

Ethics versus Legal Informed Consent— A Distinction with Little Difference

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Abstract

The core principles of dental ethics and legal standards of care have similar foundations. Both are dedicated to place the patient's best interest as primary and the practitioner's interest as secondary. Similarities between ethics and the law demonstrate that most often there may be distinctions but little core differences. Informed consent principles illustrate the comparison between dental ethics and the law.

Speaker Introduction by Dr. Morton G. Rivo, Program Chair

When concepts of ethical behaviors become codified, they often become law. Dr. Edwin Zinman will help us understand this process. He is well prepared to do so. Dr. Zinman is both a dentist and an attorney. He received his dental degree from the University of Pittsburgh in 1962, and subsequently qualified as a periodontist at New York University College of Dentistry. He practiced periodontics in San Francisco for several years before graduating from the University of California, Hastings College of the Law in 1972. Since then, Dr. Zinman has been engaged in the practice of law, with a particular interest in dental

and medical malpractice. He is recognized as an expert in his field; as a practitioner, author, lecturer, and teacher. He has consulted and taught at several hospitals in New York and California, and lectured in the Department of Periodontology at the University of California, San Francisco. For many years, Dr. Zinman authored the popular column, "Dentists and the Law," which appeared in 'Dental Management' magazine. Our speaker has lectured at more than 300 local, state, and national dental and legal meetings. His topic today is one of great interest to us as dental historians investigating the development of ethical principles and the laws which direct dentists' professional behaviors. Please join me in welcoming Dr. Edwin Zinman.

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Introduction

Dentists are bound ethically and legally to serve their patients. Lawsuits serve a salutary purpose in terms of benefiting not only an individual patient but also the public at large.

In dental ethics, the question to be asked is if our services are provided primarily on the patient's behalf or for the benefit of the practitioner? This ethical obligation is codified in the American Dental Association's Code of Ethics.¹ Service to the public is our primary obligation. Dedication to *service* rather than for *profit* is also our ethical duty. We should always treat for *need* and not for *greed*. By comparison, if you want to know how to define malpractice, ask yourself a simple question: What is in the patient's best interest? Not necessarily, What is in the dentist's financial interest, but What is in the patient's dental health interest. You will then know not only what the appropriate standard of care is, you will also know how to fulfill your ethical duties to the patient.

Legal and ethical obligations often represent a distinction without a substantial difference since each requires service to the patient as our primary objective. The Code of Ethics of our American Dental Association, and the legal obligation of a dentist, spells out a fiduciary relationship. A fiduciary relationship distinguishes a dentist as a professional versus the commercial interests of a trade. The commercial interest of a tradesman is to maximize profit. A dentist's interest is to maximize health. Thus, protecting the patient's best interest is both legally and ethically required.

The dental profession's concern for ethical erosions of core values culminated in the American College of Dentists and the American Dental Association jointly sponsoring an Ethics summit on commercialism in March 2006. The summit's session recommendations are reported in the California Dental Association's January 2008 article entitled "Beginning the Discussion of Commercialism in Dentistry."

Reasonable Care versus Customary Practice

As dentists, we have core value principles. "Honest Abe" Lincoln advised: "Always do the right thing; this will gratify some people and astonish the rest." What is done, commonly or customarily, may not always be reasonable or prudent care.² What is both reasonable and careful care, irrespective of how few or how many may meet that standard, is the *legal standard* of care.

Just because some dentists' over-treat does not make it right, legal, or laudable. For example, Gordon Christensen, DDS' editorial entitled "Veneer Mania" in

July 2006 *JADA* lamented that over-treatment with ceramic veneers is at an all time high. Standard of care is not 100% perfection, nor is it ideal dentistry. "Reasonable" is defined as: reasonable care, based upon reason. By reason, in dentistry, we apply evidence-based reasons.

Ethical Disclosure versus Informed Consent

Dental negligence includes rendering substandard care. Nonetheless, the ethics of our dental profession—as policed by ethics committees—rarely discipline dentists for substandard care. Lawyers therefore help police the dental profession. Informed consent includes advising the patient of treatment alternatives and treatment options.³ This is not only an ethical obligation, but also a legal obligation that requires that a patient be informed of the ABC's of "alternatives, benefits and complications."⁴ A patient has a right to know these ABC's from the dentist. Too often, what happens is that the dentist might say, "I'm going to be doing mucogingival surgery with autogenous grafting," and the patient replies, "Wonderful," but really has no idea what the dentist discussed. Informed consent has to be in lay language, so that the patient can understand what the risks are because, ultimately, it is the patient's decision. The patient may understand that it will be a beneficial result: to eliminate periodontal disease in the maxillary anterior region. In addition, the dentist or a periodontist may believe it is desirable to eliminate the periodontal disease. Nonetheless, if periodontal surgery causes significant gingival recession, the patient may complain, "I wanted to look like a star, but Lassie wasn't what I had in mind." Therefore, we have to do what is in the best interest of the patient by informing patients of our treatment consequences.

Comparing the California jury instruction of informed consent for alternatives, benefits, and complications with the Code of Ethics of our American Dental Association and respective state dental societies, all require this same disclosure, even if these risks might occur despite the best of care.⁵ However, if these risks are reasonably avoidable with due care, then the dentist causing these risks to manifest is negligent.

Informed consent includes alternatives as well as complications, so alternatives to those procedures include those that you do not perform.⁶ Let the patient know that there are alternatives so that the patient can make those choices. In addition, the patient must be told of the consequences of doing nothing.

In sum, unavoidable risks represent a maloccurrence. On the other hand, malpractitioners cause reasonably avoidable risks.

What the patient has to be told is that which a reasonable patient would want to know. What does the patient want to know? Not necessarily what the dentist would want to know, or benefit from the procedure. Explain procedures in lay terms because the patient will not understand a lot of technical jargon.

Do not use the famous Dilbert cartoon standard "If it's not immoral, it probably won't work." That is not, of course, the ethics of our profession in which the patient's best interest is required. Even if some or many practitioners do it wrong does not make it right. Thus, the majority does not rule in unreasonable treatments such as maximally invasive veneer preparations into dentin rather than minimally invasive preparations into enamel.

Warren Buffett said it well: "The fact that everybody is doing it is probably the worst excuse in the world." In one study, 90% of corporate whistleblowers were fired or demoted. Twenty-six percent of the whistleblowers required psychiatric or medical care. Nonetheless, most had a strong moral fiber to blow the whistle on misconduct. Only 16% said they would never do it again. Eight-four percent stated, yes, they would do it again, despite being fired, demoted, or having medical or psychiatric problems. Sometimes you have to swim against the corporate tides to serve society's best interests.⁷

FDA MedWatch Reporting

Companies that manufacture dental products do not always test for long-term risks. Thus, you as the practitioner and all of your patients become the ultimate guinea pigs and sometimes pay a high price for undisclosed risks. Therefore, in any new technology, choose a product that has peer-reviewed research behind it.

Marketplace testing—despite the FDA's requirement that manufacturers conduct post-marketing monitoring—has not always kept up with FDA mandates. FDA approval is only a minimum standard and provides no guarantee of product safety.⁸

We all think of ourselves, as ethical practitioners, but even the FDA will not know of a problem unless it is reported to them. The FDA, by their own MedWatch statistics, admits that it is only between 3% as in one study, or 10% in another study that complications of a product or drug are ever reported to the FDA.⁹ Our profession should take more responsibility. If there is a complication of a product, although you do not know what the complication is, it will help other patients if we file MedWatch complaints with the FDA. It is not being a whistleblower for the world to hear since MedWatch reporting is confidential. Rather, it is just calling a manufacturer's attention to a product defect causing an adverse event which the manufacturer should correct.

Non-FDA Approved Drugs

When I began practicing law 30 years ago, I frequently litigated Sargenti paste cases. Unbelievably, Sargenti formulations are still in use today albeit lacking FDA approval as a "New Drug" with proven safety and efficacy. The American Association of Endodontists' position paper (1998) states that it is below the standard of care to even use Sargenti paste. All American dental schools advise against the use of Sargenti paste. Thus, dentists who use Sargenti paste represent a negligent customary practice rather than the standard of care. We, as dentists, must practice prudently to minimize, not maximize, risks. The law requires reasonable care as the standard of care in order to minimize risks.

In a recent case, a California pharmacy sold non-FDA approved Sargenti powder to an Alabama dentist.¹⁰ The dentist not only filled the patient's root canal with toxic Sargenti paste (Figs. 1 and 2), but she filled the inferior alveolar nerve canal as well.¹¹ The patient complained of persistent burning dysesthesia pain and paresthesia. The dentist blamed the symptoms on local anesthesia injection and thus concealed the true cause of the patient's neuropathic injuries. The patient in her lawsuit alleges the dentist fraudulently informed the patient that the overfill was completely absorbable by the human body and would be gone in time. Also, the patient alleges that the dentist concealed that such a gross amount of Sargenti overfill would not likely absorb. However, even if it were to eventually absorb, the chemical neurotoxic damage to the inferior alveolar nerve from the mummifying paraformaldehyde content of Sargenti paste would remain. This patient now has permanent painful dysesthesia. As Dr. Stephen Cohen, author of *Pathways of the Pulp*, advises, "No one should be embalmed before their time."

In a seminal article, Dr. Anthony Pogrel demonstrated that the surgical removal of endodontic material

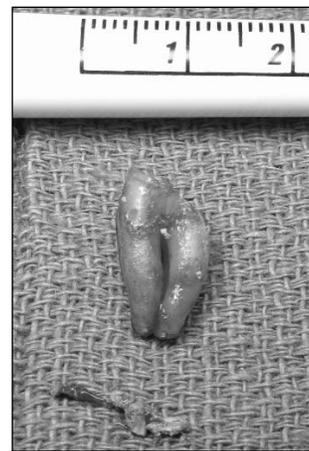
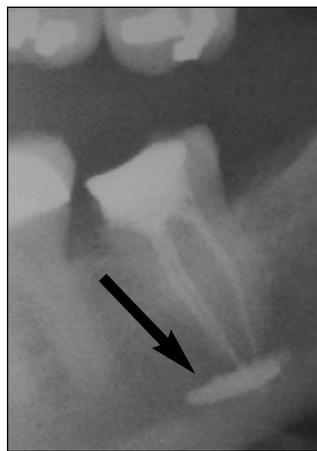


Fig. 1—Sargenti Overfill #18 Fig. 2—Microsurgical Removal

from the inferior alveolar nerve canal within the first 72 hours—before the chemical effects can do further damage—is likely to result in a 100% reversal.¹² Time is very critical. But this dentist—rather than admitting her error and advising of the potential for permanent damage and referral for immediate microsurgery, blamed the patient's pain and discomfort on the local anesthetic rather than on her injection of toxic Sargenti paste into the inferior alveolar nerve canal. Slight overfills might occur even under the best care, but a gross overfill with a toxic substance such as Sargenti paste maximizes the risk of permanent, irreversible injury.

Today, dentists have to inform patients about the risks of endodontic therapy. Since it is considered a violation of the standard of care to use Sargenti paste, then so is asking the patient to consent to its use. Asking a patient to consent to negligent care is like asking the patient to consent to assault and battery. Thus the consent is voidable and contrary to public policy.¹³

Litigation Incidence

When you go into court, you will be judged by your records. Remember the three R's of malpractice prevention: The first is Records, the second is Records, and the third is Records. It is all three D's: Document, Document, and Document.

There is a current myth that there is a litigation explosion. However, the total number of lawsuits against dentists is down, although the monetary awards in some individual verdicts may be up.

A 2007 trial in Los Angeles involved an implant that had been placed so deeply it not only went into the inferior alveolar nerve canal, it also exited out the other side (Fig. 3). As a result, that patient has permanent pain. The jury verdict was for \$1.7 million. The salutary lesson in that case was that correctly-interpreted 3D imaging would have avoided the resulting permanent burning painful dysesthesia by guiding the implantologist's correct anatomical placement. The standard of care incorporates technological diagnostic improvements. Implant surgical protocols require a safety zone of 2-3mm of implant placement superior to the inferior alveolar nerve canal.¹⁴ The dentist should have correctly used 3D imaging to minimize the risk of over-drilling.

There are many safe and effective implant systems. Implants are the state of the art, the standard of care, and they are beneficial when the proper system is placed in conjunction with 3D imaging. Perhaps your patient needs a system that you cannot provide. Perhaps you are using an implant system that is inappropriate for your patient. Use your professional judgment if you are going to inform the patient of alternative implant systems. You have to determine what is appro-

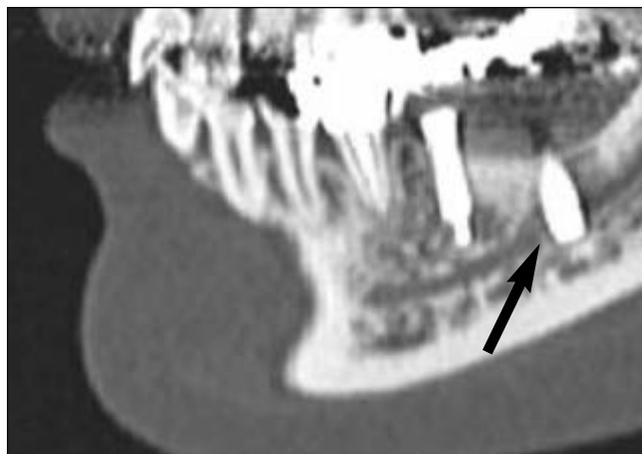


Fig. 3—3D Radiograph of Implant into IANC

priate for the patient as long as that implant system will be effective and indicated for that patient's need with minimal risk. That is what informed consent is all about, protecting the best interest of the patient.

Admission of Error

Dentists get into difficulty and/or trouble when they fail to admit a mistake. The ADA Code of Ethics requires that you must inform the patient if faulty treatment has been provided. That is our ethical obligation. We must report instances of gross or faulty dentistry.¹⁵ Although we believe we are all ethical dentists, reporting faulty care dentists is honored in the breach more than in the observance—including reporting to peer review.

The number one genesis of dental negligence litigation is if the patient feels the betrayal of trust because they find out from some other dentist what really happened.

Five states require mandatory notification of adverse events to patients. California is not on the list. It is only law in eighteen states. Thus, in 10% of the states there is, by law, a mandatory obligation to report adverse events. Aside from being sued for malpractice, it is a statutory obligation to report in those states.

Eighteen states have "I'm sorry" statutes.¹⁶ It is not an admission of negligence if you tell the patient you are sorry for what happened. This has been codified in those five states; so you are legally protected if you tell the patient you are sorry. It is not an admission of wrong-doing, but rather a demonstration of compassion. It is permissible to advise a patient, "I'm awfully sorry for what happened. I am sorry that I slipped with the drill, severed half your lip and you lost a pint of blood. Go to the hospital, plastic surgeon, or oral surgeon. Have that injury repaired immediately. Send me the bill, and once again, I'm awfully sorry." That scenario is not an admission of negligence. Rather it is an admission of your compassion for the patient. Do not

hesitate to reveal rather than conceal. Truth in dentistry is the best policy.

Increasing numbers of hospitals and professional liability insurance companies have adopted policies of frank disclosure of professional negligence and apologies for such errors. These policies have resulted in greater patient trust and forgiveness by the patient. Consequently, these fully-informed patients file fewer lawsuits compared to patients who belatedly learn from another professional the true cause of their injury and thus feel their trust was betrayed.

Senators Hillary Clinton and Barack Obama are joint sponsors of "The National Medical Error Disclosure and Compensation (MEDIC) Act." Program participants would be required to disclose the substandard error to the patient and negotiate fair compensation. The dentist would be legally protected for apologizing when disclosing the negligent act or omission. Insurance carriers' cost savings anticipated under this plan through lower administrative and legal costs will be applied to premium reduction of professional liability policies if Congress were to pass the proposed Senate bill.

Saying that you are sorry has a proven track record in non-dental settings. The Pearl Outlet¹⁷ merchant members queried purchasers why they purchased pearls. Many replied that the purchases were designed as apologies to wives or girlfriends. The Pearl Outlet then hired Zoogby International to research those persons willing to admit that they were sorry for their mistakes. Research found that persons who make more money were more willing to say, "I'm Sorry" than people who rarely or never apologize. The study showed "a person's willingness to apologize was an almost perfect predictor of their places on the income ladder." Thus, the link between income and willingness to apologize demonstrates that successful people are willing to learn from their mistakes and apologize to assuage a troubled relationship. This research proves that our ethical and legal obligation to have frank and candid disclosures of error to our patients is a practical bridge over troubled waters.

Conclusion

In many schools, entering freshmen take a pledge of honesty and integrity. Here is the UCSF SOD pledge:

"With appreciation of the responsibilities involved in the patient care I am about to provide, I do hereby pledge:

"To accept my professional responsibility to treat, to the best of my ability, all who come to me for care with confidentiality and compassion;

"To actively foster an environment of mutual trust and respect with patients, faculty and fellow students as embodied in the School's "Academic Environment Philosophy;"

"To uphold the honor and integrity of the dental profession and to contribute to its progress; and

"To continue to advance my knowledge and skills throughout the remainder of my education here at UCSF and beyond."

These pledge principles are expected of dental professionals as part of our ethical obligation to our patients throughout our professional career. When you fulfill the best interest of the patient, then you will do good for your patient and do well by the dental profession. Accordingly, protecting the patient's best interest remains our paramount goal both ethically and legally.

References

1. American Dental Association Principles of Ethics and Code of Professional Conduct, Section 1: Service to the Public and Quality of Care.
2. Restatement Second of Torts, Section 295A, provides: "In determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them."
3. California Dental Association Patient Bill of Rights.
4. Judicial Council of California Civil Jury Instruction 532.
5. *California Dental Association Journal* (2007) Case Study Thomason, R. "Recommended vs. Alternative Treatment Options: Is One Enough?" Vol. 35, No. 2, pp. 100-102.
6. *Vandi v Permanente Medical Group, Inc.* (1992) 7 Cal. App. 4th 1074.
7. Rothschild, Joyce. "Whistleblower Disclosures: The Battle to Control Information about Organizational Corruption." In press.
8. *David Jessen v Mentor Corporation* (2008) *DJDAR San Francisco Daily Journal* 808 citing *Medtronic, Inc. v Lohr* (1996) 518 U.S. 470, 116 S. Ct. 2240.
9. U.S. Food and Drug Administration MedWatch Safety Information and Adverse Event Reporting Program. See FDA Form 3500 for voluntary dentist reporting and FDA Form 3500A for Manufacturer Mandatory Reporting.
10. *Hellier v Porch DMD, et. al* Circuit Court of Madison County, Alabama 47-CV-2007-001493.00. See also Barrett, S. "Alabama Disciplines Three Dentists who Performed Sargenti Dental Procedure" <www.casewatch.org/board/dent/p-y.shtml>
11. Sargenti overfill radiographs and photo courtesy of J. Holmes, DDS, MD, in Fig. 1 and Fig. 2.
12. Pogrel, M. A., "Damage to the inferior alveolar nerve as the result of root canal therapy." *JADA*, Vol. 138, January 2007, 65.
13. Judicial Council of California Jury Instruction, 530.
14. Kraut, R.A, Chahal, O. "Management of patients with trigeminal nerve injuries after mandibular implant placement." *JADA*, Vol. 133, October 2002. 1351.
15. American Dental Association Principles of Ethics and Code of Professional Conduct, Section 4-C. "Justifiable Criticism."
16. "I'm Sorry" statute states: Arizona, California, Colorado, Florida, Georgia, Hawaii, Idaho, Maryland, Massachusetts, Montana, North Carolina, Ohio, Oklahoma, Oregon, Texas, Virginia, Washington and West Virginia.
17. <www.thepearloutlet.com>