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## GI-Supervised/Administered Sedation

## U.S. Food and Drug Administration Open Public Hearing

## Anesthetic and Life Support Drugs Advisory Committee

*May 7, 2008*

Annual Scientific Meeting and Postgraduate Course  
October 3 – 8, 2008, Gaylord Palms Resort and Convention Center, Orlando, Florida  
[www.acgmeetings.org](http://www.acgmeetings.org)

I am Julie Cantor-Weinberg, M.P.P., Vice President of Public Policy for the American College of Gastroenterology. I am pleased to be here today to have the opportunity to speak in support of gastroenterologist-administered sedation.

The American College of Gastroenterology is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 11,000 physicians among its membership of health care providers of gastroenterology specialty care. Although the vast majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists, and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, educational efforts directed at promoting and optimizing quality care including education around endoscopic sedation.

### The Role of Sedation in Endoscopy

The ACG has worked for years to educate the public, policymakers, and other clinicians about the importance of colon cancer screening, as colorectal cancer is the second leading cause of cancer deaths in the United States and with proper screening, it is 90 percent preventable. Nonetheless, half of the eligible population still has not been screened. Fear of discomfort and pain can be a strong disincentive to appropriate screening by colonoscopy, which is considered the gold standard of screening methods, as it is the only method that allows detection as well as removal of potentially cancerous lesions in a single procedure.<sup>1</sup>

Our members consider sedation during endoscopic procedures – including colonoscopies – a medical necessity, with more than 98 percent utilizing sedation during these procedures.<sup>2</sup> Sedation reduces or eliminates patient anxiety and discomfort and thereby increases patient tolerance of these procedures, allowing gastroenterologists to more easily perform a thorough exam with better outcomes.

The profession of gastroenterology has had more than four decades of experience in using a wide range of sedation agents. In the U.S. currently the most commonly used agents are meperidine, fentanyl, midazolam, diazepam and propofol. Complications associated with sedation in endoscopy are rare, occurring in less than one in every 10,000 persons.<sup>3</sup> The most common complications involve a temporary decrease in the rate of the amount of oxygen in the blood, breathing or heart rate. Gastroenterologists are well trained to respond to these and other such rare complications.

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<sup>1</sup> Denberg TD, et al. "Predictors of non-adherence to screening colonoscopy." *Journal General Internal Medicine* 2005; 20:1068-70.

<sup>2</sup> Cohen LB, et al. Results of a nationwide sedation survey. Endoscopic sedation in the United States: results from a nationwide survey. *Am J Gastroenterology* 2006; 101:967-974.

<sup>3</sup> Vargo JJ. "Sedation for Your Endoscopy," at <http://www.acg.gi.org/patients/gihealth/sedation.asp>, accessed May 2, 2008.

## More Sedation Agents Would Be Welcomed

Data indicates that there is significant gastroenterologist interest in new choices for sedation. A 2006 survey of 5,000 of our members regarding current practices of endoscopy and sedation found that 39 percent believed patient discomfort is a relative shortcoming of currently approved moderate sedation agents, followed by slow onset (24 percent), delayed recovery (16 percent), and risk of complications (10 percent).<sup>4</sup> A recent comprehensive literature review found that “the majority of patients undergoing endoscopy can be satisfactorily sedated using standard drug combinations; however, the pharmacologic properties of these agents make them suboptimal for brief ambulatory procedures. The increase in the use of propofol for endoscopic sedation indicated that improved sedation methods are needed.”<sup>5</sup>

## Gastroenterologist-Administered Propofol Has Demonstrated Its Safety

There is ample scientific evidence demonstrating the safety of propofol under the supervision of gastroenterologists. In 2004, the ACG, along with our sister gastroenterology societies, the American Society for Gastrointestinal Endoscopy (ASGE) and the American Gastroenterological Association (AGA), issued a joint statement on the use of sedation in endoscopy. (With the Chair’s permission, I would respectfully request that this complete statement be submitted into the formal meeting record.) That statement recognizes that the use of propofol in endoscopy is a complex topic, both medically and scientifically, but that generally, endoscopy procedures including colonoscopy are successfully performed with moderate (conscious) sedation and that compared to standard doses of benzodiazepines and narcotics, propofol may provide faster onset and deeper sedation. Lastly, the statement found that there are ample data to support the use of propofol by adequately trained non-anesthesiologists.

Nonetheless, the current FDA-approved labeling contains a warning specifying that it should be administered “*only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.*” As a result, some states and hospitals permit propofol to be administered only by anesthesiologists or CRNAs. Such restrictions add significant and often unwarranted costs to endoscopic procedures. It should be emphasized that at the time of propofol’s initial evaluation by federal agencies for safety and efficacy, no studies utilizing propofol by non-anesthesiologists for procedural sedation were conducted or requested.

Given the significant data on the safety of gastroenterologist-administered or supervised propofol, in 2005, the College filed a proposed labeling change for propofol through the FDA (docket number 2000p-0267/CP1). Three years and many thousands of procedures later, we are still waiting for a response. Since then, the many thousands of procedures using propofol have confirmed its safety profile. In fact, a worldwide safety review published just last month found almost 500,000 cases of non-anesthesiologist administered propofol, and in that analysis, there were very few adverse events. Indeed, the study concluded by stating that “the administration of propofol by non-anesthesiologists for endoscopic procedures is safe,” and that such

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<sup>4</sup> Cohen LB, et al. Results of a nationwide sedation survey. Endoscopic sedation in the United States: results from a nationwide survey. *Am J Gastroenterology* 2006; 101:967-974.

<sup>5</sup> Cohen LB, et al. “AGA Institute Review of Endoscopic Sedation.” *Gastroenterology* 2007; 133:675-701.

administration is “one feasible solution to the high costs associated with anesthesiologist-delivered sedation for endoscopy.”<sup>6</sup> In another review of 240,000 “published patients” that have experienced gastroenterologist-directed propofol, there were zero deaths and only one intubation.<sup>7</sup>

Obviously, patient safety is key to quality care and any recommendations this committee makes. With that in mind, it is important to note “There are **no** studies to date demonstrating that NAP (non-anesthesiologist administered propofol) exhibits a higher incidence of cardiopulmonary or procedural complications than standard sedation for endoscopic procedures.”<sup>8</sup> An August 2007, evidence-based literature review concluded that “gastroenterologist-directed administration of propofol is safe and effective for patients,” and that “gastroenterologist-directed propofol sedation is medicolegally reasonable, but requires appropriate endoscopist training, patient selection and adherence to protocols for administration.”<sup>9</sup>

Training and clinical education are a key function of the College, and we have held several courses on sedation for our members. Further, as part of their gastroenterology fellowships, gastroenterologists are trained in performing procedures on all types of patients, including those who might present with moderate to high-risk complications. Such training includes assessing and monitoring patients with restricted airways. Indeed, ASGE training guidelines require that endoscopic trainees learn the appropriate role of monitoring devices for sedation.

#### Clinical Trial Data Support Fospropofol Use by Non-Anesthesiologists

It is important to note that all of the pivotal studies conducted pursuant to the NDA with Fospropofol were performed *without* anesthesiologists, including those done in association with colonoscopy. We are pleased that the NDA and clinical trial application for this sedation agent - especially the trial data on colonoscopy patients -- shows that it can be safely used by nonanesthesiologists, including gastroenterologists, with appropriate patient selection and patient monitoring. We therefore urge this committee to recommend to the FDA that the labeling permit gastroenterologist-supervised administration.

Gastrointestinal endoscopy in the U.S. usually involves a team, which the majority of the time does **not** include an anesthesiologist. Specifically, the team most commonly includes the endoscopist, one or more nurses and assistants. According to our membership survey, in only a quarter of cases, is an anesthesiologist currently used.<sup>10</sup> Further, in addition to the fact that the available science supports the safety of gastroenterologist-administered Fospropofol, the shortage of anesthesiologists makes any potential requirement that Fospropofol be administered only by anesthesiologists a significant limitation on its appropriate availability should the agency decide to approve it.

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<sup>6</sup> Deenadayalu PD et al. “Non-anesthesiologist Administered Propofol Sedation for Endoscopic Procedures: A Worldwide Safety Review,” *Gastrointestinal Endoscopy* 2008; AB107.

<sup>7</sup> ACG Task Force on Endoscopic Sedation, “Current Issues and Controversies in Endoscopic Sedation, presentation, March 14, 2008, New York, New York.

<sup>8</sup> Vargo JJ. “Propofol Demystified: It is Time to Change the Sedation Paradigm,” *Am J Gastroenterology* 2004; 1207-1208.

<sup>9</sup> Cohen LB, et al. “AGA Institute Review of Endoscopic Sedation,” *Gastroenterology* 2007; 133:675-701.

<sup>10</sup> Cohen LB, et al. Results of a nationwide sedation survey. Endoscopic sedation in the United States: results from a nationwide survey. *Am J Gastroenterology* 2006; 101:967-974.

## Conclusion

In conclusion, the College appreciates the opportunity to inform this Committee's deliberations. It is clear that there is a desire in the gastroenterology community for more choices of appropriate sedation agents, and we believe that the clinical trial evidence clearly supports gastroenterologist-supervised administration of Fospropofol. We would also appreciate the Committee's assistance in requesting that the agency consider our citizen's petition to change the labeling on propofol without further delay. The healthcare system cannot afford to wait any longer.

*Conflict of Interest Statement:* MGI Pharma, Inc. has been an exhibitor at ACG educational conferences.

## FOR IMMEDIATE RELEASE

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### **Three Gastroenterology Specialty Groups Issue Joint Statement on Sedation in Endoscopy** Gastroenterology Societies Reach Consensus on Recommendations for Sedation During Endoscopic Procedures

**March 8, 2004 (Washington, DC)** -- The American College of Gastroenterology, American Gastroenterological Association and American Society for Gastrointestinal Endoscopy today issued a jointly sponsored statement on sedation for endoscopy. The joint statement clarifies billing issues related to the administration and/or supervision of sedation/anesthesia, summarizes current data on sedative agents and makes recommendations regarding the appropriate use of anesthesia specialists for endoscopy and appropriate patient surveillance during sedation.

The statement, approved by the governing boards of the three societies, is the product of a six member committee composed of representatives from each of the three societies. The impetus for the work of the committee was confusion regarding billing issues and recent developments and trends in sedation practice, including the use of propofol.

The group made several recommendations with important implications for endoscopic practice:

- The joint society recommendations assert that: “Compared to standard doses of benzodiazepines and narcotics, propofol may provide faster onset and deeper sedation...More rapid cognitive and functional recovery can be expected with the use of propofol as a single agent.”
- The joint society recommendations indicate that there are data to support the use of propofol by adequately trained non-anesthesiologists: “Large case series indicate that with adequate training, physician-supervised nurse administration of propofol can be done safely and effectively.”
- The joint society recommendations note that: “Reimbursement for conscious sedation is included within the codes covering endoscopic procedures.”

The recommendations review key issues regarding proper billing protocols, patient safety, the management of complications and the importance of training and skills necessary to rescue patients from severe respiratory depression.

Full text of the statement follows and it may be modified as future developments occur.

## **RECOMMENDATIONS ON THE ADMINISTRATION OF SEDATION FOR THE PERFORMANCE OF ENDOSCOPIC PROCEDURES**

### **A Joint Statement of a Working Group from the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE)**

- In general, diagnostic and uncomplicated therapeutic endoscopy and colonoscopy are successfully performed with moderate (conscious) sedation.
- Compared to standard doses of benzodiazepines and narcotics, propofol may provide faster onset and deeper sedation.
- More rapid cognitive and functional recovery can be expected with the use of propofol as a single agent.
- Clinically important benefits over standard sedatives have not been consistently demonstrated in average-risk patients undergoing standard routine upper and lower endoscopy. Further randomized clinical trials are needed in this setting.
- Propofol may have more clinically significant advantages when used for prolonged and therapeutic procedures, including, but not limited to, ERCP and EUS.
- There are data to support the use of propofol by adequately trained non-anesthesiologists. Large case series indicate that with adequate training physician-supervised nurse administration of propofol can be done safely and effectively. The regulations governing the administration of propofol by nursing personnel vary from state to state.
- Patients receiving propofol should receive care consistent with deep sedation. Personnel should be capable of rescuing the patient from general anesthesia and/or severe respiratory depression.
- A designated individual, other than the endoscopist, should be present to monitor the patient throughout the procedure and should be able to recognize and assist in the management of complications.
- The routine assistance of an anesthesiologist/anesthetist for average risk patients undergoing standard upper and lower endoscopic procedures is not warranted
- Physician-nurse teams administering propofol should possess the training and skills necessary to rescue patients from severe respiratory depression.
- Complex procedures and procedures in high-risk patients may justify the use of an anesthesiologist/anesthetist to provide conscious and/or deep sedation. In such cases this provider may bill separately for their professional services.
- The use of agents to achieve sedation for endoscopy must conform to the policies of the individual institution.
- Reimbursement for conscious sedation is included within the codes covering endoscopic procedures.
- Billing separately for conscious sedation has been targeted by the OIG as a possible fraud and abuse violation, and is not recommended.

The members of the working group were: Damian Augustyn, M.D. (San Francisco, CA), Joel V. Brill, M.D. (Scottsdale, AZ), Douglas Faigel, M.D. (Portland, OR), Bergein F. Overholt, M.D. (Knoxville, TN), John W. Popp, Jr., M.D. (Columbia, SC), Maurits Wiersema, M.D. (Fort Wayne, IN).