor-supervised nurse have voiced inflammatory and inaccurate warnings regarding its use.

Regulatory bodies, medical facilities and medical societies in Oklahoma have supported restriction of the personnel who are allowed to administer Propofol. Liability and safety

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concerns have been prompted by the warning language and as a result of pressure and lobbying by anesthesia groups.

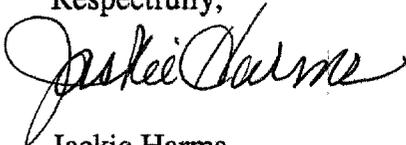
- RNs at our facility have utilized Propofol for the last several years with zero adverse outcomes.
- Surgeons have often commented that they prefer RNs to administer Propofol because they are familiar with protocol of doing frequent small doses to avoid deep sedation.
- In rural areas, anesthesia providers are in dire shortage, and to fill vacations/holidays now, we are utilizing locum tenens companies due to the difficulty in recruiting full-time anesthesia providers.
- If anesthesia providers were required to administer all conscious sedation with Propofol, the cost for the patient and the facility would increase drastically. The average cost for a locum CRNA is approximately \$1150 per 8 hour day, plus room and board, plus time-and-a-half for all hours worked over 8 per day.

In its mission to protect the public, the FDA should direct that all sedative drug information contain warnings that the medication should be administered by either a physician or a trained, dedicated, monitoring individual under Physician supervision. Neither the physician nor the trained individual need be a CRNA or an Anesthesiologist for the medication to be administered safely. However, administration should occur under controlled conditions. Both the physician and the trained person should have a clear understanding of and experience with all the drugs being used. An example of such a warning is contained in the drug information accompanying Brevital Sodium (see attached) that addresses these issues.

Physicians Desk Reference-pp1774, prescribing information as of November 2003: *“Brevital should be used only in hospital or ambulatory care settings that provide for continuous monitoring of respiratory (e.g. Pulse Oximetry) and cardiac function. Immediate availability of resuscitative drugs and age and size-appropriate equipment for bag/valve/mask ventilation and intubation and personnel trained in their use and skilled in airway management should be assured.”*

I request you consider a warning with identical language substituting “Propofol” for “Brevital”

Respectfully,



Jackie Harms
CEO

JH:pa