2720

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Sent: Friday, October 23, 2009 3:12 PM
To: IRRC
Subject: Dr. Ludwig commentary on #2720
Attachments: COCCODRILLI IRRC.wpd

To whom it may concern:

I attach my comments representing myself for State Board of Dentistry Final-Form regulation #16A-4617, IRRC #2720. Thank you.

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October 23, 2009

Arthur Coccodrilli, Chairperson
Independent Regulatory Review Commission
333 Market Street 14th Floor
Harrisburg, PA 17101

RE: Final-Form Regulation #16A-4617 (IRRC #2720)
Pennsylvania State Board of Dentistry
Dental Hygiene Scope of Practice; Local Anesthesia

Dear Chairperson Coccodrilli:

I am a retired dentist, having practiced general dentistry in Harrisburg from 1960 to 1994. During that time I was quite involved with the issues of dental practice, culminating in my election as president of the Pennsylvania Dental Association in 1986-87. In 1994, pursuant to Act 87-1996 of the General Assembly, I was appointed the first Public Health Dentist for the Commonwealth. In that capacity, I was a member of the State Board of Dentistry, serving as the designee for the Pennsylvania Secretary of Health. I resigned my state position in December, 1999.

My retirement from active practice and my state appointment, does not include retiring from an ongoing concern for the citizenry's oral and dental health. The above referenced final-form regulation does not serve to protect the public, relating to the Board's request that dentists allow dental hygienists to administer injectable local anesthetics to the public. Based on my study of the Board's proposal, described herein, this final-form regulation should be disapproved. This rulemaking proposal serves the interests of the Board in lieu of protecting the health, safety and welfare of the public.

Local Anesthesia

The therapeutic use of drugs is commonplace in dentistry. The administration of local anesthetics is considered essential whenever potentially painful procedures are contemplated. Local anesthetics are extremely safe drugs when used as recommended.

Whenever any drug is administered, including local anesthetics, two types of actions may be

observed: (1) desirable actions which are clinically sought and usually beneficial (pain relief);
and (2) undesirable actions that are uncomfortable but not seriously harmful, to those that can seriously incapacitate or prove fatal to the patient.

Chemically, current injectable local anesthetics are "amides," inorganic compounds derived from an ammonia-type compound with the replacement of an atom of hydrogen by another element. The most popular amide in use today is HCl Lidocaine. Almost all local anesthetics contain a compound (vasoconstrictor) which constricts blood vessels in the treatment area so that blood flows more slowly at the site, thereby letting the numbness last longer.

Another local anesthetic compound, i.e., "esters," are used for topical applications. They are not injected and properly applied safe to use. A newer and very effective topical, Oraqix, is a gel that is placed at or below the gum-line with a blunt needle-like tube.

There are two types of intraoral local anesthetic injections, an "infiltration" and a "nerve block." Patients are awake and fully responsive. The infiltration injection is made near a tooth or teeth to be treated, confining numbness to the treatment area. Infiltrations occur primarily in the upper jaw. The nerve block injection is made where a main nerve enters the upper or lower jaw and many teeth, bone and gums are made numb. Lower jaw nerve blocks can numb the tongue, cheek and lips. At times, finding the nerve to block is anything but easy, especially in the lower jaw. Significant numbers of patients continue to fear intraoral injections. Fear cannot be lightly dismissed by the doctor. Anything that a doctor can do to minimize a patient's stress at this time can help prevent potential

problems from developing. As safe and effective as local anesthetics drugs and techniques are, unforseen, unwanted, and undesirable events can still occur.

Other forms of anesthesia. Conscious sedation is minimally depressed consciousness in which a patient retains the ability to independently and continuously maintain an open airway and a regular breathing pattern, and to respond appropriately and rationally to physical stimulation and verbal commands. Conscious sedation may be induced parenterally or by oral medication or a combination thereof. General anesthesia is the induction of a state of unconsciousness with the absence of pain sensation over the entire body. Agents used for general anesthesia may be either gases or volatile liquids that are vaporized and inhaled with oxygen, or drugs delivered intravenously.

Dr. Stanley Malamed's premier textbook on Local Anesthesia devotes chapters on complications that can occur in local anesthesia administration. Chapter 17 is titled "Local Complications:" Seventeen pages list the following local events, i.e., needle breakage, postinjection pain, parathesia (prolonged soft-tissue anesthesia which can persist for days, weeks, or months),

facial paralysis (seventh cranial nerve paralysis of some of its terminal branches), trismus (spasm of the jaw muscles); soft-tissue injury (self-inflicted, like biting the lips, cheek and tongue while still numb), hematoma (nicking a blood vessel with blood escaping in the tissues), pain on injection (sloppy technique, dull needle), burning on injection (rapid injection, contamination of the anesthetic cartridge), and infections.

Chapter 18 is titled "Systemic Complications." Twenty-eight pages report on undesirable events involving the central nervous system and the cardiovascular system , i.e., overdosing, allergic reactions, idiosyncratic responses, central nervous system depression, cardiovascular reactions - alterations on the EKG, myocardial depression, decreased cardiac output, peripheral vasodilation, with the latter escalating to a possible cardiac arrest, and death. These events can develop between 5 and 10 minutes after an anesthetic injection(s).

Local anesthesia administration requires great concentration, knowledge of neurophysiology, pharmacology of local anesthetics, pharmacology of

vasoconstrictors, other additives, formulations of local anesthetics, maxillary arch anatomy, mandibular arch anatomy, physical and psychological evaluation, armamentaria, maxillary and mandibular injection techniques, CDC infection control guidelines, emergencies, local and systemic complications, overdosing, basic life support, and patient monitoring. As per these subjects, the Board's proposal of a minimum of 30 hours training, didactic and clinical, is ill conceived and not protective of a the public's health, safety and welfare.,

Statutory authority

The most important issue in this final-form filing, is the issue of statutory authority. In its August 30, 2008 initially proposed regulation, #16A-4617 (IRRC #2720), the dental Board cited its statutory authority(s) for its proposals. The citations given were inappropriate.

As required by law, on October 29, 2008, IRRC provided the Board with comments and questions on its initial submission. IRRC's comments and questions covered several topics.
The number one topic was statutory authority. Where in the Dental Law was the statutory authority for dentists to permit dental hygienists to administer local anesthesia? The Board's 15-page preamble to its final-form regulation submission attempts to build a case for statutory authority, primarily on pages 2, 3 and 10.

The Board's statutory strategy is to suggest that the statutory authority can be found in the

definition of "Dental Hygienist" in the Dental Law (Section 2). The Board wants IRRC to think of "administer anesthetic agents" as an "intra-oral procedure." These words are different from one another, but they mean the same. Where else would a dentist "administer" a local anesthetic? Why the name "change?" Because the definition of Dental Hygienist states that a dentist can assign "intra-oral procedures" to dental hygienists. Ergo, local anesthesia administration, being an intra-oral procedure, can be assigned by the dentist.

Ergo, there is the statutory authority.

The Board begins its strategy by "intuitively" divining the General Assembly's anesthesia intentions on page 2 of its Preamble: "The Board is of the opinion that, if the General Assembly had meant to limit local anesthesia to be performed only by dentists, it would have done so when Section 11.2 of the Dental law, pertaining to anesthesia, was amended in 2002. Therefore, it is left to the Board to "determine" whether local anesthesia falls within the range of procedures that may be performed by a dental hygienist."

"Opinions" are just that, opinions. It is very easy to derive erroneous courses of actions from opinions, which often vary based on agendas.

As to "divining," I can divine that the General Assembly was fully aware that the administration of local anesthesia was a component of the "practice of dentistry" (Section 2 of the Dental Law).

In 2002, when the General Assembly was crafting Section 11.2 (Anesthesia), the then Board had the opportunity to support and actively work for the inclusion of local anesthesia in Section 11.2 based on IRRC's very strong recommendation, given on May 12, 1993, to do so. That would have given the Board the statutory authority for local anesthesia administration by dental hygienists which the Board could have cited from 2002 to the present.

To continue with the Board's present strategy, the Board's "intra-oral procedure" innovation seeks to get statutory approval for local anesthetic administration by dental hygienists, not by legislative action, but by IRRC accepting the words in the definition of Dental Hygienist as statutory authority.

The exact words in the definition of Dental Hygienist are: "....*Licensed dentists may assign to dental hygienists intra-oral procedures which the hygienists have been educated to perform and which require their professional competence and skill but which do not require the professional competence and skill of the dentist*....."

With the Board's "intra-oral procedure" approach to statutory authority, the attending dentist

would be able to assign local anesthetic administration to a dental hygienist if the dentist opines that the procedure (*injecting a drug into the human body*) does not require the dentist's professional competence and skill in local anesthetic administration. The lesser competence and lesser skill of a dental hygienist will suffice.

On October 29, 2008, IRRC asked the Board: "How did the Board conclude that administration of local anesthesia is not a skill that requires the professional competence and skill of the
dentist?" This question might be answerable scientifically by independent researchers.

That said, the Board's goal is to convince IRRC that the "competency and skill issues" in the definition of Dental Hygienist would have no impact on the health, safety and welfare of the public, and subjective decisions by dentists, based on their "feelings"on a particular day, to assign local anesthesia administration to hygienists could just be the statutory authority that IRRC is seeking.

Does the assignment of local anesthesia to a hygienist pass the test of protecting the health, safety and welfare of the public? First, the procedure to be assigned has to be a procedure that a hygienist has been educated to perform. In Pennsylvania, none of the 11 hygiene schools educate local anesthesia administration. The Board erases that deficiency by placing an educational requirement in the final-form regulation of a minimum of 30 hours, § 33.115.

Thirty hours does not protect the health, safety and welfare of the public when one considers the dire consequences that can befall a patient by an inadequately trained individual. Graduates with a DDS or DMD degree are subject to 2 to 3 years of didactic, clinical education and local anesthetic administration in dental school clinics.

At this point, it would not be redundant to repeat words I have written on page 3. To wit: the administration of local anesthetics requires great concentration, knowledge of neurophysiology, pharmacology of local anesthetics, pharmacology of vasoconstrictors, pharmacology of other additives, formulations of local

anesthetics, maxillary arch anatomy, mandibular arch anatomy, physical and psychological evaluation, armamentaria, maxillary and mandibular injection techniques, CDC infection control guidelines, emergencies, local and systemic complications, no overdosing, basic life support, and patient monitoring. As per these subjects, the Board's proposal of a minimum of 30 hours training, didactic and clinical, is ill conceived and not protective of a the public's health, safety and welfare.

Injecting a local anesthetic drug in the human body requires an all encompassing education program. A training program should not be less than one academic year.

Framed this way, consider the message the Board is sending to Pennsylvania dental patients: **"Hello, Mrs. Smith. My hygienist will give you "novacaine" today. My hygienist is not as competent and skillful as I am in administering a local anesthetic, but I have the legal authority to allow my hygienist to give you this injection. My hygienist has had at least 30-hours of training in how to give you an injection, and how to handle any emergency that may arise. And don't you worry, I'll be nearby to help. In addition, you will be pleased to know that I accept full professional responsibility if anything goes wrong."**

No harm will befall the public if all of the local anesthesia references in this final-form regulation are <u>disapproved</u>. For the past several decades, thousands and thousands of Pennsylvania residents have received oral prophylaxes ("teeth cleanings" as the lay public might say it).

Disapproval will <u>not</u> result in the stoppage of oral prophylaxes.

A future local anesthetic regulation can be proposed that recognizes the importance of protecting the health, safety and welfare of the public, with appropriate statutory authority and meaningful education and training.

Respectfully,

Charles M. Ludwig, DDS