Comments on Dental Board of California Report to California State Legislature Regarding Findings Relevant to inform Dental Anesthesia and Sedation Standards, December 2021.

As a co-author of the 2016 DBC Pediatric Anesthesia Study<sup>1</sup> I reviewed this report with great interest. The Pediatric Anesthesia study evaluated outcomes for the 6 year period from January 1, 2010- December 31, 2015. The Pediatric Study was limited to patients aged 21 and under. This study reported a similar distribution of adverse outcomes, including hospitalization and death, as the one included in this report.

The current report included outcomes from the 4 ½ year period from Jan 1, 2017- June 30, 2021. If both reports are combined this represents data for over 10 years of data for patients aged 21 or under, from 2010-2021 including several years when no pediatric deaths occurred.

## • Summary of findings of 2016 DBC Pediatric Anesthesia Study

Between Jan 2010 and December 31, 2015, Board received notice of nine pediatric deaths between ages 0-21. In 2/9 cases board investigators found violations of the Practice Act.

- Three deaths occurred in hospital (all high risk patients) Ages 4,11,17
- One patient received office general anesthesia Age 6 in this case there was a violation of the Practice Act.
- One patient received moderate (conscious) sedation Age 3, office setting in this case there was a violation of the Practice Act.
- One patient received oral conscious sedation -Age 3, office setting
- Three cases involved local anesthesia only or local plus nitrous oxide/oxygen (surgery center, hospital, office) Ages 3, 9, 19

The current report included 3 pediatric deaths, but no violations of the dental practice act were found. The limited number of cases reported in both studies makes it difficult to reach any firm conclusions about the possible causes of adverse outcomes, however the number of pediatric hospitalization and deaths does not appear to be increasing in California.

<sup>&</sup>lt;sup>1</sup> Dental Board of California. (2016). *PEDIATRIC ANESTHESIA STUDY*. *95815*(December). https://www.dbc.ca.gov/applicants/pediatric\_anesthesia\_study.shtml

Although the current report provides important statistics related to outcomes in both pediatric and adult cases both studies are limited by the absence of information related to the total number of cases performed, therefore it is not possible to calculate the incidence and prevalance of adverse outcomes related to dental sedation and anesthesia.

The report provides statistics related to both hospitalizations and deaths by provider type, however these statistics need to be understood within the context of the number of general anesthesia/deep sedation, moderate sedation, and oral conscious sedation providers. According to DBC licensing and permit statistics as of 2020-2021<sup>2</sup> there were:

DS/GA permits - 918 (63%)

Moderate (conscious) sedation permits - 543 (37%)

Oral conscious sedation permits, (adult and minor) - 2391

Because sedation and anesthesia carry inherent risk a larger numbers of permit holders performing a greater number of cases would result in a greater percentage of adverse outcomes, including deaths and hospitalizations. Without knowing the actual number of cases performed by each permit class this cannot be reliably determined.

The number of adverse outcomes from oral sedation is low compared to other sedation modalities, despite the very large number of OCS permit holders. However there are a number of reports of adverse outcomes, including death, from pediatric oral sedation in children under age 7, which indicate the safety of oral conscious sedation for young children merits separate consideration.<sup>3</sup>,<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> Dental Board Meeting Materials, August 19-20, pages 184-185; https://www.dbc.ca.gov/about\_us/meetings/materials/20210819\_20\_brd.pdf

<sup>&</sup>lt;sup>3</sup> Lee, H. H., Milgrom, P., Starks, H., & Burke, W. (2013). Trends in death associated with pediatric dental sedation and general anesthesia. *Paediatr Anaesth*, 23(8), 741–746. https://doi.org/10.1111/pan.12210

<sup>&</sup>lt;sup>4</sup> Chicka, M. C., Dembo, J. B., Mathu-Muju, K. R., Nash, D. A., & Bush, H. M. (2012). Adverse events during pediatric dental anesthesia and sedation: a review of closed malpractice insurance claims. *Pediatr Dent*, 34(3), 231–238.

## • Effects of Co-existing disease

This report reveals a correlation between co-existing disease and adverse outcomes from dental sedation and anesthesia which would be expected based the scientific literature. However, the current study does not reveal whether a certain permit class treats a greater number of patients with co-existing disease, which would change the risk profile for that group of providers.

## • Personnel Requirements

With respect to the current California requirements for personnel there are some important differences between the 2016 ADA Guidelines for the Use of Sedation and Anesthesia by Dentists and California personnel requirements that might benefit from changes. Although SB 501 specified that there must be at least 3 persons present during pediatric sedation and anesthesia, this bill left the personnel requirements for adult sedation and anesthesia unchanged. There is currently no specific personnel requirement during sedation or anesthesia for adults, other than dental assistants must complete provider training in BLS. In contrast the 2016 ADA Guidelines specify that for moderate sedation there should be at least one individual in in provider BLS in addition to the dentist for adult patients, and that for deep sedation/general anesthesia there should be at least three persons present, including the dentist plus two individuals trained in provider BLS.

Although the ASA Moderate Sedation Guidelines included in this report indicate that the literature is insufficient to determine whether or not an individual dedicated to patient monitoring will reduce adverse outcomes,<sup>5</sup> as of 2016 thirty-three states specified that there be at least two persons present, in addition to the dentist, when general

<sup>&</sup>lt;sup>5</sup> Apfelbaum, J. L., Gross, J. B., Connis, R. T., Agarkar, M., Arnold, D. E., Coté, C. J., Dutton, R., Madias, C., Nickinovich, D. G., Schwartz, P. J., Tom, J. W., Towbin, R., & Tung, A. (2018). Practice guidelines for moderate procedural sedation and analgesia 2018. In *Anesthesiology* (Vol. 128, Issue 3). https://doi.org/10.1097/ALN.00000000002043

anesthesia is administered, and thirty one states specify that at least one person be present in addition to the dentist when moderate sedation is administered.<sup>6</sup>

In addition, twenty-nine states require the presence of a designated anesthesia monitor during sedation and anesthesia. Fourteen states specify training requirements for the sedation monitor, usually completion of an educational program offered by a professional association such as the AAOMS or ADSA.

The absence of an increase in pediatric hospitalizations and deaths over the past 10 years is encouraging. It is noteworthy that this trend was established prior to the implementation of SB 501 which includes strict new requirements directed at improving the safety of pediatric dental sedation and anesthesia. Future reports may indicate whether the implementation of SB 501 leads to further improvement in outcomes.

In the interim outcomes for patients age 46-66+ are of concern. Adverse outcomes in this age group have been reported in other states<sup>7</sup> and may be partially explained by the presence of co-existing disease, but the underlying reasons deserve additional study. Improvements in pre-operative medical evaluation and risk assessment might lead to better outcomes for high risk patients. The report on dental anesthesia by the Texan Board of Dental Examiners indicated that the length of the procedure was thought to be a risk factor. With increasing numbers of patients in this age group undergoing extensive implant rehabilitation procedures this factor merits further study.

Thank you for the opportunity to comment on this important report, and I hope you find my comments helpful.

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<sup>&</sup>lt;sup>6</sup> Dental Board of California. (2016). *PEDIATRIC ANESTHESIA STUDY*. *95815*(December). <u>https://www.dbc.ca.gov/applicants/pediatric\_anesthesia\_study.shtml</u>, page 26.

<sup>&</sup>lt;sup>7</sup> Examiners, Texas State Board of Dental Examiners: Advisory Committee on Dental Anesthesia June 2019 Report and Recommendations. *Texas State Board of Dental Examiners*. http://tsbde.texas.gov/78i8ljhbj/2019-ACDA-Report-Final.pdf