

Congress of the United States
Washington, DC 20515

December 20, 2005 1230 5 DEC 27 A9:45

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

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

Attention: Dr. Robert Rappaport, Center for Drug Evaluation and Research

Dear Dr. Rappaport:

We are writing to you in regard to a potentially dangerous patient safety issue. On June 28th, a petition (2005P-0267) was filed with the US Food and Drug Administration by the American College of Gastroenterology (ACG) related to the administration of Propofol (Diprivan) during endoscopic procedures.

Currently, the warning label on this potent anesthetic specifically states:

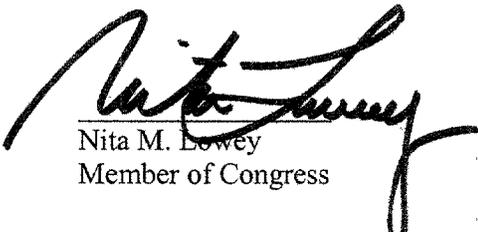
"For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available."

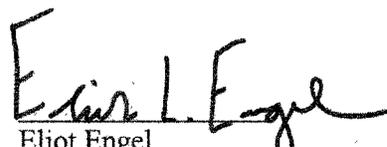
The petition asks the FDA to remove the specifications requiring individuals to be trained in the administration of general anesthesia. Anesthesiologists have years of training and experience in advanced airway support and resuscitative skills—all necessary when administering Propofol. As you know, there are no reversal agents for this anesthetic, and loosening the restrictions could only lead patient safety down a perilous, slippery slope.

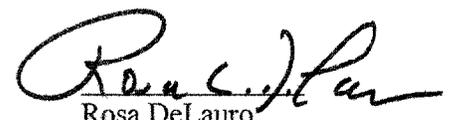
Patients deserve the safest and most effective surgical environment. Health professionals should also be educated to ensure patients are not simply receiving the right medication, but also that it is administered by the most skilled professional.

We must not ignore this grave issue. As advocates of improved patient safety, we must assiduously work to preserve patient safety

Sincerely,


Nita M. Lowey
Member of Congress
2005P-0267


Eliot Engel
Member of Congress


Rosa DeLauro
Member of Congress
C 82