Fact Check Finds Serious Flaws in ADA Report Concerning Sedation Dentistry

The American Dental Association and its Council on Dental Education and Licensure issued a report – "*Frequently Asked Questions – Resolution 37*" – designed to inform ADA members and delegates of the facts pertaining to Resolution 37, a proposed revision to the ADA's Sedation and Anesthesia Guidelines.

What follows is a summary of CDEL's FAQ and a Fact Check prepared by a group of scientists, academics, and dentists – all ADA members – who are independent of CDEL.

Q.1. What was the Council's response to the directives of the 2015 House of Delegates?

CDEL's CLAIMS:

- The Council relied on a detailed report, titled "*Report on the Risks and Benefits of Using Capnography in Dental Patients Undergoing Moderate Sedation*," prepared at its request by the ADA's Council on Scientific Affairs (CSA).

- The Council "also considered comments received…"

THE FACTS:

The 2015 ADA House of Delegates adopted Resolution 77H, which called on CDEL to work "in collaboration" with CSA to consider three issues embodied in what is now called Resolution 37.

1. Allowing dentists to have a choice of options when it comes to monitoring end tidal CO_2 for moderate sedation, "such as: continuous use of a precordial or pretracheal stethoscope, continuous monitoring of end tidal carbon dioxide, and continual verbal communication with the patient."
2. The recommended hours and content of moderate sedation courses, including a "possible option of separate course requirements for enteral and parenteral routes of sedation."
3. The rationale and guidelines for the use of Body Mass Index in conducting patient evaluations, and the timing of medical history review.

CONCLUSION: **There is substantial evidence that CDEL and CSA did not fulfill the 2015 House of Delegates mandate**

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EVIDENCE:

- In its FAQ, CDEL presents summarized evidence from CSA's "*Report on the Risks and Benefits of Using Capnography in Dental Patients Undergoing Moderate Sedation*."

  CDEL's presentation includes what it describes as the key summary statement: "the evidence demonstrates that capnography in conjunction with standard monitoring improved sensitivity of detecting adverse respiratory events and reduces the risk of hypoxemia during moderate sedation compared with standard monitoring alone."

  CDEL <u>does not respond</u> to the 2015 HOD resolution calling for CDEL to weigh options for dentists other than capnography, such as a precordial or pretracheal stethoscope, which may be equally as safe and effective as capnography, and preferred by many dentists for their ease of operation and cost savings.

- Even the title of the CSA report, "Risks and Benefits of Using Capnography…" makes it abundantly clear that the risks and benefits of suggested alternatives to capnography were not reported and, perhaps, not considered as mandated by the 2015 HOD.

- While the 2015 HOD mandated that CDEL consult with CSA on the question of how many hours of training for moderate sedation should be required, and what the content of such training should consist of, neither CDEL nor CSA indicate that any such collaboration took place. Likewise, CSA's own reports to the ADA of its activities includes no mention that it was consulted and provided an opinion as to the possible option of separate course requirements for enteral and parenteral routes of sedation.

- Discussing Resolution 37's provisions for consistent patient evaluation provisions and the rationale and guidelines for the use of Body Mass Index, CDEL's makes zero mention of consulting with CSA on the matter. Indeed, CDEL cites only itself, its beliefs, and its internal discussions – ignoring the 2015 HOD mandate that it collaborate with CSA. Once again, in CSA's own reports to the ADA of its activities provides no mention that it was consulted and provided an opinion on this issue.

- As part of the public comments submitted to the ADA pertaining to Resolution 37, Pamela Porembski D.D.S., who is the director of the ADA's Council on Dental Practice in the Practice Institute submitted comments

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on behalf of a member of the Council on Dental Practice on July 7, 2016:

"In my opinion, and the opinion of other delegates, this adopted resolution [HOD Resolution 77H – 2015] calls for evidence that CSA has studied the available science, literature and documentation of all three bullet points and has made appropriate and scientific deliberation to CDEL for their deliberation…

"Given the available evidence, the three documents submitted to us from CDEL, one can only conclude that CDEL has not fulfilled its mandate as set forth by the 2015 House of Delegates."

- **In its own FAQ, CDEL acknowledges in response to Question #8: "… not one controlled clinical study has ever been performed to demonstrate the optimal training time for dentists who provide moderate sedation."**

- The ADA's published policy on Evidence-Based Dentistry (EBD) is unambiguous:

  Evidence-based dentistry is an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences.

  ADA Resolution 37 lacks both evidence-based science to support its proposed revisions, as well as the clinical expertise of dentists. The vast majority of dentists on both ADA Councils, CDEL and CSA, do not use moderate sedation to treat their patients and thus have little if any direct experience with the method.

Q.2. Why does the proposed guideline not outline training by route of administration?

CDEL's CLAIMS:

- The Council carefully studied this matter and maintains that "moderately sedated patients via either route require the same attentiveness and monitoring; there should be no difference in the training requirements related to routes of administration."

- A review of CE courses was conducted: at least 11 providers currently meet or exceed 60 hours of instruction and 20 patient experiences.

THE FACTS:

- The ADA has pledged to set its practice and educational guidelines based on evidence and science.

  "The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research," the ADA states in its published policy statement.

  Careful study of the matter – which CDEL asserts as its justification for concluding that "there should be no difference in the training requirements related to routes of administration" – falls far short of constituting evidence-based substantiation. (Note that the vast majority of CDEL members do not provide moderate enteral sedation to their patients.)

  Dental researchers and scientists who have published on the topic of "route of sedation" have consistently concluded the exact opposite of CDEL's contention: There are scientifically demonstrated crucial differences in the response of patients, and thus the safety precautions and necessary training, when dentists use enteral versus parenteral routes of sedation.

  See: http://GetTheScience.com to review just some of the published, peer-reviewed articles on this topic.

  CDEL does not provide citations and references to published, peer-reviewed studies that support its contention and conclusions.

- Resolution 37 effectively blurs the lines between minimal sedation as currently defined, and moderate sedation. As a result, even dentists who confine their practices to providing minimal sedation may be required – in order to fully comply with the guidelines proposed in Resolution 37 – to undergo 60 hours of IV sedation training.

- We do not know what method CDEL used to assert that "at least 11 providers currently meet or exceed 60 hours of instruction and 20 patient experiences." [Three of the 11 CE course providers listed by CDEL do not list IV sedation courses: University of Alabama at Birmingham, Augusta University, and DOCS Education.]

  CDEL's assertion seems illogical on its face since current ADA guidelines pertaining to training for moderate enteral sedation call for only 24 didactic

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hours and 3 patient experiences (along with ten clinical experiences, of which seven can be videos.)

CDEL seems to be referring to existing educational programs aimed exclusively at licensing requirements for dentists who will primarily provide parenteral sedation. There are fewer than 150 seats per year available nationwide to dentists who seek to acquire such parenteral sedation training.

There are no known courses offered by any credible educational institution, for-profit or nonprofit, that provide 60 hours of didactic training and 20 live cases to those dentists wishing only to be certified to provide moderate enteral sedation.

Should Resolution 37 be approved by the 2016 ADA HOD, **the 8 (verified) parenteral CE courses that CDEL cites – based on current enrollment capacity – would require approximately 200 years to certify the more than 30,000 dentists who currently administer enteral moderate sedation, and their successors.**

[For More, See Question #7 and the related FACT CHECK.]

CONCLUSION: **The recommendations of CDEL do not comport with the ADA's Policy on Evidence-Based Dentistry, lacking peer-reviewed, science-backed substantiation, or clear clinical evidence.**

Should CDEL's recommendations be adopted by the ADA 2016 HOD, there will not be nearly enough courses to meet the demand of dentists who will need to be certified as competent to administer moderate enteral sedation.

Q.3. Why is the concomitant administration of two different oral medications considered moderate sedation?

CDEL's CLAIMS:

- The Council states that potentiation creates a net effect that is greater than the MRD of each drug alone. It cites the 2012 *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*, which state that giving enteral drugs above the MRD is considered moderate sedation. "Therefore, exceeding the MRD is already considered to be moderate sedation."

  CDEL says it could find only three published papers related to potentiation and

oral sedation: from 1986, 2007, and 2009. Two of the three paper's offer indirect support for its position.

THE FACTS:

- CDEL again fails to adhere to the ADA's own policy on evidence-based dentistry, which clearly states that in the absence of sufficient "clinically relevant scientific evidence," it must rely on "the dentist's clinical experience and the patient's treatment needs and preferences."

  The 1986, 2007, and 2009 studies are insufficient to justify the proposed changes embodied in Resolution 37, which CDEL tacitly acknowledges.

  Yet CDEL entirely ignores the extensive clinical evidence that speaks to the demonstrated safety and efficacy of using potentiation in compliance with <u>existing</u> ADA guidelines, meeting the needs and preferences of literally millions of dental patients.

  Should Resolution 37 be approved by the 2016 HOD, the impact on routine dental procedures would be unquantifiable. Before a dentist could administer a patient two drugs of any type and potency, the dentist would have to receive the equivalent of an IV sedation permit: i.e. a minimum of 60 hours of instruction and at least 20 individually-managed patients.

  CONCLUSION: **Adopting Resolution 37 and its restrictions on the administration of two different oral medications without extensive additional training, violates the ADA's policy to act in accordance with the "patient's treatment needs and preferences." The scientific justification for making it much harder for dentists to use potentiation – currently a widespread practice – is skimpy at best.**

Q.4. How do the 2016 proposed Guidelines differ from the version considered by the 2015 ADA House of Delegates?

CDEL's CLAIMS:

- The Council states that 2015's Resolution 77 and 2016's Resolution 36 are virtually identical. The main exception is that the 2016 proposed revisions eliminate references to sedation and anesthesia for children.

  CDEL and the ADA defer exclusively to the guidelines set by the American

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Academy of Pediatrics and the American Academy of Pediatric Dentistry (AAPD).

THE FACTS:

- CDEL fails to offer an explanation for this change. CDEL's abdication of responsibility for providing its own pediatric guidelines raises important unaddressed questions:

  1. The AAPD's guidelines give dentists the option of monitoring sedation patients using capnography or prechordial auscultation. Why then, does CDEL insist on more stringent monitoring regulations for adults (capnography) than it does for children, who are generally at greater risk? If CDEL is serious about protecting public safety, shouldn't that apply to all members of the public, regardless of their age?

  2. Many general practitioners provide pediatric sedation, yet are not members of AAPD and have not completed a Pediatric residency. CDEL and Resolution 37 leave ADA general dental members without pediatric sedation guidance. Why?

  3. The CDEL proposal muddies the water when it comes to the definition of "children." What age is a child for the purposes of dental treatments? The ADA previously defined a child as 13 years or younger. It has rescinded that definition.

     CDEL and the ADA now punt the question of age to the AAPD, which in turn, bases its definition on the American Association of Pediatrics' (AAP) definition. AAP defines a child as anyone under 21 years of age.

     As such, is a 20-year-old patient a "child," and if so, must general dentists now obtain PALS certification in addition to ACLS for moderate sedation? CDEL is mum on these questions.

CONCLUSION: **Like the explanation for virtually every component of Resolution 37, political posturing – *not science* – appears to be the sole motivation for CDEL's decision to allow the AAPD to set all guidelines for pediatric sedation.**

CDEL does not even feign a science, evidence-based, or clinical rationale for allowing dentists flexibility when it comes to their choice of methods for monitoring sedated children (capnography or prechordial auscultation), but not adults.

Q.5. In what ways were the dental anesthesiology communities notified that the Guidelines were under revision? Was there an opportunity to comment on the proposal?

CDEL's CLAIMS:

- The Council notes that it held a teleconference offering in-person and phoned opportunities to testify on April 21, 2016. It also provided two written comment periods. The teleconference and comment opportunities were promoted via multiple channels, including direct email notification.

  CDEL lists 18 dental anesthesiology communities of interest as those that were contacted and invited to participate.

  A total of 33 written and oral comments were received and "systematically reviewed by the Council."

THE FACTS:

- CDEL offers no explanation for why the only communities of interest that it contacted were "anesthesiology communities." Certainly, those communities needed to be included.

  Yet the community that will be most greatly impacted if Resolution 37 is approved, namely patients, was not notified of the hearing or comment periods, and was not invited to share its views.

  As the ADA's "*Policy on Evidence-Based Dentistry*" makes clear, the treatment needs and preferences of patients must be considered when establishing practice guidelines.

  For the second consecutive year, CDEL undertook no study to determine the impact Resolution 37 would have on patients, patient satisfaction, and access to care. [For More, See Question #12 and the related FACT CHECK.]

  The ADA's mission is to be patient-centered, working for the "improvement of oral health for the public." Yet the public was decidedly excluded from CDEL's deliberations.

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- CDEL provides no details about its systematic review and how it was conducted. Were all respondents treated equally or did the Council give more credence to some groups and less to others?

  Of the 18 groups invited, one in particular, Academy of General Dentists (AGD), represents the largest number of dentists who are likely to feel the impact of Resolution 37, should it be approved by the 2016 HOD.

  AGD members number more than 40,000, and after the ADA itself, AGD is the largest dental association in the United States.

  The AGD strongly opposes Resolution 37 and the additional burdens it would place on its members and patients. AGD testified to that and submitted detailed written comments to CDEL.

  AGD members regularly use moderate enteral sedation in the treatment of their patients, unlike most other members of CDEL's communities of interest.

  CDEL does not disclose how its "systematic" review of the testimony and written comments of the communities of interest weighed the AGD's comments and the vast clinical experience represented by AGD members versus, for example, the arguments of the American Association of Dental Boards, the American Society of Anesthesiologists, or State Boards of Dentistry – also considered by CDEL communities of interest. [For More, See Question #8 and the related FACT CHECK.]

  It should be noted that while most members of CDEL are also members of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which strongly supports Resolution 37, **AAOMS is not listed among the communities of interest that CDEL contacted**.

CONCLUSION: **Cosmetically, CDEL made an effort to solicit the comments and testimony of experts on the topic. But some of its "experts" were far less informed on the topic – and represented far less clinical experience with sedation dentistry – than others.**

Importantly, CDEL repeated its 2015 posture in totally excluding patients from its communities of interest and failing to make even a cosmetic attempt to study the practical and financial impact that Resolution 37, if approved, will have on patients and their access to care.

Q.6. Many dentists hold sedation permits issued by a state dental board. Are dentists' sedation permits in jeopardy if the proposed revised ADA Guidelines are adopted?

CDEL's CLAIMS:

- The Council maintains that the state legislatures and dental boards alone have the authority to establish permit/license requirements by which dentists with anesthesia permits or licenses must abide.

  "The state boards determine the requirements for dentists who administer sedation, not the ADA."

THE FACTS:

- **CDEL's answer is disingenuous at best and more likely, outright deception. In many states, the ADA guidelines are part of the regulatory language, so they automatically become governing law.** In other states, it is all but a foregone conclusion that the dental board will embrace the ADA guidelines and the legislature will vote them into law.

  The truthful answer is that if Resolution 37 is approved by the 2016 HOD, within a few years, thousands or tens of thousands of dentists nationwide will be required by law to obtain new, stricter, sedation permits or simply stop offering moderate enteral sedation to their patients.

  CONCLUSION: **While the ADA, technically, does not set state standards for those who administer sedation and anesthesia, its guidelines, as adopted by the HOD, do become law almost automatically in more than half of the states. Many thousands of dental permits will be in jeopardy if Resolution 37 is approved.**

Q.7. What CE opportunities are available to meet his new guideline?

CDEL's CLAIMS:

- The Council says it is "aware" of at least 11 CE courses with a hands-on component that "may" offer the course content and duration as proposed in Resolution 37.

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CDEL adds that it is "confident" that providers of CE on the subject of sedation and anesthesia will enrich their educational offerings to comply with the new guidelines, should Resolution 37 be approved by the 2016 HOD.

CDEL goes on to list the 11 course providers, including non-profit and for-profit educators.

THE FACTS:

- Given that Resolution 37, if approved will require the training or retraining of tens of thousands of dentists, CDEL's obvious lack of hard research to back its "confidence" that courses exist or will be created to meet the eruptive new demand is highly questionable.

  Nor does CDEL weigh in on the question here, or anywhere in its FAQ, of how much such courses will cost, how many days away from their practice dentists will need to take to fulfill the course requirements, what travel expenses will be necessary to attend the courses, and what dentists should do when they are unable to find available seats.

  [For More, See Question #12 and the related FACT CHECK.]

  As noted in the FACT CHECK for Question #2, the 8 verified CE courses that CDEL references (out of the 11 CDEL erroneously listed) refer to existing educational programs aimed exclusively at licensing requirements for dentists who will primarily provide parenteral sedation. There are fewer than 150 seats per year available nationwide to dentists who seek to acquire such parenteral sedation training. Moreover, **the courses are NOT designed to prepare dentists to provide enteral sedation.**

  There are no known courses offered by any credible educational institution, for-profit or nonprofit, that provide 60 hours of didactic training and 20 live cases to those dentists wishing only to be certified to provide moderate enteral sedation.

  CDEL made no effort to explain what, specifically, course providers should teach during the 36 hours of additional didactic training that Resolution 37 would require.

  (Neither the additional training necessary to operate capnography equipment, nor the additional focus on rescuing patients from a level of sedation deeper than intended, requires 36 hours on top of the 24 hours currently required by

existing ADA guidelines, veteran dental educators point out.

For more information, see the transcript of the National Dental Town Hall held on October 10, 2016, featuring a panel of four dental luminaries. The transcript is available at: http://tinyurl.com/Dionne-Transcript.)

CONCLUSION: **There are not and will not be sufficient courses (for decades to come) to meet the needs of the dental profession, should Resolution 37 and its stricter sedation permit requirements be approved.**

CDEL's "confidence" is not based on a thorough investigation of the capabilities of CE providers.

Q.8. I provided comment to CDEL; why was my advice overlooked?

CDEL's CLAIMS:

- The Council answers that while it "did not agree with all points made," all input was systematically reviewed and considered.

  In response to the feedback it received, the Council acknowledges that "the majority of evidence" it relied on came in the form of expert opinion.

  It further explains that "not one controlled clinical study has ever been performed to demonstrate the optimal training time for dentists who provide moderate sedation," adding that such a study "may be nearly impossible to fund or conduct or to be cleared by an institutional review board."

  CDEL points to its own council members' "expertise in contemporary educational principles," adding, "We rely on our Anesthesiology Committee experts…to evaluate anesthesiology information and provide CDEL with the best recommendations."

THE FACTS:

While there are not randomized controlled trials or published, peer-reviewed studies that bear on every single aspect of ADA Resolution 37, there are – *contrary to CDEL's assertion* – numerous scientific and evidence-based journal articles detailing research that contradicts CDEL's position.

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See: http://GetTheScience.com to review just some of the published, peer-reviewed articles on this topic. Also, note the citations of other related research at the bottom of each article posted at GetTheScience.com.

CDEL fails to provide citations or references to published, peer-reviewed studies that support the major assertions contained in Resolution 37.

- CDEL offers no explanation for how – in the admitted absence of even one controlled clinical study – it settled on Resolution 37's 250% increase in the required number of didactic hours that will govern dentists wishing to provide moderate enteral sedation, should the 2016 HOD approve the new guidelines. [Resolution 37 also increases the number of cases required to be certified for moderate enteral sedation by 100% and live cases by 667%.]

- **CDEL presents zero evidence substantiating that the current ADA guidelines, adopted by the 2007 and 2012 HOD, are inadequate to provide for patient safety.**

- CDEL indicates that it favored the expert opinions of its own members and members of CDEL's Anesthesiology Committee over those of other experts and organizations that submitted testimony and written comments opposed to Resolution 37.

  Doing so, once again, flies in the face of the ADA's "Policy on Evidence-Based Dentistry," which does not place the expertise of ADA members who are appointed to various ADA Councils and Committees ahead of science, peer-reviewed research, the clinical experience of dentists, or the treatment needs and preferences of patients.

  Service on ADA Councils and Committees is vital to the organization but does not confer superior knowledge or expertise on Council and Committee members.

  - Among those whose expert views and clinical experience CDEL considered but felt sufficiently competent to ignore in part or in full are:

    - **Academy of General Dentistry** representing more than 40,000 dentists, including the largest number of dentists of any dental group (other than the ADA, itself) that already use moderate enteral sedation in their practices.

    - **American Academy of Pediatric Dentistry** representing 9,900 members who serve as primary care and specialty providers for millions of children

from infancy through adolescence.

- **American Dental Society of Anesthesiology** representing 5,000 members who primarily engage in the practice of anesthesiology in dentistry, either local or general.

- **American Society of Dentist Anesthesiologists** representing approximately 4,500 dentists who have completed a minimum of two years of full-time postdoctoral training in dental anesthesiology.

- **DOCS Education**, which has trained more than 20,000 dentists in sedation dentistry techniques that comply with existing ADA guidelines and state regulations. More than 20 million Americans have received care from DOCS Education-trained dentists, who conform to the current ADA Guidelines, without incident.

- **Rickland G. Asai, DMD, 11th District ADA Trustee** representing Alaska, Idaho, Montana, Oregon, and Washington. Dr. Asai, an advocate for access to affordable dental care, is one of eight ADA Trustees who in August 2016 voted against allowing Resolution 37 to come before the 2016 HOD.

- **The California Dental Association** represented by Gayle Mathe, CDA Public Affairs.

- **Idaho State Dental Association** represented by Susan Miller, executive director, and John E. Hisel Jr., DDS.

- **Texas Academy of General Dentistry** represented by Brooke Elmore, DDS, FAGD, TAGD Advocacy Council Chair.

- **Dr. Mark Walker**, chair of an eight-member task force organized by Dr. Linda Williams and composed of representatives from each of the five states in ADA District XI. Dr. Williams, Caucus Chair, ADA District XI, submitted separate written comments to CDEL.

- **Raymond Dionne, DDS, PhD**, a leading pain scientist and dental educator who has published more than 100 scientific manuscripts related to his work on pain and pain control. His career includes more than 20 years of private practice experience and more than 30 years of clinical research. He was an investigator in the National Institute of Dental and Craniofacial Research for 25 years, where he also served as Chief of the Pain and Neurosensory Mechanisms Branch and Clinical Director.

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- **Fred Quarnstrom, DDS, FASDA, FAGD, FICD, FACD, CDC**, who has taught 253 nitrous oxide sedation courses and 117 oral conscious sedation courses with or without nitrous oxide sedation. Dr. Quarnstrom has published more than 50 papers on sedation and written chapters in three books on fear and pain control.

- **Anthony Carroccia, DDS, MAGD, ABGD**, a general dentist who possesses a Comprehensive Conscious Sedation Permit in Tennessee and serves on the TDA Committee for Anesthesia, Sedation and Scope of Practice. Dr. Carroccia teaches nitrous oxide-oxygen monitoring courses to assistants and administration to hygienists. In 2009, Dr. Carroccia was named the National Sedation Safety Dentist of the Year.

- **Martin Elson, DDS, Immediate Past President of the Rhode Island Oral and Maxillofacial Surgeons** and Christy D. Durant, Esq., Legal Counsel for the Rhode Island Oral and Maxillofacial Surgeons.

- **Rocky L. Napier, DMD, FACD, FICD, FPFA**, a member of the American Academy of Pediatric Dentistry and American Academy of Pediatrics, and President-Elect of the South Carolina Dental Association. Dr. Napier provided more than $640,000 of free and uncompensated care in 2015 alone.

CONCLUSION: **CDEL's reliance on its own members, members appointed to its Anesthesiology Committee, and hand-selected outside experts raises important questions of bias. Why did CDEL give the recommendations of certain individuals and groups legitimacy to the total or partial exclusion of other clearly qualified experts and organizations, such as those listed above?**

CDEL offers no specifics whatsoever about what its "systematic" evidentiary review process consisted of, nor does it provide a detailed list of published citations to support is conclusions and recommendations.

The lack of transparency in CDEL's process – especially after inviting public comment and testimony – undermines the Council's credibility, and calls into serious question the scientific, evidence-based validity of Resolution 37.

Q.9. Why is the new definition of operating dentist proposed?

CDEL's CLAIMS:

- The Council says that changing the definition to "operating dentist" from "qualified dentist" – as proposed in Resolution 37 – is intended to bring clarity in the face of some state legislatures and regulators who have set specific definitions pertaining to the clinical operative dentist who works with an anesthesia provider.

  CONCLUSION: **This is a change that appears benign and unlikely to impact ADA members or their patients. If the redefinition was proposed separately from the other provisions of Resolution 37, it is unlikely the new terminology would face meaningful opposition.**

Q.10. How many states currently require dentists to monitor expired CO_2 via capnography during moderate sedation?

CDEL's CLAIMS:

- The Council notes that at least 15 states "mention" capnography in their laws or in dental board policy for moderate sedation, "either as a requirement, a monitoring option, or as a proposed regulation."

THE FACTS:

- CDEL could have, but chose not to, describe along with each of the 15 states it cites whether the mentions are specifically about monitoring as a requirement, option, or proposal.

  It makes a difference, especially in clarifying an issue as contentious as Resolution 37.

  Given CDEL's open advocacy for Resolution 37, it is safe to assume that if a majority of the 15 states noted by CDEL currently *require* capnography, CDEL would have said as much.

  CONCLUSION: **Thirty-five states do <u>NOT</u> currently even *mention* capnography as a monitoring option. Moreover, CDEL fails to inform ADA members which state**

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or states absolutely require it.

CDEL's lack of full disclosure on this matter smacks more of a panel of biased advocates than an impartial council of experts trying to present unbiased facts to the 2016 HOA and other ADA members so that they can make an informed decision.

Q.11. What is the approximate cost of a capnography?
Q. 12. Will these new guidelines increase the cost of dental care or decrease access to care for some patients?

CDEL's CLAIMS:

- The Council states, "in general, a capnograph can range in price from $800-$3,000." [*Question 11*]

  CDEL then cites its own estimate to conclude, "The equipment needed to monitor end-tidal CO2 should not appreciably increase the cost of delivering moderate sedation or decrease its availability to patients." [*Question 12*]

  CDEL labels the $800-$3,000 equipment cost as "a reasonable investment to identify more respiratory complications and support risk management and patient safety."

- CDEL states unequivocally, "There is no evidence* demonstrating that the cost of care will increase, that patient access to sedation will decrease or that the number of sedation permits will decrease" should the 2016 HOD approve Resolution 37.

THE FACTS:

- CDEL deliberately ignores the salient fact that the cost of capnography equipment is the least onerous of the costs associated with Resolution 37.

  Should Resolution 37 be approved by the 2016 HOD, dentists who wish to provide their patients moderate enteral sedation will have to buy the capnography equipment; train themselves and their team on its correct usage; pay tuition to enroll in a 60-hour course to qualify them to provide moderate enteral sedation; be away from their practice for an extended time to

complete the course and its requirement to participate in 20 live training cases; and pay for travel, meals, and hotel should the course be offered in an 'away' venue.

CDEL also does not calculate the costs to dentists of being unable to provide moderate enteral sedation to patients if the dentists are unable to enroll in a course on a timely basis, either due to the dentists' own scheduling conflicts, or the lack of availability of sufficient CE providers.

- CDEL can only claim* that "there is no evidence demonstrating that the cost of care will increase" because it made no effort in 2015 or 2016 to conduct even a superficial economic impact study to determine the real costs of Resolution 37 to dentists, and how those costs will be passed along to patients.

  While the ADA's mission, since 1859, has been to be a "patient-centered" association, CDEL's assertion – *without one iota of supporting evidence* – that Resolution 37 will not impact the cost or availability of care dishonors that mission statement.

  One needn't be an economist to understand that when dentists are required to invest heavily in additional out-of-office education – such as required by Resolution 37, impacted dentists will need to find a way to recoup their expenses and lost production. Charging higher fees, with the concomitant burden that places on patients, is certain to reduce access to care.

  Given Resolution 37's requirements that increase the number of didactic hours required to provide moderate enteral sedation by 250%; the number of cases by 100%; and the number of live cases by 667%; it is only logical to believe – despite CDEL's unsupported contention – that many dentists will opt, instead, to simply stop obtaining sedation permits.

  * *In 2015 and again in 2016, TEAM 1500 issued a summary of its own economic impact study forecasting the effect on dentists and patients, should ADA Resolution 37 (originally called Resolution 77) be approved. The study was conducted between June and September 2015, drawing on data and calculations obtained from a cross-section of practicing oral health care professionals, dental school academics, regulatory experts, and financial forecasters.*

  The study was headed by Dean Rotbart, a Pulitzer Prize-nominated financial journalist and former investigative reporter at The Wall Street Journal.

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Among TEAM 1500's findings:

- *Higher dental fees and longer wait times to see a qualified dentist will drive patients away en masse. Within five years, an estimated 250,000 patients who currently visit a dentist on a regular basis will stop going.*

- *The cost of training required by Resolution 37 will run as high as $50,000 or more per dentist, when tuition, travel, and lost productivity are included.*

- *The total number of dentists available to provide sedation dentistry will decline by 5% to 7% annually, factoring in the retirement and attrition of existing dentists. Within five years, the number of general dentists who are qualified to provide moderate enteral sedation could decline by more than 30% nationwide.*

TEAM 1500, formed in 2006, advocates on behalf of patients and access to affordable health care. TEAM is an abbreviation of Trust for Equal Access Medicine. The group is a coalition of more than 1,500 health care providers and others concerned with patients' rights.

CONCLUSION: **CDEL's focus on the cost of capnography equipment in these two FAQ questions is a form of misdirection. It is the training costs, lost production, and related travel expenses that need concern dentists, not only for their own economic well-being but also for the financial well-being of their patients.**

CDEL's contention that "there is no evidence" demonstrating the economic impact on dentists and their patients ignores a three-month independent analysis undertaken by a former Wall Street Journal reporter and a patients' rights group. In 2015 and 2016, CDEL, itself, made no effort whatsoever to conduct a study to gauge the likely impact of Resolution 37 on patients.

Q.13. When and why were the Sedation and Anesthesia Guidelines developed?

CDEL's CLAIMS:

- The Council states that the Guidelines, which have been revised ten times since they were first established in 1971, are intended to "assist dentists in the delivery of safe and effective sedation and anesthesia. The revisions "reflect emerging practice and scientific principles."

THE FACTS:

- The existing ADA Guidelines governing the use and teaching of sedation and anesthesia were last significantly revised in 2007 and approved by the 2007 HOD. (In 2012, the Guidelines were minimally revised again by the HOD.)

  In compliance with the 2007/2012 Guidelines and applicable state regulations, tens of millions of patients have received moderate enteral sedation treatments safely, effectively, and without incident.

  The 2007/2012 Guidelines, in accordance with the stated purpose for such guidelines, do reflect emerging practice and scientific principles and are widely supported by the dentists who regularly administer moderate enteral sedation.

- **The revisions to the use and education guidelines proposed in Resolution 37, unlike those adopted in 2007/2012, do NOT reflect emerging practice and scientific principles – and they are opposed by virtually all dentists who actually administer moderate enteral sedation to patients.**

  Moreover, there is no supportive science whatsoever for the preponderance of the recommended revisions, and CDEL has not produced any supportive evidence-based research to substantiate its recommended Guideline revisions.

  The existing practice and clinical evidence pertaining to sedation and anesthesia overwhelmingly negate the need for Resolution 37. The revisions contained in Resolution 37 were conceived and drafted by oral surgeons, academics, and other ADA specialists who do NOT provide patients moderate enteral sedation. These Council and Committee members do not qualify as representing "emerging practice" clinicians.

  CONCLUSION: **CDEL's charter is to update the ADA's use and teaching guidelines for sedation as needed. In Resolution 37, CDEL has proposed broad unneeded, unjustified, and scientifically unsound changes to the existing ADA 2007/2012 Guidelines that have proven – above and beyond dispute – to protect patients when dentists administer moderate enteral sedation in accordance with the existing Guidelines.**

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Q.14. What is the process for proposing revisions to the House of Delegates?

CDEL's CLAIMS:

- The Council notes that in keeping with a directive from the House of Delegates, it reviews the ADA's sedation and anesthesia guidelines every five years. It cites "changes in practice and science" to explain the reasons the guidelines have recently been updated more frequently.

  CDEL notes that along with its Anesthesiology Committee, its seeks input from the "anesthesia communities of interest." It further explains that its Anesthesiology Committee, which carefully studies the issues and provides technical and scientific input to CDEL, includes "representatives from":

  - American Academy of Periodontology
  - American Association of Oral and Maxillofacial Surgeons
  - American Dental Society of Anesthesiology
  - American Society of Dentist Anesthesiologists
  - American Society of Anesthesiologists
  - American Academy of Pediatric Dentistry

  This year, CDEL adds, a member of the ADA's Council on Scientific Affairs also participated in committee meetings.

  CDEL writes that it "considers the Committee's recommendations and circulates proposed revisions to its dental anesthesiology communities of interest."

THE FACTS:

- The composition of CDEL and its Anesthesiology Committee is heavily weighted toward oral surgeons and other specialists, and greatly underrepresented by general dentists and those who regularly use moderate enteral sedation in a clinical setting.

  There is no mandate from the House of Delegates to exclude general dentists. Nor does the HOD dictate that in considering its actions, CDEL should only rely on "dental anesthesiology communities of interest."

  The dominance of specialists on the Committee warps the objectivity of the entire process. The lack of transparency, especially as it pertains to the specific

changes in “practice and science” that CDEL cites, invites questions as to whether Committee members are acting solely in the best interests of patient safety.

- CDEL’s wording might be interpreted to indicate that the Anesthesiology Committee is comprised of designated “representatives from” the various anesthesiology groups its lists – meaning that the outside groups selected a member to represent them. It’s unclear if this is the case.

  Another interpretation of CDEL’s wording is that members of the Anesthesiology Committee are also members of the various outside anesthesiology associations, but not officially designated representative of those groups – and without any such official standing.

- **The 800-pound gorilla in the room, which CDEL fails to address in its response to this question and throughout its 15-Question FAQ, is why CDEL is focusing on, and making recommendations pertaining to, moderate enteral sedation, when the overwhelming majority of dental fatalities cited in the general news media over the past decade have taken place in practices using deep sedation/general anesthesia – not moderate enteral sedation.**

  If there is any area of dentistry that cries out for closer scrutiny and possibly stricter training and practice guidelines it is deep sedation/general anesthesia.

  Oral surgery is the sole discipline in all fields of modern medicine that allows doctors to administer deep sedation/general anesthesia while also performing the procedure.

  Legislators in California unanimously approved a bill in August 2016, popularly known as Caleb’s Law, that specifically would establish a committee to study the safety of pediatric anesthesia. The bill’s sponsors have stated that they find it “disconcerting” that oral surgeons are not required to treat patients using a separate anesthesia provider.

  Caleb’s Law does not concern moderate enteral sedation. Yet CDEL and its Anesthesiology Committee, comprised primarily of oral surgeons, does not even raise the issues that are at the center of Caleb’s Law and tragedies impacting dental victims in oral surgeons’ offices nationwide. Why?

  CONCLUSION: **CDEL does not appear to be acting in the best interests of all dentists and their patients as its only priority. CDEL’s arbitrary inclusion of some experts and evidence, and exclusion of others, taints its recommendations and conclusions.**

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The most serious issue facing professional dentistry and public safety surrounds deep sedation/general anesthesia – not moderate enteral sedation.

The very credibility of the ADA as a champion of evidence-based science and public health is threatened by CDEL's action and the duplicity of Resolution 37.

Q.15. What information was used to develop the proposed revised Guidelines?

CDEL's CLAIMS:

- The Council responds that its Committee on Anesthesiology "relied on current standards of care, guidelines of other medical and dental organizations, the scientific literature, current state regulations for sedation, and the expertise of practitioners, academicians and state dental board members…"

THE FACTS:

- Tens of thousands of dentists regularly use moderate enteral sedation in their practices, in accordance with existing ADA guidelines and full compliance with state regulations, safely and without incident.

  The experts that the Committee on Anesthesiology and CDEL relied upon, with scant few exceptions, have little if any experience with moderate enteral sedation. As a result, a small group of "textbook" experts is attempting to dictate to a multitude of ADA members with substantial clinical experience how to best protect their patients.

  Any effort to reflexively impose sedation standards from the medical community on the dental community is misguided. Dentistry has a long and distinguished record of setting the standard for safe, effective, sedation and anesthesia. Many dental sedation standards, including the common use of Nitrous Oxide, do not conform to medical standards. Likewise, dentistry stands alone among all medical fields in permitting a single dentist to administer deep sedation/general anesthesia while also performing the procedure.

  Among all the experts CDEL cites, not a single group representing those who regularly use moderate enteral sedation supports Resolution 37 or make the argument that revisions to the existing ADA sedation guidelines are essential to protect patient safety.

Though it's doubtful that CDEL intends to insult the large group of dentists who currently use moderate enteral sedation in their practices, CDEL ignores the truth: **These dedicated dentists who use moderate enteral sedation would be the very first to demand changes in the existing ADA guidelines if they felt their patients were at risk.**

- CDEL asserts that "current standards of care," "the scientific literature," and "current state regulations" are among the sources that the Committee on Anesthesiology and it relied on.

  We find no objective evidence to support the assertion that these three sources, in particular, offer validation of the revisions proposed in Resolution 37. Only those experts who don't provide their patients with moderate enteral sedation – and have no professional experience administering it – appear convinced that the existing guidelines governing this common form of sedation are insufficient.

  CONCLUSION: **CDEL failed to weigh or place sufficient weight on the vast clinical experiences of the tens of thousands of dedicated dentists who regularly use moderate enteral sedation in their practices. Instead, the Council turned to "textbook" experts who seem compelled to recommend the changes proposed in Resolution 37 for change sake alone. There is no public health crisis in enteral sedation dentistry and no compelling need for Resolution 37.**

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