

To the FDA: (Docket no.- 2005P-0267)

This letter is to express my opinion about the issue of possibly removing from the package insert of propofol the warning that the drug should be administered only by those trained in the administration of general anesthesia and NOT involved in the conduct of the surgical / diagnostic procedure. It is really amazing to me that removing this warning is even up for debate. It would increase the risk to the patients many many fold to have someone trying to conduct a colonoscopy, for example, while trying to tend to the patients respiratory status while under the respiratory depressant effects of propofol. Propofol is a very potent drug with a great propensity of suppressing one's respiratory drive. It is not uncommon for patients to go apneic (stop breathing) while under the effects of propofol. I can't imagine a gastroenterologist stopping in the middle of the colonoscopy (that is if he happens to notice that the patient is not breathing) to either mask ventilate the patient (something that they never do in their specialty) and/or intubate the patient. Propofol is a safe drug, but it isn't so safe that people administering the drug do not require training in airway management (which gastroenterologists don't have). I believe the gastroenterologists have an economic motive in this push. It is my strong opinion that patient safety should be the first consideration in this issue. It is very likely that anyone reading this letter will one day have a colonoscopy and I can promise you that when you do you do not want the same person who is performing the procedure, also supervising someone else in the administration of the propofol for your sedation. Propofol is an excellent drug for use in these procedures but it should always be administered by someone trained in the field of anesthesia, as airway management is a possibility at any moment during the procedure.

Sincerely,



Jack Anderson, M.D.

Anesthesiologist / Medical Director
The Montgomery Surgical Center

2005P-0267

C 79