RI Senate- Health and Human Services

April 30, 2026

Re: Testimony in Opposition to Senate Bill 3184

Dear members of the Senate Health and Human Services Committee,

My name is Alexander Cohen, MD, and I live in East Greenwich, RI. I am an anesthesiologist at Brown University Health and the Brown University Department of Anesthesiology. I hold roles as Vice Chair and Medical Director of Perioperative and Periprocedural services at Rhode Island Hospital, and I am currently the President of the Rhode Island Society of Anesthesiologists (RISA).

I am writing to strongly oppose Senate Bill 3184. While I recognize that this year's bill includes revisions intended to address concerns raised during the 2025 session, the fundamental issues remain unresolved. Regardless of changes to specific language or drug lists, the core impact of this bill is reduced patient access and an unnecessary intrusion into clinical practice.

For decades, Rhode Island has successfully used a model in which appropriately trained non-anesthesiologists administer sedation within well-defined clinical protocols and escalation pathways. This approach has been safe and effective when supported by the robust oversight and infrastructure already in place across our state's healthcare system.

My continued opposition centers on three primary points:

1. Clinical regulation vs. legislation: Clinical practice evolves rapidly. Statutory law is not well suited to regulating medical care because it cannot keep pace with peer-reviewed evidence and changes in standards of care. Patient safety is best advanced through clinical guidance and institutional protocols that can be updated as evidence evolves.
2. Existing oversight and safety standards: The concerns raised by this bill are regulatory and are already addressed through existing federal and accreditation requirements. CMS Conditions of Participation and Joint Commission standards require health systems to create and evaluate sedation services and to monitor outcomes. Oversight belongs to the Rhode Island Department of Health, which has specialized expertise in implementing and enforcing these standards.
3. Decreased patient access: By imposing rigid statutory constraints on a model that has been safe for decades, Senate Bill 3184 would create avoidable barriers to care. It risks disrupting high-volume sedation services that allow patients to receive timely procedures close to home.

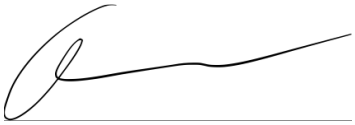
Attached to this written testimony are the following support documents:

1. Support Document #1: Propofol vs. fentanyl package inserts (images). Demonstrates that propofol has no FDA black box warning, while fentanyl does.
2. Support Document #2: Society for Pediatric Sedation (SPS) home page (image). Illustrates that many well-known institutions nationally use similar non-anesthesiologist sedation models.
3. Support Document #3: SPS publication on adverse events during pediatric sedation/anesthesia (abstract/image). Summarizes adverse event incidence and nature in non-operating-room settings.
4. Support Document #4: "Non-anesthesiologist administered propofol sedation for endoscopic procedures: A worldwide safety review" (2008) (abstract/image).
5. Support Document #5: CMS regulations and guidance on moderate sedation for procedural services (April 14, 2017) (excerpt/image).
6. Support Document #6: American Society for Gastrointestinal Endoscopy (ASGE) position statement on non-anesthesiologist administration of propofol for GI endoscopy (2009) (excerpt/images).

These attached materials demonstrate that Rhode Island's current regulatory framework aligns with widely accepted national standards and safe practice models. Senate Bill 3184would disrupt systems that already work and would decrease access for patients who rely on timely procedural care.

Thank you for your time and for considering the negative impact this bill will have on healthcare access in our state. I respectfully urge the committee to vote against Senate Bill 3184.

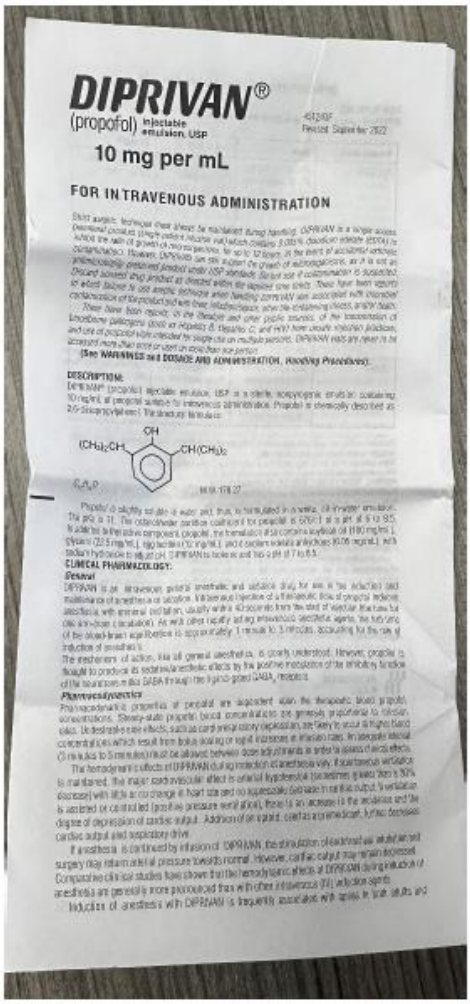
Sincerely,



Alexander Cohen, MD East Greenwich, RI Senate District 35

Support Documents (Attachments)

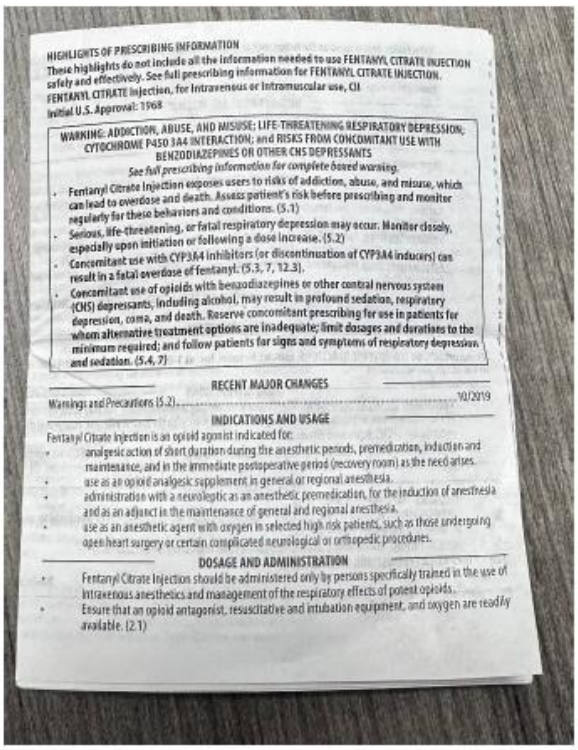
Support Document #1. Images of actual propofol package insert (opened 5/8/2024) showing no black box warning (left) and actual fentanyl package insert (opened 5/8/2024) showing a black box warning (right). A black box warning is the first item on a package insert and is literally surrounded by a “black box.”



DIPRIVAN®
(propofol) injectable emulsion, USP
Revised: September 2022
10 mg per mL
FOR INTRAVENOUS ADMINISTRATION

DESCRIPTION:

CLINICAL PHARMACOLOGY:



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FENTANYL CITRATE INJECTION safely and effectively. See full prescribing information for FENTANYL CITRATE INJECTION.
FENTANYL CITRATE injection, for Intravenous or Intramuscular use, CII
Initial U.S. Approval: 1968

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS
See full prescribing information for complete boxed warning.
- Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. (5.2)
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl. (5.3, 7, 12.3).
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.4, 7)

RECENT MAJOR CHANGES
Warnings and Precautions (5.2) 10/2019

INDICATIONS AND USAGE
Fentanyl Citrate Injection is an opioid agonist indicated for:
- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as an opioid analgesic supplement in general or regional anesthesia.
- administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

DOSAGE AND ADMINISTRATION
- Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids.
- Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available. (2.1)

Support Document #2. Society for Pediatric Sedation (SPS) home page with well-known member institutions.

Support Document #3. Society for Pediatric Sedation (SPS) publication on adverse events during pediatric sedation/anesthesia.

ABSTRACT

OBJECTIVE. We sought to use a large database of prospectively collected data on pediatric sedation and/or anesthesia for diagnostic and therapeutic procedures to delineate the nature and the frequency of adverse events that are associated with sedation/anesthesia care for procedures that are performed outside the operating room in children.

METHODS. Data were collected by the Pediatric Sedation Research Consortium, a collaborative group of 35 institutions that are dedicated to improving sedation/anesthesia care for children internationally. Members prospectively enrolled consecutive patients who were receiving sedation or anesthesia for procedures. Data on demographics, primary illness, coexisting illness, procedure performed, medications used, outcomes, airway interventions, and adverse events were collected and reported on a Web-based data collection tool.

RESULTS. A total of 26 institutions submitted data on 30 037 sedation/anesthesia encounters during the study period from July 1, 2004, to November 15, 2005. Serious adverse events were rare in the institutions involved in this study; there were no deaths. Cardiopulmonary resuscitation was required once. Less serious events were more common with O_2 desaturation below 90% for >30 seconds, occurring 157 times per 10 000 sedations. Stridor and laryngospasm both occurred in 4.3 per 10 000 sedations. Unexpected apnea, excessive secretions, and vomiting had frequencies of 24, 41.6, and 47.2 per 10 000 encounters, respectively.

CONCLUSIONS. Our data indicate that pediatric sedation/anesthesia for procedures outside the operating room is unlikely to yield serious adverse outcomes in a collection of institutions with highly motivated and organized sedation services. However, the safety of this practice depends on the systems' ability to manage less serious events.

www.pediatrics.org/cgi/doi/10.1542/peds.2006-0313

doi:10.1542/peds.2006-0313

Key Words
pediatric sedation, adverse events, complications

Abbreviations
AAP—American Academy of Pediatrics
PSRC—Pediatric Sedation Research Consortium
ASA—American Society of Anesthesiologists
NPO—nil per os
CPR—cardiopulmonary resuscitation

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Support Document #4. Abstract: "Non-anesthesiologist administered propofol sedation for endoscopic procedures: A worldwide safety review." Published 2008 (Gastrointestinal Endoscopy).

883

Non-anesthesiologist Administered Propofol Sedation for Endoscopic Procedures: A Worldwide Safety Review

Viju P. Deenadayalu, Emely F. Eid, John S. Goff, John A. Walker, Lawrence B. Cohen, Ludwig T. Heuss, Shajan Peter, Christoph Beglinger, James Sinnott, Patrick D. Gerstenberger, Anthony C. Clarke, Harold Munnings, Magdy Z. Rofail, Iyad M. Subei, Rodger A. Sleven, Akira Horiuchi, Kuldip Sandhu, Paul A. Jordan, Douglas K. Rex

Background: Propofol administration for endoscopic procedures by anesthesia specialists is costly. Non-anesthesiologist administered propofol sedation (NAP) is rapidly evolving but is controversial due to concerns about safety, mainly respiratory depression. Our goal was to determine the overall number of endotracheal intubations, neurologic injuries, and deaths and mask ventilations associated with NAP for endoscopic procedures. Methods: We reviewed all published abstracts and papers utilizing NAP for endoscopic procedures. To the best of our knowledge, we also contacted all gastroenterologists performing NAP for endoscopy to participate in our safety review. All contacted gastroenterologists submitted their updated data on safety. To perform our literature search, we queried Ovid Medline (1966-August 2007). The following complications were available in all patients: endotracheal intubations, neurologic injuries, and death. We also investigated whether mask ventilation was more frequent with EGDs versus colonoscopies, when available. Results: A total of 456,918 (213,527 published and 243,391 unpublished) NAP procedures were collected in our database. Endotracheal intubations, neurologic injuries, and deaths were 4, 1, and 3, respectively (data available for all patients). The deaths occurred in a patient with widely metastatic pancreatic cancer, a severely handicapped patient with mental retardation, and a patient with an extensive history of polysubstance abuse. In 2 of the 3 deaths, a decision to withdraw life support was made by the families of the patients. The overall number of cases requiring mask ventilation was 322 out of 400,769 cases with data available. Mask ventilation rates were compared between EGDs and colonoscopies for studies and sites specifying risk by procedure type. Fifty of 123,768 patients and 11 of 97,429 patients required mask ventilation during their EGD or colonoscopy, respectively ($p < 0.001$; chi-square test). In the remaining 261 patients requiring mask ventilation, the type of endoscopic procedure performed was unclear. Conclusions: The administration of propofol by non-anesthesiologists for endoscopic procedures is safe. Mask ventilation was required more frequently with EGDs compared to colonoscopies. NAP is one feasible solution to the high costs associated with anesthesiologist-delivered sedation for endoscopy.

Support Document #5. CMS regulation and guidance: descriptions of moderate sedation for procedural services (April 14, 2017).

J. Moderate Sedation Services Furnished in Conjunction with and in Support of Procedural Services

Anesthesia services range in complexity. The continuum of anesthesia services, from least intense to most intense in complexity is as follows: local or topical anesthesia, moderate (conscious) sedation, regional anesthesia and general anesthesia. Moderate sedation is a drug induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Moderate sedation does not include minimal sedation, deep sedation or monitored anesthesia care.

Support Document #6. Excerpts from the American Society for Gastrointestinal Endoscopy (ASGE) position statement: non-anesthesiologist administration of propofol for GI endoscopy. Published 2009 (Gastrointestinal Endoscopy).

Recommendations

1. The safety profile of NAAP is equivalent to that of standard sedation with respect to the risks of hypoxemia, hypotension, and bradycardia for upper endoscopy and colonoscopy (grade 1B).
2. The safety profile of NAAP when it is administered during ERCP and EUS appears to be equivalent to that of standard sedation. However, the worldwide experience with NAAP during these procedures is insufficient to draw definitive conclusions about its use in these settings (grade 1C).

Summary

1. The administration of propofol and standard sedation by nonanesthesiologists is comparable with respect to their efficacy and safety profiles. Proper training and patient selection are crucial for the safe practice of NAAP sedation.
2. Gastroenterologists and registered nurses in many countries have successfully acquired the skills necessary to safely administer propofol-based sedation. Both didactic and hands-on experience as well as airway training and a preceptorship are currently believed to be important elements of a training program.
3. Most studies show that NAAP sedation is superior to standard sedation regimens regarding time to sedation and time to recovery. Patient satisfaction with propofol sedation ranges from equivalent to slightly superior when compared to standard sedation.
4. The use of anesthesiologist-administered propofol for healthy individuals undergoing elective endoscopy without risk factors for sedation-related complications is very costly, with no demonstrated improvement in patient safety or procedural outcome.
5. Further comparative trials of NAPS and BPS are warranted.