



8515 GEORGIA AVENUE, SUITE 400  
SILVER SPRING, MARYLAND 20910-3492  
301 628-5000 • FAX 301 628-5001  
[www.NursingWorld.org](http://www.NursingWorld.org)

KAREN A. DALEY, PhD, MPH, RN, FAAN  
PRESIDENT

MARLA J. WESTON, PhD, RN  
CHIEF EXECUTIVE OFFICER

December 23, 2010

Ms. Michele M. Leonhart  
Deputy Administrator  
Drug Enforcement Administration  
Attention: DEA Federal Register Representative/ODL  
8701 Morrisette Drive  
Springfield, Virginia 22152

Docket No. DEA-327

Submitted electronically to <http://www.regulations.gov>

Re: **Schedules of Controlled Substances: Placement of Propofol Into  
Schedule IV: Notice of Proposed Rulemaking, Docket No. DEA-338**  
75 Fed. Reg. 66196 (Oct. 27, 2010)

Dear Deputy Administrator Leonhart:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on this proposed rule. The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of health care professionals in the United States. We represent RNs in all roles and practice settings, through our state and constituent member nurses associations, and organizational affiliates. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and advocating before Congress and regulatory agencies on health care issues affecting nurses and the public. Our members include Advanced Practice Registered Nurses (APRNs) such as Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse Midwives (CNMs).

ANA supports this proposed rule by the Drug Enforcement Administration (DEA) for placement of propofol, including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. We concur with the DEA's concerns about the diversion and abuse of propofol and the need for higher level restrictions to prevent and protect against such misuse, especially by health care professionals. This support is consistent with the position taken by the American Association of Nurse Anesthetists which represents CRNAs who are anesthesia professionals and frequently administer propofol as part of their practice.

Propofol was approved by the Food and Drug Administration as an ultra-short acting intravenous anesthetic in 1989 and has achieved effective and widespread use in the past two decades. It is now very widely administered to adults who require monitored anesthesia care sedation, combined sedation, and regional anesthesia. Propofol is also indicated for the sedation of intubated and mechanically ventilated patients in intensive care units. Propofol is also approved for use with children for the induction and maintenance of general anesthesia.

### **Propofol Abuse is a Particular Problem for Health Care Professionals**

At subtherapeutic doses, propofol can cause an individual to be relaxed and produce feelings of elation, euphoria and reduced inhibitions, creating a potential for abuse.<sup>1, 2</sup> The DEA has noted reports of individuals developing dependencies on propofol, sometimes leading to daily injections. Propofol abuse is directly associated with significant adverse health effects, including pancreatitis, pulmonary edema, and cardiovascular and respiratory depression, and can even lead to death. Death from propofol toxicity is due to severe respiratory depression.<sup>1, 3</sup>

Sadly, the abuse of propofol is primarily by health care professionals who have ready access to it. Among 126 academic anesthesiology programs in the U.S. included in a survey, 18 percent reported the diversion or abuse of propofol.<sup>4</sup> Abuse is mainly by anesthesiologists, nurse anesthetists and resident physicians who access propofol in hospitals and clinics due to a lack of controls.<sup>5</sup> Propofol abuse among the public is not reported in several different surveys of drug use. For example, there is no reported use of propofol in the National Survey on Drug Use and Health of people in the United States aged 12 years old or older.<sup>6</sup>

---

<sup>1</sup> Roussin A, Montastruc J-L, and Lapeyre-Mestre M. (2007). Pharmacological and clinical evidences on the potential for abuse and dependence of propofol: a review of the literature. *Fundamental and Clinical Pharmacology*, 21, 459-466.

<sup>2</sup> Zacny JP, Lichtor JL, Coalson DW, Finn RS, Uitvlugt AM, Flemming DC, and Apfelbaum JL. (1992). Subjective and psychomotor effects of subanesthetic doses of propofol in healthy volunteers. *Anesthesiology*. 76 (6), 696-702.

<sup>3</sup> Iwersen-Bergmann S, Rösner P, Kühnau HC, Junge M, and Schmoldt A. (2001). Death after excessive propofol abuse. *International Journal of Legal Medicine*, 114 (3), 248-251.

<sup>4</sup> Wischmeyer PE, Johnson BR, Wilson JE, Dingmann C, Bachman HM, Roller E, Tran ZV, and Henthorn TK. (2007). A survey of propofol abuse in academic anesthesia programs. *Anesthesia and Analgesia*, 105(4), 1066-1071.

<sup>5</sup> Weetman DB, Mascardo LA, Ross MB, and Abramowitz PW. (2004). Propofol as a drug of diversion. *American Journal of Health-System Pharmacy*. 61(11), 1185-1186.

<sup>6</sup> Substance Abuse and Mental Health Services Administration. (2008). *Results from the 2007 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.

## **Further Action is Needed to Reduce Abuse of Propofol**

The ANA has for decades recognized the significant problems caused by substance abuse, having first passed a resolution on drug abuse in 1970. At present, there is an ease of access to propofol as a non-controlled substance which does not require it to be secured in a facility. Placement of propofol into schedule IV of the Controlled Substances Act will require that the drug be in a secure environment which should reduce the diversion and abuse of this anesthetic.

The ANA recognizes, however, that the mere act of scheduling other drugs and medications has not stopped their abuse, addiction and diversion. Therefore, the ANA also recommends that the Drug Enforcement Administration carefully consider and undertake further action to prevent the abuse, addiction and diversion of propofol. This will result in more productive health professionals who can provide high quality patient care.

## **Conclusion**

We appreciate the opportunity to comment on this important rule. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Louise Kaplan, PhD, ARNP, FNP-BC, FAANP, ANA Department of Practice and Policy at [louise.kaplan@ana.org](mailto:louise.kaplan@ana.org) or 301-628-5044.

Sincerely,

A handwritten signature in black ink that reads "Marla J. Weston". The signature is written in a cursive, flowing style.

Marla J. Weston, PhD, RN  
Chief Executive Officer  
American Nurses Association

cc: Karen A. Daley, PhD, MPH, RN, FAAN  
President  
American Nurses Association