



# ANESTHESIOLOGY NEWS

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## POLICY & MANAGEMENT

ISSUE: FEBRUARY, 2006 | VOLUME: 32:02

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## Question of Who Should Administer Propofol Is Polarizing Two Specialties

### Gastroenterologists' Petition to FDA Seeks Labeling Change

Michael Dreyfuss

The FDA warning label for Diprivan (propofol, AstraZeneca) currently 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. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available."

On June 28th of last year, the American College of Gastroenterology (ACG) filed a petition with the U.S. Food and Drug Administration (FDA) seeking to have the labeling modified to allow gastroenterologists to administer propofol during endoscopic procedures.

This request has caused a good deal of controversy between the gastroenterology community and anesthesia providers.

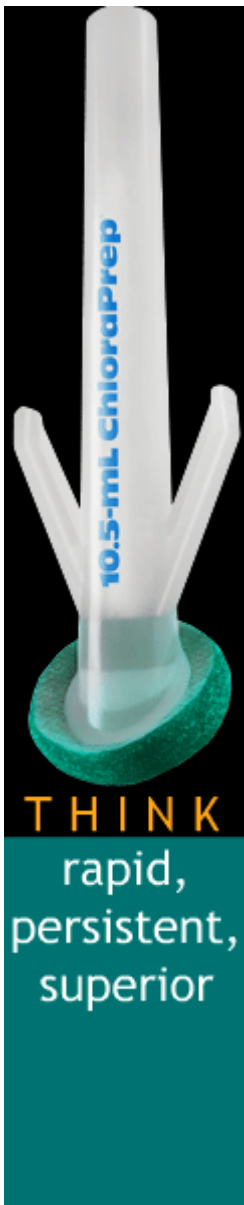
"I am most impressed by the lack of apparent cooperation between the specialties and the polarization that has occurred," observed Michael L. Kochman, MD, Professor of Medicine and Surgery at the University of Pennsylvania School of Medicine, Philadelphia. "This has not been constructive at all and has led to many different policy and practice changes—some on local hospital and practice levels—that may not be beneficial to patient safety."

In "The Science and Politics of Propofol" (Am J Gastroenterol 2004;99:2080-2083), Douglas K. Rex, MD, Professor of Medicine at Indiana University School of Medicine, wrote, "The gastroenterology and anesthesia communities should work together to explore mechanisms to expand propofol use or an alternative for endoscopy in a safe and cost-effective manner."

He further noted, "Propofol use for endoscopy is increasing rapidly. Its administration by registered nurses under the supervision of endoscopists has thus far proven safe, but is not realistically feasible in most U.S. endoscopy units. Therefore, propofol in the United States is being administered almost entirely by anesthesiologists. The transition to anesthesiologist-delivered sedation for endoscopy is being accompanied by increased costs, which in turn have the potential to adversely affect endoscopic practice."

As Dr. Rex commented, in "Sedation Issues in the Ambulatory Surgery Center" (available at: [www.ddw.org](http://www.ddw.org)), "The downside of anesthesiologists is that they bill





separately and thus increase the total cost of procedures. In some ambulatory surgery centers, endoscopists have lost major contracts because of utilization of anesthetists."

There is no question that money has colored the debate.

In a reply to questions from Anesthesiology News, the ACG stated, "Data on non-anesthesiologist-administered propofol experience has become sufficiently robust to suggest the need for a change. The current labeling serves to substantiate the false proposition that propofol cannot be safely administered by anyone who is not an anesthesiologist or a certified registered nurse anesthetist (CRNA)."

"The apparent vocal and most important issue is one of patient safety, but it appears that a major underlying concern is one of control and is therefore financially driven, as the cost of the procedure is significantly increased when an anesthesiologist is present," said Dr. Kochman. "There is no evidence in large, peer-reviewed publications that properly trained individuals, including gastroenterologists and others, have an increased reported number of adverse outcomes in the setting of ambulatory endoscopy."

The Multi-GI Society (American College of Gastroenterology, American Gastroenterological Association and American Society for Gastrointestinal Endoscopy) has issued a joint statement on sedation for endoscopy (available at: [www.asge.org/nspages/practice/patientcare/3groupJointStatement.cfm](http://www.asge.org/nspages/practice/patientcare/3groupJointStatement.cfm)):

"There are data to support the use of propofol by adequately trained non-anesthesiologists," the statement asserts. "Large case series indicate that with adequate training, physician-supervised nurse administration of propofol can be done safely and effectively."

Not everyone agrees.

"Non-anesthesiologists have no business giving propofol," Gary H. Hoffman, MD, told Anesthesiology News. Dr. Hoffman is Senior Surgical Attending at Cedars-Sinai Medical Center, Los Angeles. "If you're only worried about patient safety, you need to have someone who is trained in airway management and managing the patient. Some of the lowest malpractice insurance premium rates in the country are granted to anesthesiologists. Why? Because they've taken such tremendous steps to monitor patients' safety. There is no reason to do these procedures without an anesthesiologist."

Marc E. Koch, MD, MBA, an anesthesiologist and President and Chief Executive Officer of Somnia, Inc., New Rochelle, N.Y., testified about the administration of propofol before the FDA:

"Because there are no antagonistic agents for this anesthetic [propofol], it is crucial that a formally educated and trained anesthesia provider, with primary and sole responsibility for advanced airway and resuscitative support, be responsible for its administration."

The American Society of Anesthesiologists (ASA), in response to written questions from Anesthesiology News, stated, "Propofol is a powerful anesthetic agent that can produce unpredictable levels of sedation along the continuum from sedation to general anesthesia. There are no drugs that can quickly reverse the effects of propofol."

"The most important aspect of this debate is not money," Dr. Koch told Anesthesiology News. "It's about patient outcomes and patient safety."

"It is my professional and personal opinion that putting economic interests before patient care is counter to our mission and training," he added.

Several professional organizations recognize the risks involved in the administration of

propofol. Among them are the ASA, the American Association of Nurse Anesthetists, the Joint Commission on the Accreditation of Healthcare Organizations, the American Association of Accreditation for Ambulatory Surgical Facilities, boards of nursing in 12 states and, most recently, the New Jersey State Supreme Court.

"This may all become a moot point," concluded Dr. Kochman. Newer drugs such as fospropofol and its related compounds may be approved without the wording that accompanies propofol. In addition, there are automated delivery devices presently in trials that may also obviate the safety concerns raised."

The question is, what will the warning label for propofol say when the dust has settled?

Based on interviews with **Michael L. Kochman, MD, Marc E. Koch, MD, Gary Hoffman, MD**; information from the **American College of Gastroenterology** and the **American Society of Anesthesiologists**; an article published in the **American Journal of Gastroenterology** (2004; 99: 2028-2083); and information available at: [www.ddw.org/user-assets/documents/PDF/session\\_hands\\_outs/2005/051605/Sedation\\_Issues\\_in\\_the\\_Ambulatory\\_Surgery\\_Center\\_Rex.pdf](http://www.ddw.org/user-assets/documents/PDF/session_hands_outs/2005/051605/Sedation_Issues_in_the_Ambulatory_Surgery_Center_Rex.pdf) and [www.asge.org/nspages/practice/patientcare/3groupJointStatement.cfm](http://www.asge.org/nspages/practice/patientcare/3groupJointStatement.cfm).

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