

I believe that the current package labeling for propofol is appropriate and should be retained. The current labeling states: (1) propofol should be administered by an individual trained in the administration of general anesthesia and (2) that individual should NOT be involved in the surgical or diagnostic procedure for which propofol is being administered. This injunction is an important patient safety warning.

Patients' responses to propofol are quite variable. During propofol sedation it is common for patients to enter a deeper level of sedation than intended. Deep sedation and general anesthesia are associated with the potential for airway compromise and/or apnea. The treatment of airway obstruction or apnea requires early recognition of the problem and advanced airway skills for its management. ACLS or PALS training does not ensure proficiency in airway management. Unless the person administering the sedation is able to manage the airway obstruction or apnea quickly and effectively, the patient may suffer injury or death. Safe patient care requires early recognition of these problems. It is inconsistent with good patient care for the individual who is administering propofol sedation to participate in the surgical or diagnostic procedure. The person administering propofol must devote his/her complete attention to the patient.

Unlike narcotics and benzodiazepines, propofol does not have a pharmacologic antagonist. This underscores the importance of practitioners having advanced airway skills and having their attention focused solely on the patient.

I urge you to continue to support safe patient care by rejecting the petition to change the labeling of propofol.