

House Committee Health and Human Services
RI State House 82 Smith Street
Providence RI 02903

May 13, 2024

Re: Testimony in Opposition to House Bill 8237 entitled An act relating to the business and professions- nurse anesthetists

Dear Chairperson Donovan and members of the HHS Committee,

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

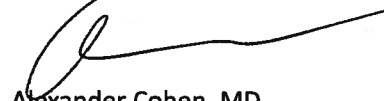
This written testimony will support my in-person testimony to the committee on May 14, 2024 to **vehemently oppose House Bill 8237**. Attached to this written testimony are the following items:

1. Package inserts from Propofol (no FDA black box warning) and Fentanyl (with FDA black box warning)
2. The cover page from the Society for Pediatric Sedation website showing the many esteemed institutions who provide sedation using the same model used at RIH.
3. Abstract from article: Incidence and Nature of Adverse Events During Pediatric Sedation/Anesthesia for Procedures Outside the Operating Room: Report From the Pediatric Sedation Research Consortium
4. Abstract from Article: Non Anesthesiologist Administered Propofol Sedation for Endoscopic Procedures: A Worldwide Safety Review. Published 2008. Gastrointestinal Endoscopy.
5. CMS Regulations and Guidance- Brief description of Moderate Sedation as Distinct from other types of Anesthesia. Published April 14, 2017.
6. Portions from the American Society for Gastrointestinal Endoscopy Position Statement: nonanesthesiologist administration of propofol for GI Endoscopy. 2009. Gastrointestinal Endoscopy Journal.

The documents attached demonstrate a practice of having non-anesthesiologists safely administer propofol in multiple settings (both adult and pediatric) and a regulatory framework that is consistent with practices across the state of Rhode Island.

Thank you for your time reviewing this testimony against House Bill 8237.

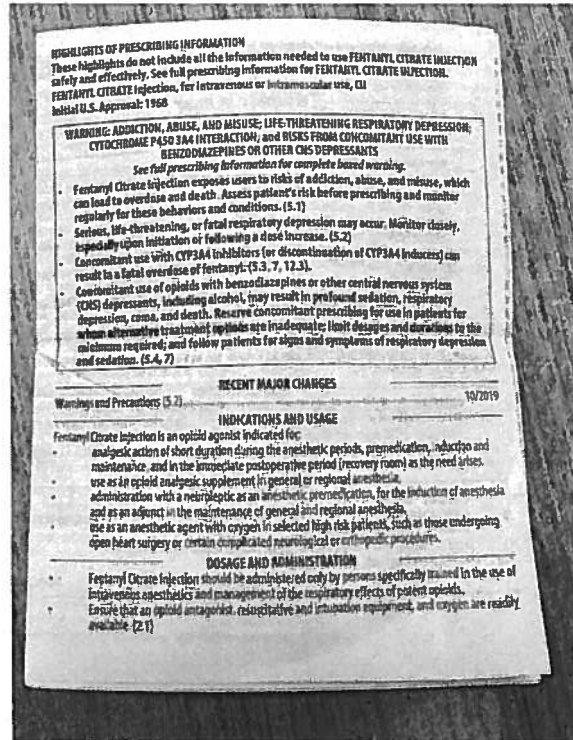
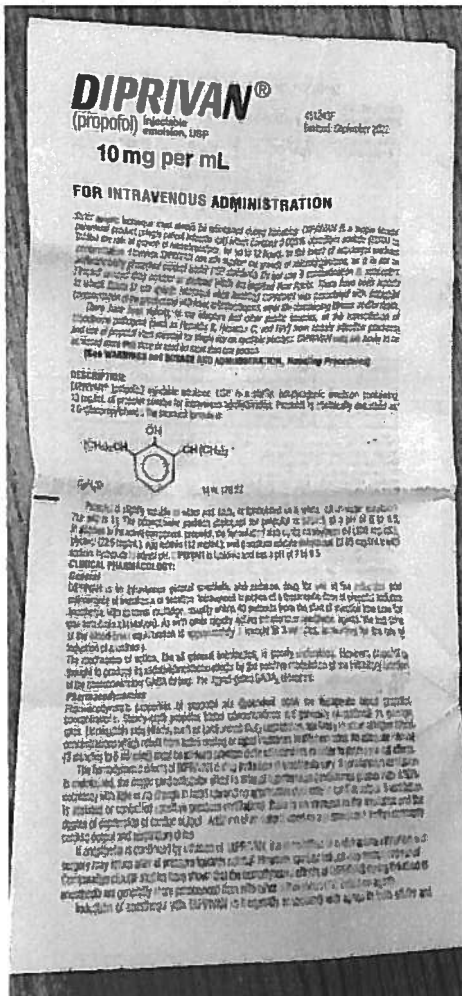
Sincerely,



Alexander Cohen, MD
East Greenwich, RI
House District 30

Support Documents

#1- Image of actual Propofol package insert (opened 5/8/2024) showing no black box warning (left). Image of actual Fentanyl package insert (opened 5/8/2024) showing a black box warning (right). The black box warning is the first item on any package insert and is literally surrounded by a "black box".



#2- Society for Pediatric Sedation Home Page with well-known members.

The image shows a screenshot of the Society for Pediatric Sedation (SPS) website. At the top is a blue navigation bar with the SPS logo and the text "Society for Pediatric Sedation Safe and Sound". To the right of the logo are menu items: "About SPS", "Annual Conference", "Education", "Research", "Quality & Safety", "Membership", and "Resources".

Below the navigation bar is a section titled "Our Mission" with four columns: "EDUCATION", "QUALITY & SAFETY", "GET INVOLVED", and "RESEARCH". Each column contains a representative image: a medical procedure, a diagram with "PATIENT SAFETY" in the center, a group of people holding hands, and a laboratory setting.

At the bottom of the page is a white banner with a blue wave graphic above it. On the left, it features the SPS logo and a star icon with the text "Society for Pediatric Sedation Center of Excellence in Pediatric Sedation 2024-2028". To the right of this are logos for several member hospitals: "LWHealthKids", "Children's" (with a profile icon), "Children's Hospital LOS ANGELES", "Children's Hospital of Philadelphia", "Cincinnati Children's", "Connecticut Children's", "dell children's Ascension", "St. Jude Children's Research Hospital", "UPMC CHILDREN'S HOSPITAL OF PITTSBURGH", and "Yale New Haven Health Yale New Haven Children's Hospital".

#3- Society for Pediatric Sedation Adverse event publication.

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 O₂ 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.

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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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#4- Abstract Non Anesthesiologist Administered Propofol Sedation for Endoscopic Procedures: A Worldwide Safety Review. Published 2008. Gastrointestinal Endoscopy.

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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, Rodrigo A. Steven, 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.

#5- CMS Regulation and Guidance, descriptions of Moderate Sedation for Procedural Services

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.

#6- Portions from the American Society for Gastrointestinal Endoscopy Position Statement: Nonanesthesiologist administration of propofol for GI Endoscopy. 2009. Gastrointestinal Endoscopy Journal.

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.