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Drugs that should be controlled Ephedrine and Propofol

This report addresses questions concerning drugs that I recommend to be controlled. It also includes an article concerning recent drug diversion in Colorado. Documentation by various authorities are include in this documentation.

Ephedrine IS a controlled drug. DEA idetifies it as a "list" drug. Colorado identifies it as a schedule ii drug.

Propofol is recommended to be controlled by various professional associations and the DEA. Articles included.



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Don't want a \$1 million fine? Pay attention to regulated drugs

December 1, 2011

Don't want a \$1 million fine? Pay attention to regulated drugs

[Editor's note: In this issue of Same-Day Surgery, we put a special focus on compliance with regulated drugs. We've talked with some of the top pharmacy consultants in the country to find out foolproof systems for avoiding diversion and theft. These stories will help you decide where to focus your time and energy, while avoiding liability.]

A hospital-affiliated clinic and surgery center in Oklahoma have been fined \$1 million in a settlement over claims that they failed to comply with federal regulations regarding record-keeping and inventory of regulated drugs, according to a media report.¹

The parent company of the clinic and surgery center notified officials at the state and federal levels when they realized there were discrepancies in their inventories following the transfer of narcotics to the surgery center from the clinic, according to the report. Upon identifying inconsistencies, the clinic disclosed the discrepancies to the state Board of Pharmacy and the Drug Enforcement Administration (DEA). Investigators found that St. Anthony had not complied with all of the inventory and documentation requirements of the Federal Comprehensive Drug Abuse Prevention and Control Act.¹ No further details were released. Failure to comply with the federal requirements is subject to civil penalties of up to \$10,000 per violation.

A spokesperson for the parent company was quoted as saying they are committed to improving their regulatory compliance efforts and that corrective actions have been taken.

"We're facing in this country a terrible epidemic to controlled substances, including substances dispensed at medical facilities," says **Sanford Coats**, JD, U.S. attorney in the Western District of Oklahoma in Oklahoma City. "Tracking is absolutely critical."

According to **Robert Troester**, executive assistant to the U.S. attorney in the Western District of Oklahoma, a situation becomes problematic not when there is a "single isolated missing form, but a systemic failure to keep control of documents and inventory."

The incident involving the Oklahoma healthcare providers is not isolated, Coats says. While most healthcare providers probably have good compliance programs in place, "some have been sloppy or haven't given it the due attention it needs," he says.

The federal fine comes at a time of increased focus on narcotics. Michael Jackson's death, blamed on propofol, has raised public concern about that drug, while there has been growing recognition of propofol abuse by medical providers. The DEA is considering designating propofol as a controlled substance. In the meantime, some hospitals and surgery centers already are accounting for items such as propofol as though they were designated as such.

Sheldon S. Sones, RPh, FASCP, president of Sheldon S. Sones and Associates, a safe medication and pharmacy consulting firm in Newington, CT, says, "Although it is important to remain compliant with federal and state requirements, I feel it is equally important to insulate the facility's stakeholders from the pain of controlled drug diversion issues. Thus, orchestrating a system that is both compliant and is structured appropriately is the end goal." Consider these suggestions:

- **Have a pharmacist consultant review your policies and practices.**

OA Center for Orthopaedics, in Portland, ME, addressed the issue of compliance with a team that included **Linda Ruterbories**, ANP, director of surgical services and program development, a staff nurse who was a compliance specialist, the PACU supervisor, and an anesthesiologist who subcontracted with the facility. Sones was hired to review the facility.

He told the managers that they needed to change their procedures regarding samples of pregabalin. "Obviously, because they are a controlled substance, they needed to go into the Pyxis system and be dealt with in a different manner than before," Ruterbories says. Also, the staff had not been considering injectable Brevital to be a controlled substance. "Brevital is like propofol in a way, in that you wouldn't expect someone to abuse it or deviate from using it in the manner for which it was intended, but if it's a controlled substance, it needs to be treated as a controlled substance," Ruterbories says.

Traditionally, the staff members would pull narcotics from the Pyxis at the request of the anesthesiologist, who would document how much was used. Staff would waste the remainder. Sones recommended that they give the anesthesiologist a box with all of the anticipated medications for the day and have the anesthesiologist document specific patient use or, alternatively, draw the medications through the Pyxis on a patient-by-patient basis. He said either approach has to ensure thorough documentation of who received what, by whom, and when. Ruterbories points out that medications can be kept in locked anesthesia carts during business hours. Anesthesia staff, as well as others, should be monitored for any behavior changes that might indicate diversion, experts suggest.

- **Spot check narcotics waste.**

Nurses handle this responsibility at OA Center for Orthopaedics. They look at individual patient records and report any physicians or nurses about whom they have questions, Ruterbories says.

"We're looking to establish patterns obviously," she says. (See "Anesthesia Medication Reconciliation 2011 template" with the online issue. For assistance, contact customer service at (800) 688-2421.)

Incorrect narcotic counts and patients who don't receive relief after being given pain meds might be signs of diversion, says **Bonnie Brady**, RN, CNOR, administrator at Specialty Surgical Center of Sparta, NJ. (*For more information on narcotics counts, see story, below.*) "I have heard of substituting saline for narcotics," Brady says.

Be alert to odd behavior of your staff, Ruterbories advises. Atypical behaviors might include anxiety, belligerence, sweating, tremors, and compromised medical decisions. Random drug testing is one approach to such behavior, Ruterbories says.

- **Consider security measures.**

A few years ago at OA Center for Orthopaedics, thieves stole an anesthesia badge that was in an unlocked container and used it to enter the medication room and force open the Pyxis system. "Any system is only as good as the criminal trying to get into it," Ruterbories says. "They took all our narcotics."

The room is now locked down from 7 p.m. to 7 a.m. and is tied to the center's alarm system. Additionally, the administrators installed dead bolt locks that require a key. "It's not 100% foolproof; someone could find the key," Ruterbories says.

Centers also could consider installing a security camera in the medication room, which might deter thefts.

- **Review your system of ordering narcotics.**

At OA Center for Orthopaedics, the medical director "has to sign the DEA form so he's aware of all the narcotics we're ordering," Ruterbories says. The nurse compliance officer works with him on the ordering and obtaining of narcotics, she says.

Brady says. "Regulated drugs that are delivered should not be lying around when delivered but handed to a dedicated staff member to count and lock up."

At Specialty Surgical Center, any two nurses can count narcotics, Brady says. "That prevents any one nurse from being in total control of the count," she says. "Drugs are counted at the beginning and end of the shift and anytime there is a new staff member coming on at night."

Reference

1. Associated Press. St. Anthony pays \$1 million fine over non-compliance with federal drug inventory control rules. July 29, 2011.

Sources

- **Sheldon S. Sones**, RPh, FASCP, President, Sheldon S. Sones and Associates, 15 Coachmen Lane, Newington, CT 06111. E-mail: Shelsones@aol.com. Web: www.Sheldonsones.com. Sones is a safe medication and pharmacy consultant to more than 110 ambulatory surgery centers in the Northeast.

Daily counts help avoid diversion

Daily counts of regulated drugs are one step to ensure compliance and to avoid diversion, says **Sheldon S. Sones**, RPh, FASCP, president of Newington, CT-based Sheldon S. Sones and Associates, a safe medication and pharmacy consulting firm.

"We ensure that daily counts are performed at the location of controlled drug distribution as well as the larger 'safe,' which is counted on dispensing as well as monthly," says Sones, who points out that state requirements might differ.

Additionally, expect anesthesia providers to document clearly in the anesthesia record their controlled drug administration trail, he says. (*For more on the narcotics trail, see story, below.*) Consider these additional suggestions from Sones:

- Anesthesia providers should attest to drugs drawn for the work day and returned with another licensed individual.
- Records of controlled drug received should be retrievable and organized in such a way as to permit review of invoices.
- All discards of controlled drugs should be in a "real time" manner with witnessed signatures. Furthermore, the discards should be done in a manner that renders them "nonretrievable"
- Pharmacy consultant oversight should be performed on a monthly or quarterly basis with a review and attestation of compliance and accurate inventory.

Can you trace the narcotics trail?

To avoid diversion, address storage, documentation, and quality assurance, suggests **Sheldon S. Sones**, RPh, FASCP, president of Newington, CT-based Sheldon S. Sones and Associates, a safe medication and pharmacy consulting firm.

Drugs drawn for the day should have a trail that validates who took what drugs and when. "Likewise, on return to the main storage areas for the day, the same documentation should exist," Sones says. "Daily inventories of all stocks should be validated, and the federally required 'Biennial Controlled Drug Inventory' should be retrievable and in good stead."

The emphasis is on the word "trail," Sones says. He asks, "Can you identify what was delivered through your front door, who used what, and that what remains in stock is a quantitative 'match'?"

- **Ensure your records are in order.**

The anesthesia record and the PACU record should be explicit as to what was administered, by whom, and when, Sones says. "One of the things we do on our routine visits is what I call a 'correlation' where we tag anesthesia records and compare them to controlled drug usage records to ensure the 'match.'" Sones says. "It speaks volumes to the commitment that the facility has to ensure compliance and control."

- **Don't try to be solve the crime.**

When looking for signs of potential diversion, "abnormal behavior of individuals with access to controlled drugs, casual documentation, illegibility, and even sometimes patient 'under-response' to heretofor routine dosing are all reasons for suspect," Sones says.

If an issue is identified, communicate the problem to the administrator, clinical director, medical director, the Drug Enforcement Administration (DEA) registrant, which is the person who holds the DEA license; management company (if there is one), he says. "Basically, go up the leadership chain," Sones says.

Also, contact the legal authorities including state officials and DEA, he advises. "The facility should not take extraordinary detective-type efforts on its own," Sones says. "The facility, however, should aggregate data, information, and have a log of information gathered."



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Denver endoscopy center nurse pleads guilty to stealing drugs: 5 things to know

Written by Laura Dyrda | December 20, 2018 | [Print](#) | [Email](#)

A Denver endoscopy clinic nurse pleaded guilty to stealing controlled substances from the center after having admitted to similar allegations with her previous employer, according to a [Fox 21 report](#).

Here are five things to know:

1. Mary Panza, the nurse, pleaded guilty to stealing drugs from Ridge View Endoscopy Center where she had been responsible for tracking the center's drugs. According to the report, instead of handling the drugs appropriately she emptied wasted medication into vials with other drug labels.
 2. Ms. Panza said she diverted drugs from the center once per week for 10 months.
 3. Prior to her appointment at Ridge View, Ms. Panza engaged in similar drug diversion while employed by Denver Endoscopy.
 4. In August, Ms. Panza was taken to the hospital after she was found unconscious at her home with a syringe in her hand. Officers found fentanyl vials in her bathrobe and purse at that time.
 5. Her sentencing is scheduled for March 2019.
-

DENVER - A Parker nurse has pled guilty to stealing drugs from the Lone Tree endoscopy clinic where she worked, according to the U.S. Attorney's Office in Denver.

Prosecutors said Mary Panza, also known as Mary Bowers, pled guilty Tuesday to obtaining a controlled substance by deceit.

According to prosecutors, on August 3, Panza was found unconscious on the floor of her bathroom with a syringe in her right hand. First responders administered Narcan to revive her, and determined she had taken fentanyl. Officers found six vials of Benadryl and one vial of Promethazine in her purse, which she used to hide the fentanyl. They also found multiple syringes and a rubber tourniquet in her bathroom.

When she arrived at the hospital, officers found multiple vials of fentanyl in her bathrobe. They determined she had gotten the painkiller from Ridge View Endoscopy Center, where she was in charge of tracking the drug. She would empty wasted medication into vials labeled with the names of other drugs, according to prosecutors. She did this about once a week for 10 months. She also admitted to doing the same thing at her prior employer, Denver Endoscopy, on a handful of occasions.

Should Diprivan (propofol) be a controlled substance?

*By Elizabeth Landau
CNN.com Health Writer/Producer*

The general anesthetic Diprivan (propofol) has been making headlines as questions about Michael Jackson's death abound. A nurse who had worked for the singer told CNN that Jackson requested the drug because he had trouble sleeping, and The Associated Press reported that it had been found in his home. Diprivan is not approved as a sleep aid by the Food and Drug Administration. [Read more about propofol.](#)

It turns out that propofol, used routinely for surgeries and procedures such as colonoscopies, has been a point of concern among some anesthesiologists because of the potential for abuse by health care workers. A 2007 study published by the International Anesthesia Research Society found that about 18 percent of the 126 academic anesthesia programs in the United States had at least one reported instance of propofol abuse within the previous 10 years.

Researchers also found that six out of 16 residents (about 38 percent) who abused propofol died from it. While these are small numbers, lead author Dr. Paul Wischmeyer, professor of anesthesiology at the University of Colorado, believes this is indicative of a larger problem.

People who abuse propofol tend to have had trauma earlier in life, and take the drug to escape it, Wischmeyer said. These people also tend to be impulsive and risk-taking, he said.

Wischmeyer became passionate about the issue because one of his classmates in residency died from using the drug.

"I know physicians that have reached their hands into sharps boxes, where all of the needles are disposed of, to pull out old, used syringes of this stuff that have been used in other patients, and then use it on themselves," he said.

The drug affects two important brain receptors, one of which is associated with marijuana, and the other is targeted by anti-anxiety drugs such as Valium, he said.

"Once someone has tried this drug in a way that they remember it, they very much always choose to try it again," he said.

Some people may die from propofol abuse because the drug itself becomes contaminated when it sits out for too long, like "spoiled milk," he said. There is also a risk of overdose.

"The difference between being high and being dead is a cc or two," Wischmeyer said.

If propofol is the direct cause of death, it should show up in an autopsy in urine, blood, and possibly hair, he said. But it does depend on how long before death the drug was injected.

Should propofol be considered a controlled substance that needs to be "scheduled," with tight distribution and strict accounting of its use? Anesthesiologists are still debating this.

On the down side, stricter pharmacy control of Diprivan would involve increased costs and administrative oversight, the study authors noted. Although there have been documented cases of propofol abuse, it is still much less frequent than abuse of opioids and benzodiazepines, which are governed by strict federal laws and local pharmacy control, they wrote.

But Wischmeyer advocates that it should be a controlled substance because of how lethal it is. He argues that having an extra layer of accounting, as there is with many painkillers and sedatives in hospitals, would not delay the supply of drug for the patients who need them. It was only with Wischmeyer's group's study that the anesthesiology community became more aware of the growing abuse problem, he said.

Most anesthesia programs do not keep track or control of propofol stocks, the authors wrote.

The drug does not produce a "high" per se, but does give the person who takes it a euphoric feeling upon waking up, said Dr. Hector Vila, chairman of the Ambulatory Surgery Committee for the American Society of Anesthesiologists.

For more information about the propofol issue among anesthesiologists, read [the study](#) and check out [Anesthesiology News](#).

***Editor's Note:** Medical news is a popular but sensitive subject rooted in science. We receive many comments on this blog each day; not all are posted. Our hope is that much will be learned from the sharing of useful information and personal experiences based on the medical and health topics of the blog. We encourage you to focus your comments on those medical and health topics and we appreciate your input. Thank you for your participation.*

Post by: [Elizabeth Landau - CNN.com Health Writer/Producer](#)

Filed under: [Addiction](#)

Next entry » [CDC launches environmental health site](#)

« Previous entry [Heady advice on lice](#)

<http://thechart.blogs.cnn.com/2009/07/06/should-diprivan-propofol-be-a-controlled-substance/comment-page-1/>

Securing Propofol *Position Statement*

The American Association of Nurse Anesthetists (AANA) supports the well-being, safety, and professional self-care of Certified Registered Nurse Anesthetists and Student Registered Nurse Anesthetists. The AANA recognizes that anesthesia professionals have an increased occupational risk of substance use disorder, as well as the professional and personal consequences of substance use disorder.¹⁻⁴

Since the introduction of propofol into the healthcare market, the incidence of healthcare professionals' abuse of propofol continues to increase.⁵ Propofol is among the most commonly abused drugs by anesthesia professionals.⁶ This abuse is primarily due to ease of access, rapid onset of action, short duration of action, and feelings of elation and euphoria.^{2,5,7-18} Access to highly addictive drugs, including propofol, is a significant risk factor for substance use disorder among anesthesia and other healthcare professionals.^{2,3,5,10-15,19-21} Research also suggests that exposure to propofol aerosolized in the operating room may sensitize personnel to later abuse.^{5,22-24} Unfortunately, the first sign of propofol abuse or addiction is often death.^{12,13,16-19}

Because healthcare professionals who divert drugs, such as propofol, pose a risk to their patients, employers, coworkers, and themselves, the AANA takes a strong position on the need to secure propofol within facilities.²⁵

Position

Recommendation for Classification by Federal Drug Enforcement Administration

-  Since 2010, it has been the AANA's position that, due to the risk of abuse, propofol warrants, at a minimum, Schedule IV controlled substance classification.^{7,12,20,26,27}

Recommendations for Facilities

-  The AANA strongly recommends that facilities with propofol on formulary develop and implement methods to reduce the likelihood of propofol diversion, such as placing propofol in a secure environment only accessible by those professionals identified in a medication management policy.
-  Establish a comprehensive workplace substance use disorder policy, which includes propofol, and addresses drug storage, abuse and diversion, methods to prevent drug diversion, and reentry to clinical practice.^{1,10,25,28} Propofol should be addressed in this comprehensive policy.
 - o Detailed information on Drug Diversion Prevention Strategies and Reentry to Clinical Practice is listed in [Addressing Substance Use Disorder for Anesthesia Professionals, Position Statement and Policy Considerations](#).¹
-  Educate all healthcare professionals on the nature and scope of drug diversion and impairment in the workplace, signs and behaviors of drug diversion and impairment, appropriate response, and proper ways to report drug diversion and impairment.^{1,21,25}

- Detailed information on Identifying Those at Risk and Signs and Behaviors of Impairment and Drug Diversion is listed in [Addressing Substance Use Disorder for Anesthesia Professionals, Position Statement and Policy Considerations](#).¹
- When propofol diversion and abuse is suspected, use an extended drug testing panel and protocols that identify anesthesia drugs to include propofol.^{1,29}

AANA Resources

- Addressing Substance Use Disorder for Anesthesia Professionals, Position Statement and Policy Considerations
www.aana.com/AddressingSUD
- Substance Use Disorder Workplace Resources
www.aana.com/SUDWorkPlaceResources
- Peer Assistance
www.AANAPeerAssistance.com

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American Society of Anesthesiology Issues New Recommendations for Safe Use of Propofol

Caroline Helwick

October 21, 2009

October 21, 2009 (New Orleans, Louisiana) — At its 2009 annual meeting, the American Society of Anesthesiology (ASA) is formalizing recommendations to facilitate the safe use of propofol. At a press briefing, a panel of ASA Directors described the new recommendations and their rationale.

John Dombrowski, MD, from Washington, DC, said that the recent death of Michael Jackson raised safety concerns about the anesthetic agent, but "we were looking at these issues way before his death."

Kenneth Elmassian, DO, from East Lansing, Michigan, who is president-elect of the Michigan Society of Anesthesiologists, added that "there has been recent notoriety for this drug, which is actually a safe and marvelous agent." Approximately 30 million Americans undergo anesthesia each year, and 90% of these cases involve propofol, he noted.

"But it needs to be provided in an appropriate setting in which physiologic rescue can be performed if needed," he emphasized.

ASA Position

The ASA unequivocally maintains that propofol should be used in a medical setting by professionals trained in the provision of general anesthesia, with proper supervision by a physician trained in anesthesia and qualified to provide rescue should too much drug be given. Building upon this position, the ASA is making several new recommendations, the panel said.

In March 2009, the ASA Board of Directors voted to recommend to the Drug Enforcement Agency (DEA) that propofol be labeled a controlled substance. The tighter control and monitoring that accompany scheduling of the drug is expected to reduce the potential for abuse.

In a 2007 study of 126 academic anesthesiology programs (*Anesth Analg*. 2007;105:897-898), 18% of the centers reported at least 1 incident of abuse over 10 years, involving 25 individuals, 7 of whom died. This represented a 5-fold increase from previous surveys and provided the impetus for the recommendations, Dr. Elmassian said. These recommendations were cited in the DEA's recent decision to make fospropofol, a short-acting "light" version of propofol, a schedule IV controlled substance, he said.

The ruling, which is expected to become official November 3, means that its use must be controlled and documented. The requirements for a schedule IV drug are less stringent than for schedule II controlled substances (i.e., narcotics), and compliance should be simple, he explained.

The prevailing belief, before the 2007 study, was that propofol abuse simply did not occur, Dr. Dombrowski added. "Indeed, [cases of abuse] are very rare, but when they occur they are tragic," he observed. He cited 1 example of an anesthesiologist injecting propofol 50 times a day to catch naps and stay alert. This anesthesiologist is now undergoing rehabilitation for substance abuse, he said.

"By making this a controlled substance, we will know when a provider is using it inappropriately."

The ASA representatives said they are hopeful that the DEA will also consider making propofol a schedule IV drug.

ASA Outlines Recommendations for Safer Administration of Propofol

Data from other sources have led to recommendations for more thorough monitoring of the patient receiving propofol, said Hector Vila, MD, from Tampa, Florida, who is chair of the ASA Ambulatory Surgery Committee.

This information is coming from the Closed Claim Project (a retrospective case-review system), the Anesthesia Quality Institute, and the Anesthesia Patient Safety Foundation. Summary analyses from the Closed Claim Project recently documented the association between propofol and adverse events related to breathing.

From 1989 to 2005, the FDA received 186 reports of deaths among patients receiving propofol, and this is considered an underestimate. "This does not include the 'near misses'," Dr. Elmassian pointed out. "Most of us have been involved in rescuing patients from the precipice."

As a result, during the annual meeting, the ASA House of Delegates approved the following safety monitoring proposals:

- Monitoring for exhaled carbon dioxide should be considered during endoscopic procedures in which sedation is provided with propofol alone or in combination with opioids and benzodiazepines, especially during these procedures on the upper gastrointestinal tract.
- Careful attention to airway management must be provided during endoscopic retrograde cholangiopancreatography procedures performed in the prone position where ventilatory monitoring, airway maintenance, and resuscitation could be especially difficult.

"The use of these approaches will lead to increased patient safety," Dr. Vila predicted. "The technology is widely available in the anesthesia delivery system already and is not expensive."

Dr. Dombrowski added that, "in addition to having the anesthesiologist keep his or her eye on the patient, measuring exhaled CO₂ adds another layer of protection."

He emphasized that anesthesiologists are "in the forefront of patient safety." The Institute of Medicine, he noted, has singled out anesthesiologists "as the leaders in quality and safety," mainly because of the technological advances in the field (i.e., pulse oximetry), the standardization of medications and equipment, and improvements in training.

Dr. Elmassian, Dr. Dombrowski, and Dr. Vila have disclosed no relevant financial relationships.

American Society of Anesthesiologists (ASA) 2009 Annual Meeting: Press Briefing. Presented October 19, 2009.

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Propofol (Diprivan®)

January 2013
DEA/OD/ODE

Introduction:

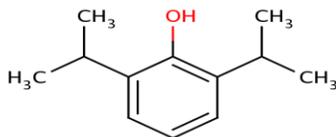
Propofol (2,6-diisopropylphenol, U.S. patent 4,447,657) is a short acting intravenous anaesthetic and marketed (Diprivan®, AstraZeneca) as a sterile emulsion. It is currently available in the United States as a prescription medication for use in human and veterinary medicine.

Licit Uses:

Propofol is a nonbarbiturate sedative, used in hospital settings by trained anesthetists for the induction, maintenance of general anesthesia, and sedation of ventilated adults receiving intensive care, for a period of up to 72 hours.

Chemistry:

Propofol, or 2,6-diisopropylphenol (C₁₂H₁₈O, MW = 178.271) is a simple molecule and its chemical structure is shown below.



Pharmacology:

Propofol produces loss of consciousness rapidly within 40 seconds of an intravenous injection. Its duration of action is short with a mean of 3 to 5 minutes following a single bolus dose of 2 to 2.5 mg/kg of body weight. Studies investigating the recovery profile of propofol have reported that patients anaesthetized with propofol wake-up "elated", "euphoric", and "talkative". Clinical studies indicate that 50% of participating subjects reported "liking" on the Visual Analog Scale and showed preference for propofol over placebo. Sub-anesthetic doses of propofol are reported to produce feelings of "being high", light-headedness, spaced out and sedation. Propofol at anesthetic doses is reported to cause dream incidence in 20% to 60% of the exposed population.

The primary effect of propofol is potentiation of GABA-A receptors. Similar to barbiturates and benzodiazepines, propofol has been shown to produce rewarding and reinforcing effects in animals. Sub-anesthetic and anesthetic doses of propofol have been shown to increase dopamine concentrations in the nucleus accumbens (brain reward system) in rats.

Propofol has a fast onset of action and crosses the blood-brain barrier very quickly. Its short duration of action is due to rapid distribution from the central nervous system to other tissues. Approximately 70% of the dose is excreted in the urine within 24 hours and 90% is excreted within 5 days of administration.

Propofol has a narrow window of safety. Induction of anesthesia with propofol is associated with cessation of breathing in some adults and children. Prolonged high dose infusions of propofol for sedation in adults and children have been associated with cessation of breathing, breakdown of heart muscle, and heart and kidney failure leading to death in some cases, referred as "Propofol Infusion Syndrome". Propofol abuse may also cause accumulation of fluid in the lungs, cardio-respiratory depression and death. There is no antagonist or reversal medication for propofol toxicity.

Illicit Uses:

Case reports and surveys published in scientific literature indicate that propofol is abused for recreational purpose, mostly by anesthetists, practitioners, nurses and other health care staff. Some fatalities occurred from propofol abuse. A survey of propofol abuse in academic anesthesia programs revealed that 18% (23 of 126) of anesthesiology departments in the United States experienced one or more individuals abusing propofol in the last 10 years (up to mid-2006) and two departments had more than one incidence of abuse. The incidence of propofol abuse among all anesthesia personnel was 0.10%. The mortality among anesthesiologists abusing propofol was 28% (7 deaths in 25). This survey also suggested that among anesthesiology staff, the incidence of propofol abuse increased compared to the previous survey reported in 2002.

Propofol is rarely encountered by law enforcement personnel or submitted to forensic laboratories for analysis. This may be, in part, due to its non-control status. According to the National Forensic Laboratory Information System and the System to Retrieve Information from Drug Evidence (STRIDE), there were 13 propofol reports from Federal, state, and local forensic laboratories from January 2010 to June 2012. Two of these were reported in the first six months of 2012.

User Population:

Propofol is mostly abused by health care staff including anesthetists, practitioners, nurses and technicians.

Control Status:

Propofol is not scheduled under the Controlled Substances Act.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section, Fax 202-353-1263, Telephone 202-307-7183, or Email ODE@usdoj.gov.

Colorado Revised Statutes Annotated
Title 18. Criminal Code
Article 18. Uniform Controlled Substances Act of 1992
Part 1
Definitions § 18
102. Definitions

...
(15) "Immediate precursor" means a substance which is a principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used, or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture....

Colorado Revised Statutes Annotated
Title 18. Criminal Code
Article 18.
Uniform Controlled Substances Act of 1992
Part 2. Standards and Schedules § 18

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204. Schedule II...

(2) Unless specifically excepted by Colorado or federal law or Colorado or federal regulation or more specifically included in another schedule, the following controlled substances are listed in schedule II:

(f) Any material, compound, mixture, or preparation containing any quantity of the following substances:

(l) Immediate precursor to amphetamine and methamphetamine: phenylacetone (Some trade or other names: phenylpropanone; P2P; benzyl methyl ketone; methyl benzyl ketone.), **ephedrine**, alpha phenylacetoacetonitrile, phenylacetic acid, and 1 phenylnitropropene;

...
Colorado
Revised Statutes Annotated
Title 18. Criminal Code
Article 18. Uniform Controlled Substances Act of 1992
Part 4.

Offenses and Penalties

§ 18

418. Exemptions

(1) The provisions of section 18

414 shall not apply to:

(2) All combination drugs that are exempted by regulation of the attorney general of the United States department of justice, pursuant to section 1006(b) of Public Law 91 513(84 Stat. 1236), known as the "Comprehensive Drug

Abuse Prevention and Control Act of 1970", on or after July 1, 1981, are exempted from the provisions of part 1 of article 42.5 of title 12, C.R.S., part 2 of article 80 of title 27, C.R.S., and part 3 of this article.

(Editorial note: part 3 contains C.R.S.A. § 18

308 (3)(a), which requires a prescription for dispensing all Schedule II Controlled Substances).