



AMERICAN ACADEMY OF ANESTHESIOLOGIST ASSISTANTS

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February 13, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket Number 2005P-0267; Comments Opposing Citizen Petition Requesting Change in Propofol (Diprivan®) Labeling

Attention: Dr. Robert Rappaport
Center for Drug Evaluation & Research

Dear Dr. Rappaport,

The American Academy of Anesthesiologist Assistants (AAAA) would like to thank you for the opportunity to submit comments in response to the petition submitted by the American College of Gastroenterologists (ACG) seeking the removal of warning language from the package insert for propofol (Diprivan®). At the present time, the package insert for propofol (Diprivan®) states:

“For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.”

The AAAA supports the two basic implications of this statement: 1.) propofol should only be administered by those practitioners trained in the administration of general anesthesia, and; 2.) those persons shall not be directly and concurrently engaged in the conduct of the surgical/diagnostic procedure so that their full vigilance can be devoted to the state of the sedated patient. These two statements support the well-established principle that during any surgical/diagnostic procedure there be an independent practitioner whose sole responsibility is administration of propofol and proper monitoring of the patient to assess level of consciousness and to identify early signs of cardiovascular or respiratory compromise. The corollary benefit of this practice is that the practitioner performing the procedure is free to devote his/her full attention to the procedure, thereby improving patient safety.

2005P-0267

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By way of background, the AAAA, founded in 1975, is the national education and representative organization of anesthesiologist assistants (AA) organized to improve the level of anesthesia care provided to patients undergoing surgical/diagnostic procedures. Undoubtedly, the paramount mission of our members is to continually raise the level of patient safety.

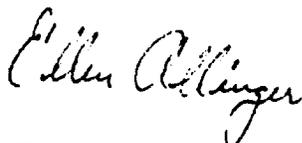
Propofol is a powerful anesthetic agent, whose administration carries with it all the associated risks of general anesthesia. Individual patient reactions to such a pharmaceutical agent can be varied and extremely unpredictable. Because the level of anesthetic depth can unintentionally change rapidly during administration of propofol, the clinician administering such agents must be able to recognize and rescue a patient experiencing any number of complications associated with general anesthesia. Moreover, propofol differs from other agents utilized during conscious sedation (i.e. benzodiazepines and narcotics) in that propofol does not have a direct antagonist or reversal medication.

As petitioned by the ACG, *removing the warning label from propofol would unnecessarily increase patient risk* by allowing non-anesthesia personnel to administer a powerful anesthetic agent while at the same not sufficiently monitoring the sedated patient, *and* attempting to perform surgical/diagnostic procedures that demand his or her full attention.

For the reasons discussed above, the Food & Drug Administration (FDA) should deny the proposed petition.

Thank your for your consideration.

Sincerely,



Ellen Allinger, AA-C
President
American Academy of Anesthesiologist Assistants

Attachment: AAAA Position Statement on Utilization of Propofol by Non-Anesthesia Personnel

STATEMENT ON USE OF PROPOFOL BY NON-ANESTHESIA PERSONNEL
American Academy of Anesthesiologist Assistants (AAAA)

(DATE SUBMITTED: February 10, 2006)

Due the recent movement by some non-anesthesia physician specialties (i.e. gastroenterologists, emergency room, pediatricians, etc.) to allow the use of propofol for deep sedation during surgical/diagnostic procedures, the American Academy of Anesthesiologist Assistants supports the position that anesthetic agents, such as propofol, should be administered only by trained anesthesia personnel, under the supervision of a qualified anesthesiologist.

At the present time, the package insert for propofol (Diprivan®) states:

“For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.”

The AAAA supports the two basic implications of this statement: 1.) propofol should only be administered by those practitioners trained in the administration of general anesthesia, and; 2.) those persons shall not be directly and concurrently engaged in the conduct of the surgical/diagnostic procedure so that their full vigilance can be devoted to the state of the sedated patient. These two statements support the well-established principle that during any surgical/diagnostic procedure there be an independent practitioner whose sole responsibility is administration of propofol and proper monitoring of the patient to assess level of consciousness and to identify early signs of cardiovascular or respiratory compromise. The corollary benefit of this practice is that the practitioner performing the procedure is free to devote his/her full attention to the procedure, thereby improving patient safety.

Propofol is a powerful anesthetic agent, whose administration carries with it all the associated risks of general anesthesia. Individual patient reactions to such a pharmaceutical agent can be varied and extremely unpredictable. Because the level of anesthetic depth can unintentionally change rapidly during administration of propofol, the clinician administering such agents must be able to recognize and rescue a patient experiencing any number of complications associated with general anesthesia. Moreover, propofol differs from other agents utilized during conscious sedation (i.e. benzodiazepines and narcotics) in that propofol does not have a direct antagonist or reversal medication.

Simply, it is in the best interests of the patients to limit the use of such an anesthetic agent to anesthesia practitioners who are trained not only to administer this drug, but recognize, diagnose, and appropriately respond to its unintended effects. Anesthesia practitioners, be they anesthesiologists, anesthesia residents in training, anesthesiologist assistants (AA), or certified registered nurse anesthetists (CRNAs), have the clinical knowledge and technical skills necessary to respond to any adverse respiratory or cardiovascular events resulting from administration of propofol.