

# United Press International

## Propofol label change contested

By Catherine Sharoky  
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A petition to the Food and Drug Administration to relax restrictions on the administration of an anesthesia drug during certain office-based procedures could put patients' safety at risk, experts told United Press International.

The American College of Gastroenterology filed a petition last month with the FDA asking for the warning label on the anesthesia drug Diprivan (propofol) be removed. The label states that the drug should be handled by those trained in the administration of general anesthesia -- anesthesiologists and certified registered-nurse anesthetists.

"The labeling change would make the use of propofol available to gastroenterologists who want to use the drug without incurring the expense to patients and payers ... of having to use an anesthesiologist," Dr. Douglas K. Rex, former ACG president, told United Press International. "So it's really all about the cost."

Anesthesia providers are reimbursed between \$100 and \$400 per procedure, depending on insurance, according to the petition. Removing the necessity of having an anesthesiologist present during routine colonoscopies, for example, and other endoscopic procedures would reduce costs and increase efficiency, the petition states.

Marc Koch, president and chief executive officer at Somnia Inc., an office and ambulatory anesthesia service company in New York City, said ACG is putting financial issues before patient safety and patient outcome.

"This is a potent medication to which patients react in a very patient-specific way, which can vary from patient to patient," Koch told UPI. "The skills, expertise and knowledge of a trained anesthesia provider ... is really something that should be taken with a high degree of importance."

Propofol is different from other anesthetic drugs currently used during office-based surgeries, because it induces sedation rapidly and the sedation level of the patient can fluctuate greatly, he said. Unlike other anesthetics, propofol does not have a reversal agent that can be used if the patient is overmedicated.

"Once you give it, you can't take it back," Koch said, noting that propofol also can cause airway obstructions, so those administering the drug must have experience in positioning the head and neck to keep the airway opened properly, and they must have training in circulatory resuscitation and artificial ventilation.

Propofol has many positive effects, however, Rex noted, making it an anesthetic agent of choice for office-based procedures, including colonoscopies. It brings patients out of sedation faster, which leads to less post-operative recovery time, and allows patients to resume normal activities faster than with other general anesthetics.

The label on Diprivan does not specifically limit its use to anesthesiologists and nurse anesthetists, said Jim Minnick, communications and external relations director at AstraZeneca Pharmaceuticals LP in Wilmington, Del.

In an e-mail, Minnick also told UPI that patients sedated with propofol must be monitored continuously while the drug is being used, and emergency equipment must be immediately accessible in case of airway obstruction.

Dr. Robert Stoelting, president of the Anesthesia Patient Safety Foundation, said in an e-mail that propofol can be safely administered in the low doses necessary for minimally invasive procedures such as colonoscopies by those not specifically trained in general anesthesia. The drug must be administered

by a "trained health care professional who is dedicated to monitoring the patient and who is capable of recognizing inadequate breathing."

At present, nursing boards in 13 states prohibit registered nurses who are not specifically certified in anesthesia from administering propofol during procedures.

"A (registered nurse) does not have the same airway management training that an anesthesia-provider does," Debora Moore, perioperative nursing specialist in the center for nursing practice at the Association of Perioperative Registered Nurses, told UPI.

In other states, however, propofol can be administered by registered nurses not specifically trained in anesthesia.

"Evidence shows now that there are nearly 100,000 patients that have been given propofol for endoscopic (procedures) by non-anesthesiologists safely," Rex said.

He said as long as registered nurses are adequately trained, they understand the drug and its effects and are able to take care of any problems that could develop, then propofol can be safely administered by non-anesthesiologists.

The FDA has until the end of December to respond to the request by the ACG to look into removing the warning label, but FDA spokeswoman Susan Cruzan said the department will likely begin reviewing the petition much sooner.

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