



# AMERICAN COLLEGE OF GASTROENTEROLOGY

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February 2, 2012

Margaret A. Hamburg, M.D.  
Commissioner

U.S. Food and Drug Administration (FDA)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg,

The American College of Gastroenterology (College) is writing you today to convey our deep concern over the current shortage of sedative drugs used in endoscopy centers and hospitals. Members across the United States are experiencing tremendous difficulty in accessing certain sedative and narcotic agents that are used routinely during endoscopic procedures such as colonoscopy. We urge the FDA to use its full authority under current law to help resolve these shortages as supplies continue to dwindle.

The College is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers over 12,000 physicians among its membership of health care providers of gastroenterology specialty care – with a focus on the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of ACG have been, and continue to be, promoting evidence-based medicine and optimizing quality of patient care.

The current shortages of fentanyl (Sublimaze), meperidine (Demerol), and midazolam (Versed), all of which are available as generic products, are forcing many of our members to cancel patient appointments due to the rationing of these drugs, or in many cases, simply an inability to procure the drugs from suppliers. In addition to its impact on patient access to healthcare services, the shortages of these drugs will result in increased cost to the healthcare system as gastroenterologists must substitute these moderate sedation agents with other sedatives such as propofol that may require the presence of an anesthesia professional. The additional cost of an anesthesia provider administering monitored anesthesia care adds considerably to the overall cost of endoscopy.

We urge the agency to expeditiously investigate this matter and take appropriate federal action to help ensure adequate supplies of fentanyl, meperidine, and midazolam are restored.

Please contact Brad Conway, Vice President of Public Policy to further discuss this important issue impacting clinical gastroenterology. The College is happy to provide more information on the experiences of our membership in dealing with the shortages when treating patients or to assist the Agency in any way.

Sincerely,

A handwritten signature in cursive script that reads "Lawrence R. Schiller".

Lawrence R. Schiller, MD, FACG  
President  
American College of Gastroenterology

CC:

Douglas Throckmorton, M.D.  
Deputy Director, CDER

Capt. Valarie Jensen, R.Ph.  
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