Dental Amalgam Beneficence
- first do no harm -

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Abstract

Dental amalgam restorations typically consist of 50% mercury, 35% silver, 13% tin, 2% copper, and a trace of zinc. Today, there is a growing body of scientific research that indicates the dose of mercury released by the amalgam causes harm to every exposed person and developing fetus. Therefore, it is reasonable and conservative to believe that the dose of mercury released from an amalgam is a poison.

Because amalgam constituents are substantially equivalent to devices that existed in interstate commerce prior to the May 28, 1976 enactment of the Medical Device Amendments in the United States, the federal Food and Drug Administration permits them to be marketed under regulatory controls. State dental boards commonly adopt the American Dental Association's *Principles of Ethics and Code of Professional Conduct* (ADA Code) as an ethical standard for all dentists in their state. The ADA Code does not address some aspects of classical biomedical ethics and it contains a veracity aspect. Their combined effect: (1) discourages amalgam removal for health reasons, and (2) in a circuitous way, allows for amalgam installation.

To discourage the amalgam and other products like it from entering the market place, state policies or statutes that allow for dental restoration removal for health reasons are needed. The policies or statutes need to allow for aspects of autonomy, beneficence, and justice that are not addressed by the present ADA Code. The suggested policy or statute will inspire enterprise and result in a phase out and eventually the ban of the amalgam and amalgam-like products from entering the market place.

Keywords: dental, amalgam, ethics, mercury, government, policy, statute.

1. Thesis Statement

> *Authenticity (autonomy) always trumps authority (heteronomy).*
>
> *Mankind censures injustice, fearing that they may be victims of it and not because they shrink from committing it.* Plato

The dental amalgam exists because a dentist cannot legally peer-review restorative material installed by another dentist and inform the patient that (based on his or her belief) a hazard is present, then properly replace it if the patient concurs. When a state statute legalizes that process and procedure, the amalgam will disappear forever.

> Suggested Dental Peer-Review Statute A patient may be informed of research pertaining to dental restorative material. A patient may have dental restorative material replaced in accordance with recognized techniques.

2. Introduction

Each dental amalgam restoration, which is commonly called a "*silver filling*" by its installers, slowly releases mercury into its host's body. Ever since the amalgam was introduced into the market place, there has been an issue as to whether it causes harm (i.e., the dental amalgam issue). Today, there is a growing body of scientific research that indicates the dose of mercury released by the amalgam causes harm to every exposed person and developing fetus. Therefore, it is reasonable and conservative to believe that the dose of mercury released from an amalgam is a poison.

The Oath of Hippocrates (circa 400 B.C.) established the moral tradition of our culture's health care system. Its essence has been summarized as, the *first do no harm* tradition of health care. It has been the premier value of health care practice and administration for more than two millennia. Most patients are naïve about health care practices and implicitly place their trust in professionals and the health care systems to honor that tradition.

Because amalgam constituents are substantially equivalent to devices that existed in interstate commerce prior to the May 28, 1976, enactment of the Medical Device Amendments in the United States (U.S.), the federal Food and Drug Administration (FDA) permits them to be marketed under regulatory controls. State dental boards commonly adopt the American Dental Association's *Principles of Ethics and Code of Professional Conduct* (ADA Code) as an ethical standard for all dentists in their state. The ADA Code does not, however, address some aspects of classical biomedical ethics and contains a veracity aspect. The combined effect is that a dentist is not allowed to peer-review restorative material installed by another dentist, discuss with a patient the results of recent scientific research associated with existing dental restorations, independently decide that the dose of mercury released from an amalgam is a poison, and then remove their amalgams for health reasons. That allows for installation of the amalgam in a circuitous way.

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Two alternative courses of government action have been proposed to phase out amalgam use: 1) to discourage amalgam installation by requiring that dentists initially present an adverse message to patients before they are installed (i.e., informed consent), or 2) encourage amalgam removal by allowing for professional outreach by dentists.

Informed consent allows for amalgam installation if the patient concurs. For people who believe that the dose of mercury released from an amalgam is a poison, advocating for informed consent before installation of an amalgam does not adhere to the *first do no harm* tradition. Because of the long-standing *first do no harm* tradition, most patients will assume that a dentist and a system, which requires informed consent, abides by the tradition. The patient will not perceive and interpret an adverse message if one is presented. So discouraging amalgam installation by requiring dentists to initially present an adverse message to patients is a fallacy (debased and dysfunctional non sense).

The *first do no harm* tradition allows a dentist, who believes that the dose of mercury is a poison, to remove an amalgam for health reasons. The ADA Code, however, does not allow that. It allows: (1) an organizational consensus, which mandates that the dose is not a poison, to prevail over individual autonomy in dentistry, and consequently (2) the ADA to maintain an organizational grip concerning the dental amalgam issue. The ADA will lose their organizational grip when: (1) the veracity aspect of the ADA Code is removed and replaced or pre-empted, and (2) the aspects of biomedical ethics that are not addressed by the ADA Code become available to dentists. Then dentists will not be restricted from discussing with patients the results of recent scientific research associated with existing restorations, such as the amalgam. Dentists will also be able to remove existing restorative material, like the amalgam, in a professional-like manner if the patient concurs (i.e., professional outreach). As professional outreach grows, dentists will less likely install amalgams and more likely properly remove them. It will inspire enterprise, and result in a phase out and, eventually, the ban of the amalgam.

Legally allowing for professional outreach will also send a circuitous message, compatible with the *first do no harm* tradition, to the FDA that does not pre-empt their authority and make them appear as if they have made an unconservative decision regarding whether the dose of mercury released from an amalgam is a poison.

3. Dentral Restorations

3.1 Dental amalgam installation

Dental Amalgams Dental amalgam restorations were introduced into the U.S. market place during the 1830s. Installed dental amalgams weigh between 0.1 and 1 gram. They typically consist of 50% mercury, 35% silver, 13% tin, 2% copper, and a trace of zinc. The net result of the tendency for metallic bonding between amalgam metals is a weak repulsion, which causes a sustained release of mercury and other metals into the host's body. Each amalgam releases on the order of 10 micrograms of mercury every day [1-4]. Patients with more than ten amalgam restorations can receive as much as 100 micrograms of mercury every day. Mercury is the single most toxic non-radioactive metal; the minutest amount damages cells. The amalgam has a systematic and widespread use in dentistry. Each year in the U.S. on the order of 100 million amalgams are installed [5]. The amalgam is the dominant source of mercury in most individuals and the predominant source in the U.S. population [4,6].

Scientific Studies Ever since the amalgam was introduced into the market place, there has been an issue as to whether it does harm (i.e., the dental amalgam issue). Today, there are more than 1,000 published scientific studies that document ill effects caused by the mercury released from an amalgam. Some of these studies were performed using animal subjects. Other studies were performed using human subjects with existing amalgams. One study was performed using children as subjects. Among other effects, this research has documented that mercury:

- Crosses the placenta into tissue of a developing fetus, including its brain [7]
- Is capable of inducing autoimmunity [8].
- Challenges kidney function [9].
- Increases the prevalence of multiple antibiotic resistant intestinal bacteria [10].
- Lowers fertility [11].
- Is present at elevated levels in the brain tissue and blood of people with memory loss known as Alzheimer's [12, 13, 14].
- Is transported into the brain, where it:
  - o Inhibits binding of GTP to tubulin (a dominant lesion of Alzheimer's) [15].
  - o Degenerates the neurite membrane structural integrity of nerve growth cones (the other dominant lesion in Alzheimer's). Only mercury can degenerate the neurite membrane structural integrity of nerve growth cones [16].

The scientific process has never refuted the results of these studies. Thus, it is reasonable and conservative to believe that results of scientific research performed on animal subjects and human subjects with existing amalgams indicate that the dose of mercury released from a dental amalgam causes harm to every exposed person, as well as a developing fetus.

3.2 Dental amalgam removal

Standard of Care The International Academy of Oral Medicine and Toxicology (IAOMT) has established a Standard of Care for amalgam removal [17]. If it is followed, the chance of having mercury released into the patient during amalgam removal is much reduced. Standard IAOMT removal protocol consists of:

- Place a rubber dam around the tooth to isolate it from the body.
- Provide an alternative source of air to the patient.
- Place a saliva ejector under the dam to remove mercury vapor that escapes the rubber dam.
- Use high volume evacuation with an isolated attachment.
- Section amalgams and remove them in large pieces.
- Dispose of rubber dam and amalgam particles in an environmental container.

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Scientific Studies Scientific studies have documented that after amalgam removal, the body releases its accumulated mercury [18, 19, 20, 21, 22]. The usual concentration pattern of mercury in blood after amalgam removal is:

- A 30 percent increase during the first and second day.
- A steady decrease after the second day.
- A decrease to 50 percent of the pre-removal level after 90 days.
- A decrease to 10 percent of the pre-removal level after 1 year.

> World Health Organization Consensus Statement: "….the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any ….. adverse health effects" [23].

Thus, It is reasonable and conservative to believe that the results of scientific research indicate that amalgam removal eliminates a source of harm.

3.3 Dental composites

The composite is the most commonly used alternative dental restoration to the mercury amalgam. It has a tooth color appearance. A composite takes more time and talent than an amalgam to install, so it costs about twice as much.

The composite consists of a polymer matrix with filler particles. Typical polymers are complex hydrocarbons such as dimethacrylate (Bis-GMA), or urethane dimethacrylate (UDMA). Both Bis-GMA and UDMA have highly volatile constituents that evaporate rapidly during installation. The residual constituents of Bis-GMA and UDMA remain and hold the filler together. Quartz, lithium aluminum silicate, and barium, strontium, or zinc glasses are filler particles; they are common earth minerals that make up soil and rock. The safety of this mix has been evaluated by scientific assessment and investigation. The results demonstrate beyond a reasonable doubt that a composite's potential health risk for all patients is next to nil. These results have been published and never refuted by the scientific process [24, 25, 26].

4. The dose makes the poison

Paracelsus made the statement, "the dose makes the poison;" it has become the fundamental concept of toxicology. Who decides what dose of mercury makes a poison? In the U.S. there are five parties involved with deciding what dose makes a poison for mercury released from the dental amalgam. They are the federal government, dental organization, state government, patient, and dentist.

4.1 Federal government

Food and Drug Administration The federal government gained the authority and responsibility to regulate products used in medicine and dentistry with the Food and Drug Administration (FDA) Modernization Act of 1997, Safe Medical Devices Amendments of 1990, and the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938. The intention of this Act and its amendments is to ensure that devices intended for human use are safe and effective.

> Medical Device Amendments of 1976 An Act to amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes [27].

The U.S. Department of Health and Human Services (DHHS) is the department of the federal government responsible for administering the Federal Food, Drug, and Cosmetic Act and its amendments. Agencies, services, administrations, and other organizations within the DHHS that are involved with administering the Act are the U.S. Public Health Service (USPHS), the National Institutes of Health (NIH), the Center for Disease Control and Prevention (CDC), and the FDA. The FDA has been given the authority and responsibility to regulate products or devices used in dentistry. The FDA's regulations concerning dental products are presented in Title 21, Section 872 of the Code of Federal Regulations.

> FDA's Mission The FDA Modernization Act of 1997 affirmed the FDA's public health protection role and defined the Agency's mission [28]:
>
> To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.
>
> With respect to such products, protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled, and; public health and safety are protected from electronic product radiation.
>
> Participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.
>
> As determined to be appropriate by the Secretary, carry out the above paragraphs in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors and retailers of regulated products.

Federal Loophole Federal regulations address the distribution of drugs and devices.

> As used in this section the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user [29].

The FDA has classified components of the amalgam as two separate devices. Dental mercury is classified as a Class I dental device [30]. Amalgam alloy is classified as a Class II dental

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device [31]; it consists of a silver, tin, copper, and zinc mix. Because dental mercury and amalgam alloy are substantially equivalent to devices that existed in interstate commerce prior to the May 28, 1976, enactment of the Medical Device Amendments, the FDA permits them to be marketed under regulatory controls [32, 33]. This predication of dental mercury and amalgam alloy does not denote FDA approval of these devices [34]. Any representation that creates an impression of FDA approval is misbranding [34]. Manufacturer's are required to provide the FDA with a Premarket Notification [35] before they are permitted to market dental mercury and amalgam alloy. This notification needs to include "labeling" that describes the device, its intended use, and directions for its use [36]. To ensure dentist, dental personnel, and patient safety, the labeling for dental mercury and amalgam alloy needs to provide information regarding proper handling and use [37].

Labeling information is presented in the "directions for use" packaged with the dental mercury and amalgam alloy when shipped. These directions commonly contain trituration, condensation, carving, burnishing, and polishing requirements for the preparation and installation of an amalgam in a patient's tooth. The following warning is commonly presented in the directions [38, 39].

> Warning This dental amalgam product contains mercury. The placement of a dental amalgam in a patient will increase the level of mercury in the body of the patient. The use of a rubber dam may decrease the amount of mercury absorbed by a patient during the removal or placement of an amalgam.
>
> The health authorities of the various countries including Canada, Germany, France, the United Kingdom, Norway and Austria have recommended against the placement or removal of an amalgam in certain individuals such as pregnant and nursing women and persons with impaired kidney function. You should check with the authorities in your country that govern the practice of dentistry and dental materials to determine what recommendations or restrictions apply to the use of dental amalgams. The United States Food and Drug Administration and the World Health Organization have stated that there is no basis for any restrictions on the use of amalgams. In rare cases, a patient may suffer a localized hypersensitivity reaction to the dental amalgam.
>
> Proper care should be taken when handling this product. Protective measures such as the wearing of gloves, using the product in a well ventilated area, using an enclosed amalgamator when mixing the product, proper disposal of spent capsules and any excess unused amalgam, and the use of HGX, or similar-type mercury absorbing compound in the event of spillage, should be employed. These precautionary procedures should always be used in addition to procedures recommended by your local regulatory agency and dental association.

The FDA permits dental mercury and amalgam alloy to be marketed with the above warning in its directions for use. The FDA acknowledges that hypersensitivity reactions, while very rare, may occur with the amalgam. The warning does not specifically acknowledge the consistent hazard caused by a sustained release of mercury from each amalgam restoration.

Dental mercury and amalgam alloy arrive at a dental office as two separately classified devices. Dentists assemble these devices to form an amalgam. This process is allowed because products or devices that dentists assemble solely for use in their practice are specifically excluded from federal regulation.

> The foregoing subsections of this section shall not apply to practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice [40].

Federal Review of the Amalgam The FDA has the authority to ban devices that are on the market.

> Whenever the Secretary finds, on the basis of all available data and information, that a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; then he may initiate a proceeding to promulgate a regulation to make such device a banned device [41].

In 1993 the USPHS made the following statement after a comprehensive review of literature:

> "…current scientific evidence does not show that exposure to mercury from amalgam restorations poses a serious health risk in humans, except for an exceedingly small number of allergic reactions" [42].

The USPHS also published the following inconclusive statement on what dose makes a poison pertaining to mercury released from the dental amalgam.

> While it is clear that mercury vapor is continually released from dental amalgam, it is not clear that this exposure leads to toxicity. However, the potential for toxic effects due to low levels of exposure to mercury vapor from dental amalgam restorations must not be disregarded [42].

Despite the following proposal, the FDA has not published any scientific study (simulating amalgam installation) that demonstrates the dose of mercury released from a dental amalgam is not a poison:

> The FDA Dental Products Panel, the Committee to Coordinate Environmental Health and Related Programs (CCEHRP) Risk Assessment Subcommittee, and CCEHRP Benefits Subcommittee on Amalgam, as well, have proposed that well designed scientific studies be conducted to precisely define potential toxic effects, if any [42].

A 1997 USPHS report provided the following conclusion, updating the 1993 USPHS conclusion:

> In 1997, with input from a broad cross-section of scientists and dental professionals within USPHS, the FDA completed a review of nearly 60 studies that were published in peer reviewed scientific literature and were cited by citizens groups

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that petitioned the agency for stringent regulatory actions against dental amalgam. The analysis of the cited studies indicated that the current body of data does not support claims that individuals with dental amalgam restorations will experience adverse effects, including neurologic, renal or developmental effects, except for rare allergic or hypersensitivity reactions [43].

In February 2002, the FDA produced the following statements regarding the dental amalgam [44]:

> FDA and other organizations of the U.S. Public Health Service (USPHS) continue to investigate the safety of amalgams used in dental restorations (fillings). However, no valid scientific evidence has ever shown that amalgams cause harm to patients with dental restorations. FDA is aware that some manufacturers have advised in their labeling against using amalgams in very young children and pregnant or nursing women.
>
> In January 1993, the USPHS published a broad scientific report about the safety and use of dental amalgam and other materials commonly used to fill dental cavities. These conclusions were reaffirmed by USPHS in 1995 and 1997. Since then, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) have continued to study the issue. The National Institute of Dental & Craniofacial Research at NIH has also provided money to study the safety of dental amalgams and to develop non-mercury alternatives. This effort includes research and clinical studies of dental amalgam use in children. These studies are ongoing and will require several years of follow-up in order to detect possible subtle and long-range health effects.
>
> Also, USPHS scientists analyzed about 175 peer-reviewed studies submitted in support of three citizen petitions received by FDA after the 1993 report. They concluded that data in these studies did not support claims that individuals with dental amalgam restorations will experience problems, including neurological, renal or developmental effects, except for rare allergic or hypersensitivity reactions.

The FDA apparently is kowtowing to the bias of amalgam advocates who claim that data obtained: 1) from studies using animal subjects are not relevant to humans, and 2) using human subjects with existing amalgams are not generated with controlled research. On the basis of those justifications, amalgam advocates claim there is no study that indicates the dose of mercury released from an amalgam causes harm to humans. These amalgam advocates apparently believe that only controlled studies, where amalgams are installed in humans for research purposes, are relevant to the dental amalgam issue. The Nuremberg Code addresses when it is ethical to use human subjects for biomedical research. Because of the large body of scientific data generated using animal subjects and humans with existing amalgams, which indicates the dose of mercury released from an amalgam causes harm to every exposed person and developing fetus, according to the Nuremberg Code it is not appropriate to perform research with humans as subjects.

> No experiment should be so conducted where there is an a priori reason to believe that death or disabling injury will occur. The Nuremberg Code, Point 5 (1947) [45].

In 2006, in order to address concerns raised by the public related to adverse health effects of mercury released from the dental amalgam, the FDA organized a scientific assessment, which was based on 34 peer-reviewed articles and released as a draft for the purposes of a panel and committee review [46]. Some excerpts from this draft assessment are presented below.

> In order to address recent concerns related to adverse health effects of dental amalgam, the FDA Associate Commissioner for Science in May 2006 charged the Acting Director of FDA's National Center for Toxicological Research (NCTR) with preparing an assessment of the state of the science regarding the potential health risk of mercury in dental amalgam and to present the assessment to the Medical Devices Advisory Committee and the Peripheral and Central Nervous Systems Drugs Advisory Committee in September 2006. The purpose of the assessment is to determine whether peer-reviewed literature published since 1997, when the USPHS update report on amalgam was released (USPHS 1997), substantially changes the comprehension of the health risk of mercury in dental amalgam. Using recent reviews conducted by other U.S. government agencies including the Agency for Toxic Substance and Disease Registry (ATSDR – 1999, 2005) and the Environmental Protection Agency (EPA – 2002) and relevant additional peer-reviewed research studies, NCTR scientists were charged with providing an assessment and conclusions regarding significant new information and health risks from mercury in dental amalgam. Specifically, what contributions have peer-reviewed studies published after 1997 made to the understanding of human health risks posed by exposure to mercury in dental amalgam?
>
> The previous reviews of the scientific literature pertaining to health risk from mercury in dental amalgam conducted by U.S. government agencies and international bodies were used as the foundation upon which to build the present literature review. The approach was to build on these previous reviews, rather than duplicate these previous extensive efforts. Consequently, the majority of the present review focused on the in-depth evaluation of 34 peer-reviewed, primary research studies selected for their scientific merit and their potential to provide the most significant and new information regarding health risks associated with exposure to mercury vapor.
>
> Based on an evaluation of the extensive literature reviews conducted by ATSDR (1999, 2005) and EPA (2002), and an assessment of the health effects-based exposure reference values for elemental mercury derived by those agencies and WHO and American Conference of Government Industrial Hygienist (ACGIH), no information was found that would change the comprehension of health risks for inorganic or elemental mercury and mercury in dental amalgam. In an effort to obtain new information that might improve understanding or change risk estimates for the use of dental amalgam, twenty-four peer-reviewed scientific articles published primarily since the reviews conducted by ATSDR and EPA and ten peer-reviewed articles for the ATSDR and/or EPA reviews deemed to contain important and relevant information were critically reviewed. Compared to previous analyses performed by USPHS, no significant new information was discovered from the review of these 34 articles that would change the risk estimates by FDA for the use of dental amalgam.

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One of the 34 peer-reviewed articles was a prospective study with a relatively large sample size (n=534) carried out in children, who were aged 6 to 10 years, and had no restorations prior to entering the study. Each child was given either mercury amalgam (n=267) or dental composite (n=267) restorations. Scientific monitoring was performed for 4 to 5 years to assess the effects of mercury released from the amalgam on these children. As a result of this study, the authors concluded that "…there were no statistically significant differences in adverse neuropsychological or renal effects observed over the 5-year period in children whose caries were restored using either dental amalgam or composite materials [47]."

On September 6 and 7, 2006, a joint meeting was held of the Dental Products Panel (CDRH) and the Peripheral and Central Nervous System Drugs Advisory Committee (CDER). The panel and committee met to discuss and make recommendations to the FDA regarding the potential adverse health risks associated with exposure to mercury released from the dental amalgam. The joint committee was comprised of 24 panelists, including consultants. Fifty-two speakers presented information about the amalgam. The committee then deliberated on a series of questions the FDA has posed on its review of amalgam literature. To the question of whether the 34 peer-reviewed articles "objectively and clearly presented the current state of knowledge about the exposure and health effects related to the dental amalgam," the committee voted no by a 13 to 7 margin. To the question of whether it was reasonable to conclude the amalgam was safe based on information presented in the 34 articles, the committee voted no by a 13 to 7 margin. Some of the reasons cited by the majority were that conclusions could not be made because the evidence was often contradictory and that conclusions based on limited research should not be made [48].

Summary and Conclusion Federal regulations have a loophole that allows the amalgam to be assembled in dental offices and installed in patients. This does not denote FDA approval of the amalgam. So the amalgam is truly an unregulated product that dentists assemble. By allowing dental mercury to be distributed the FDA has essentially decided that the dose released from an amalgam is not a poison. It is reasonable to believe that the FDA and other federal organizations have made an unconservative decision.

The FDA has not accepted results of research performed on animal subjects and humans with existing amalgams that indicates the dose of mercury released from an amalgam consistently causes harm to every exposed person and, developing fetus. Neither the FDA, nor any other federal organization, has published any accepted scientific study (simulating amalgam installation) to demonstrate amalgam safety. On September 7, 2006, a panel and committee of government health advisors voted 13 to 7 to reject a draft report's conclusions about amalgam safety.

4.2 Dental organization

The Dentist's Pledge The American Dental Association (ADA) is the dominant dental organization in the U.S. At dental school graduation ceremonies, graduating dentists usually take a pledge. The ADA House of Delegates has approved "The Dentist's Pledge," which is as follows [49]:

> I, (dentist name), as a member of the dental profession, shall keep this pledge and these stipulations.
>
> I understand and accept that my primary responsibility is to my patients, and I shall dedicate my self to render, to the best of my ability, the highest standard of oral health care and to maintain a relationship of respect and confidence. Therefore let all come to me safe in the knowledge that their total health and well-being are my first consideration.
>
> I shall accept the responsibility that as a professional my competence rests on continuing the attainment of knowledge and skill in the arts and sciences of dentistry.
>
> I acknowledge my obligation to support and sustain the honor and integrity of the profession and to conduct myself in all endeavors such that I shall merit the respect of my patients, colleagues, and my community. I further commit myself to the betterment of my community for the benefit of all of society.
>
> I shall faithfully observe the *Principles of Ethics and Code of Professional Conduct* set forth by the profession.
>
> All this I pledge with pride in my commitment to the profession and the public it serves.

The ADA's Code of Ethics The ADA's *Principles of Ethics and Code of Professional Conduct* contains the following statement {50].

> The dental profession holds a special position of trust within society. As a consequence, society affords the profession certain privileges that are not available to members of the public-at-large. In return, the profession makes a commitment to society that its members will adhere to high ethical standards of conduct. These standards are embodied in the ADA *Principles of Ethics and Code of Professional Conduct* (ADA Code). The ADA Code is, in effect, a written expression of the obligations arising from the implied contract between the dental profession and society.

The ADA Code contains the following principles of ethics and professional conduct {50}.

> Patient Autonomy The dentist has a duty to respect the patient's right to self-determination and confidentiality (self-governance).
>
> Beneficence The dentist has a duty to promote the patient's welfare (do good).
>
> Non-Malfeasance The dentist has a duty to refrain from harming the patient (do no harm).
>
> Justice The dentist has a duty to treat people fairly (fairness).
>
> Veracity The dentist has a duty to communicate truthfully (truthfulness).

> Dental Amalgam Based on available scientific data the ADA has determined through the adoption of Resolution 42H-1986 (Transaction 1986:536) "...that the removal of amalgam restorations from the non-allergic patient for the al-

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leged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation of the dentist is improper and unethical."

Unsubstantiated Representations A dentist who represents that dental treatment recommended or performed by the dentist has the capacity to cure or alleviate diseases, infections or other conditions, when such representations are not based upon accepted scientific knowledge or research, is acting unethically.

Classic Biomedical Ethics The Oath of Hippocrates (circa 400 BC) established the moral tradition of Western culture's health care system. The Oath's essence contains these four and other concepts concerning health care: 1) a learned person will make decisions about a professional practice, 2) those decisions will be a benefit to patients, 3) those decisions will keep patients from harm and injustice, and 4) a specialty practitioner may peer-review the procedures and products of another practitioner of the same specialty. A contemporary translation of the Oath is as follows (underlining is added to emphasize aspects of the oath that are relevant to the four concepts presented above) [52]:

I swear by Apollo the Physician and by Asclepius and by Health and Panacea and by all the gods as well as goddesses, making them judges [witnesses], to bring the following oath and written covenant to fulfill in accordance with my power and my judgment; to regard him who has taught me this technique as equal to my parents, and to share, in partnership, my livelihood with him and to give him a share when he is in need of necessities, and to judge the offspring [coming] from him equal to [my] male siblings, and to teach them this technique, should they desire to learn [it], without fee and written covenant, and to give a share both of rules and of lectures, and of all the rest of learning, to my sons and to the [sons] of him who has taught me and to the pupils who have both make a written contract and sworn by a medical convention but by no other. And I will use regimens for the benefit of the ill in accordance with my ability and my judgment, but from [what is] to their harm or injustice I will keep [them]. And I will not give a drug that is deadly to anyone if asked [for it], nor will I suggest the way to such a counsel. And likewise I will not give a woman an estructive pessary. And in a pure and holy way I will guard my life and my technique. I will not cut, and certainly not those suffering from stone, but I will cede [this] to men [who are] practitioners of this activity. Into as many houses as I may enter, I will go for the benefit of the ill, while being far from all voluntary and destructive injustice, especially from sexual acts both upon women's bodies and upon men's, both of the free and of the slaves. And about whatever I may see or hear in treatment, or even without treatment, in the life of human beings -- things that should not ever be blurted out outside --I will remain silent, holding such things to be unutterable [sacred, not to be divulged], If I render this oath fulfilled, and if I do not blur and confound it [making it to no effect] may it be [granted] to me to enjoy the benefits both of life and of technique, being held in good repute among all. Oath of Hippocrates 400 BC

The following four classic principles of biomedical ethics evolved from the Oath of Hypocrites; they pertain to both patients and physicians [53]:

Autonomy – a physician may disclose information that can benefit a patient. Each patient has the right to make choices for him/her self. Part of the essence of this principal is similar to the freedom of speech that is guaranteed to U.S. citizens by the first amendment of the constitution.

Beneficence – physicians have a responsibility to benefit patients. Positive steps can be taken to both prevent and remove sources of harm from the patient.

Non-malfeasance – physicians should refrain from practices that cause unnecessary harm to patients. In a professional care setting, a physician may be morally and legally blameworthy if the standards of due care are not met.

Justice – decisions can be made impartially. Everyone is entitled to health care. Part of the essence of this principal is similar to the freedom of religion or beliefs that is guaranteed to U.S. citizens by the first amendment of the constitution.

The essence of the Oath and these four principles of biomedical ethics have been summarized as the *first do no harm* tradition of health care. It has been the premier tradition of health care practice and administration for more than two millennia. A naïve patient implicitly places his or her trust in professionals and health care systems to honor that tradition.

ADA and the Amalgam According to the ADA Code, the dental profession holds a special position of trust within society [50]. The code does not state that the ADA itself holds a special position of trust within society. This dodge of trust or duty has been expressed in a superior court demurrer as follows:

The American Dental Association (ADA) owes no legal duty of care to protect the public from allegedly dangerous products used by dentists. The ADA did not manufacture, design, supply or install the mercury-containing amalgams. The ADA does not control those who do. The ADA's only alleged involvement in the product was to provide information regarding its use. Dissemination of information relating to the practice of dentistry does not create a duty of care to protect the public from potential injury [54].

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Even with this expressed lack of duty to protect the public the ADA has effectively concluded that the dose of mercury released from an amalgam is not a poison for patients. The veracity aspect of the ADA Code, and the following two public statements, respectively made in 1990 and 1998, express this conclusion:

> The strongest and most convincing support we have for the safety of dental amalgam is the fact that each year more than 100 million amalgam fillings are placed in the United States. And since amalgam has been used for more than 150 years, literally billions of amalgam fillings have been successfully used to restore decayed teeth [5].

> The ADA's Council on Scientific Affairs Statement: "The Council concludes that, based on available scientific information, the amalgam continues to be a safe and effective restorative material" [55].

Comparison of the ADA Code with Classic Biomedical Ethics The ADA Code does not address some aspects of classical biomedical ethics and contains a veracity aspect. This omission and alteration are described below.

Autonomy The veracity aspect of the ADA Code binds a dentist to communicate only accepted scientific knowledge or research. The ADA, however, has not accepted scientific research indicating that mercury released from the amalgam is a hazard and does harm. The ADA Code restricts dentists from communicating with their patients the results of scientific research pertaining to amalgam hazards. Thus a dentist lacks autonomy in the amalgam issue.

Beneficence Both the Oath and the principles of biomedical ethics allow for repairing harm done, while this is not addressed by the ADA Code.

Justice This principle allows decisions like what dose of mercury makes a poison to be made impartially by individual dentists. The ADA Code does not allow that.

Veracity The ADA Code contains a veracity aspect, which means truthful communication. Classic codes of biomedical ethics have commonly not specifically included veracity as a primary principal, because its essence is contained with in autonomy, non-malfeasance, beneficence, and justice.

Thus, the ADA has decided that the amalgam is a safe and effective restorative material for patients. It is an unconservative decision. Because the ADA has legally stated they do not have, "…a duty of care to protect the public from potential injury," it is not appropriate for them to make that decision.

The ADA Code does not address aspects of autonomy, beneficence, and justice that allow individual dentists to peer-review another dentist's work and decide for patients with existing amalgams that the dose of mercury they are receiving is a poison. That essentially is an ethics-gap. The ADA Code also has a veracity aspect that does not allow a dentist to communicate this decision to a patient and properly remove an amalgam if the patient concurs. That effectively acts as a gag-rule. In a circuitous way, both the ethics-gap and gag-rule allow for amalgam installation

> Power tends to corrupt, and absolute power corrupts absolutely. Lord Action 1887

4.3 State governments

State governments have statutes that empower dental boards to license dentists and police the practice of dentistry. Most, if not all, of these statutes allow dental boards to adopt policies that become part of the state administrative code. Dental boards commonly make a policy that the dose of mercury released by an amalgam is not a poison by adopting the ADA Code, with its veracity aspect, as an ethical standard for all dentists in their state. That policy even applies to dentists who are not members of the ADA. A dentist often has to agree to abide by the ADA Code when applying for and renewing a license, thereby effectively restricting him from independently deciding what dose of mercury is a poison for patients with existing amalgams.

> Ethical Standards -- The *"Principles of Ethics and Code of Professional Conduct"* of the American Dental Association is adopted by reference as the ethical standard for dentists and applies to all dentists in the state [56].

By allowing the veracity aspect of the ADA Code to be adopted as an ethical standard, states have effectively established a non-autonomous policy for dentists, whereby the dose of mercury released by the amalgam is not a poison. This makes amalgam removal for health reasons malfeasance and, in a circuitous way, it makes amalgam installation non-malfeasance.

Most members of state dental boards belong to the ADA. On the basis of the ADA Code, state dental boards have taken disciplinary action against dentists who have independently concluded that the dose of mercury released from existing amalgams is a poison and who have provided amalgam removal recommendations to patients based on that reason [57]. The disciplinary action has varied from loss of license to restrictions placed on practice.

4.4 Patient

A patient is first exposed to the *first do no harm* tradition at birth and, subsequently, often received the benefit of it during situations when health care is needed. Because of: 1) the complexities of science and its relationship to a practice that they do not understand, and 2) the many benefits they and their parents have received from health care practitioners, a naive patient innocently places his or her trust in any professional who performs a health care service to honor the *first do no harm* tradition.

The knowledge of dentistry and understanding of science varies widely among patients. Some patients will become aware of the amalgam's hazards through communication with other patients and easily decide that the dose of mercury is a poison.

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Other patients never will. The ADA Code does not prohibit patients from deciding that the dose of mercury released from an amalgam is a poison and requesting that they be removed. So a dentist can remove amalgams from a patient if they request it.

Our society, however, has a system of professionalism that originated with the Oath of Hippocrates. The Oath's essence allows a learned professional to make the fundamental decisions of a health care practice, such as what dose of mercury is a poison. The Oath also allows the professional to inform a patient when they believe a hazard exists. Most patients trust professionals to make these decisions and to inform them if they believe that a hazard exists with a product.

4.5 Dentist

A dentist's first responsibility is to *first do no harm* to his or her patients'. A dentist completes a graduate school curriculum that educates him/her in the science pertinent to the dental profession. The dentist then becomes licensed in a system established by state statute to perform the service as a professional. With true professionalism, under the principles of justice and autonomy, a dentist is able to independently make fundamental decisions such as what dose of mercury makes a poison and communicate it to their patient(s). Under the principle of beneficence, that decision should apply to both new and existing dental restorations. The fee a patient pays for this service is reimbursement for those professional decisions.

If a dentist believes that the dose of mercury released from an amalgam is not a poison; then, according to the *first do no harm* tradition it is acceptable for the dentist to install the amalgam. If another dentist believes that the dose of mercury released is a poison, then the *first do no harm* tradition allows him/her to remove an amalgam for health reasons.

A dentist's second responsibility is to *first do no harm* within the profession. A person educated in the science and the art of dentistry should know best what is an appropriate dental service and product. It is a dentist's responsibility to establish within his/her profession what dose of mercury makes a poison. If a product has systematic and widespread use, it should be evaluated using both scientific assessment and investigation using non-human subjects. The results should demonstrate beyond doubt that potential poisonous exposures for all patients are next to nil. The results should be published and not be refuted by the scientific process. A dentist should be able to inform patients of the results of any scientific research that he/she believes is pertinent to the patient's health.

A dentist's third responsibility is to *first do no harm* to him or herself. Scientific studies have also been performed to explore the effect that mercury has on dentists due to their occupational exposure to the amalgam [58, 59]. Based on results of these studies, many dentists have concluded that the dose of amalgam mercury they occupationally expose themselves to is a poison. Therefore, to protect themselves, dentists are installing fewer amalgams [60].

5. Government action

People who believe that the dose of mercury released from an amalgam is a poison have proposed two alternative government approaches to discourage amalgam installation: 1) requiring informative action before amalgam installation, or 2) encouraging professional outreach by allowing dentists to examine existing dental restorations and remove them if they believe that a hazard exists. State statutes or federal regulation that require informative action by dentists, such as: 1) having patients read and sign informational documents, 2) posting of warning signs, and 3) distribution of brochures or fact sheets before amalgam installation have been termed informed consent. They lack prudence in the *first do no harm* tradition because of the fallacies (debased and dysfunctional non sense) described below. Whereas encouraging professional outreach with an amalgam removal policy or state permissive statute will inspire enterprise, cause an amalgam phase out, and eventually their ban as described below.

> Most folks have it backwards. They try to manage others, and invite themselves; when what we're called to do is manage ourselves and invite others. Tracy Lenda

5.1 The fallacies of informed consent pertaining to amalgam installation

Informed Consent is Contrary to Tradition Requiring informed consent before the installation of any harmful product, such as the amalgam, does not adhere to the *first do no harm* tradition that evolved from the Oath, which has been taken by Western physicians for more than two millennia. Because of the long-standing tradition, patients assume that dentists abide by it and not The Dental Pledge. The Oath implies that physicians will not install harmful products. Therefore, discouraging the installation of any harmful product by a dentist, with an adverse message to the patient, is contrary to tradition.

> "…I will use regimens for the benefit of the ill…from [what is] to their harm or injustice I will keep [them]…" Oath of Hypocrites, circa 400 BC

> The patient may doubt his relatives, his sons and even his parents, but he has full faith in his physician. He gives himself up in the physician's hands and has no misgivings about him. Therefore, it is the physician's duty to look after him as his own. Charaka, circa 78

> A form of government that is not the result of a long sequence of shared experiences, efforts, and endeavors can never take root. Napoleon Bonaparte, circa 1800

Informed Consent Originally Was Meant for Experimental Purposes Two purposes of traditional informed consent are: 1) to provide the patient with complete information with which to make a decision prior to receiving a procedure that is an experiment, and 2) to protect the physician from liability (provided that the procedure is properly executed according to the prevailing standard of care and without negligence). In general the experiment should: 1) yield fruitful results for the good of society, unprocurable by other methods, and 2) not be con-

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ducted when there is reason to believe that death or disabling injury will occur. Informed consent, which became formalized with the Nuremberg Code, was not meant as a health care approach for products and procedures that have widespread and systematic use. The amalgam is a product that is placed in the teeth of many patients on a routine and not an experimental basis.

> The voluntary consent of the human subject [for an experiment] is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The Nuremberg Code, Point 1, 1947 [45].

> Except for the prudent correction of an imminent danger, I will neither treat any patient nor carry out any research on any human being without the valid informed consent of the subject…understanding that research must have as its purpose the furtherance of the health of that individual. Modern Day Hippocratic Oath (1995) [61].

Informed Consent Demeans Professionalism A dentist completes a graduate school curriculum that educates him/her in the science of the dental profession. He/she then becomes licensed to provide dental services as a professional. With true professionalism, the fundamental decisions of a practice, such as what dose of mercury is a poison and proper products to use, are made by the dentist. The fee a patient pays for this service is reimbursement for these professional decisions. If a dentist is required to inform a patient of hazardous products used and does so before its installation, part of the responsibility of choice then shifts to the patient. The amalgam will then become more of a consumer product and less of a professional product. Thus, professionalism is demeaned by statutory informed consent pertaining to amalgam installation.

> The difference between a professional person and a technician is that a technician knows everything about his job except its ultimate purpose and his place in the scheme of things. Richard W. Livingston

Informed Consent Will Be Done With a Positive Message There is a growing body of scientific research and other information pertaining to amalgam. Some of the information is incautious; such as the ADA's Council on Scientific Affairs 1998 Statement "The Council concludes that, based on available scientific information, the amalgam continues to be a safe and effective restorative material."

Due to the long-standing *first do no harm* tradition; any information given by a dentist to a patient before installing an amalgam will always contain a bias indicating it could be inert. That bias is justified because no controlled study has directly proven the dose of mercury an amalgam releases causes harm to humans. And every U.S. citizen is entitled to a bias by the first amendment of the constitution (freedom of beliefs).

The amalgam is a highly studied product and the complete amount of information about it will never be presented to a patient during the short time of a dental visit. If a dentist follows through with informed consent before installing an amalgam, because of the long-standing *first do no harm* tradition of health care, there will be a positive message with the information presented**.** That positive message will be justified by unconservative, dubious research.

> Bias and impartiality are in the eye of the beholder. Lord Barnett

> There are no specific diseases. There are only specific disease conditions. Florence Nightingale

Informed Consent Will Be Rarely If Ever Done With a Negative Message Denial, justification, and bias are part of human nature. Dictation of a alternative bias won't be performed through a dentist who does not have it. A dentist who has knowingly performed a harmful act by installing amalgams is rarely if ever going to comply with presenting an adverse message about his professional history just because a new statute requires it. The greatest fear of amalgam installing dentists is disclosure; they are not going to disclose themselves.

> Free speech, to be free, has to cover everyone, not just the politically fashionable. Robert J. Samuelson

> The more I study the world, the more I am convinced of the inability of brute force to create anything durable. Napoleon Bonaparte

Informed Consent Allows For Amalgam Installation Informed consent allows a dentist to install an amalgam if a patient concurs. For people who believe the dose of mercury released is a poison, advocating for informed consent before amalgam installation does not adhere to the *first do no harm* tradition.

The immediate cost of an amalgam is about half that of a composite restoration. The decision of the majority of patients will set the morality. If a majority of patients consent to amalgam installation, then it may become non-malfeasance.

> The majority sets the morality. Machiavelli

> Whoever desires to found a state and give it laws, must start with assuming that all men are bad and ever ready to display their vicious nature, whenever they may find occasion for it. Machiavelli

Informed Consent Pre-empts Federal Responsibilities Because of a federal loophole, amalgam constituents are distributed and assembled by dentists in and unregulated manner. The patient, or parent(s), who probably are voters and taxpayers, has participated in developing a federal system that today has legal authority and responsibility to regulate the products used in dentistry. Most patients trust the federal system to watch out and protect them from harmful products. The FDA has made an

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unconservative decision and might keep to it if statutes and regulations that allow for amalgam installation pre-empt their authority.

> Real merit of any kind cannot long be concealed; it will be discovered, and nothing can depreciate it but a man exhibiting it himself. It may not always be rewarded, as it ought; but it will always be known. Lord Chesterfield

Changing the Responsibility Approach to our Health Care System will Cause Confusion for Generations Changing from a parochial to a rationally based measurement system has been a source of difficulty and confusion for more than 200 years. Changing from a professionally-based to a consumer-based health care system will also cause confusion for several generations.

> Scientists had another idea which was totally at odds with the benefits to be derived from the standardization of weights and measures. They adopted to them the decimal system on the basis of the meter as a unit; they suppressed all complicated numbers. Nothing is more contrary to the organization of the mind, of the memory, and of the imagination. The new system of weights and measures will be a stumbling block and a source of difficulties for several generations. It's just tormenting the people with trivia. Napoleon Bonaparte

A Federal Provision for Informed Consent Already Exists, But Has Not Been Implemented A federal provision for informed consent is provided in the Medical Device Amendments of 1976. It is part of the United States Code. The FDA has never implemented informed consent pertaining to amalgam installation, because of the above listed fallacies.

> Notification If the Secretary determines that (1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk [62].

5.2 Professional outreach

The FDA claims there is no study that indicates the dose of mercury released by an amalgam causes harm to individuals, and the ADA has decided that the amalgam is a safe and effective restorative material for patients. Both the FDA and ADA are entitled to those biases by the first amendment of our constitution (freedom of beliefs).

Each individual dentist, however, is also entitled to his/her own bias. Many dentists silently believe that data obtained from studies using animal subjects are relevant to humans. They also silently believe that data obtained using human subjects with existing amalgams are generated with prudent research. On the basis of those justifications, many dentists believe the dose of mercury released from an amalgam causes harm to humans.

Each year, dentists are installing fewer amalgam and more composite restorations. Consequently, amalgam installation is declining [60]. This amalgam phase-out is occurring on a volunteer basis because scientists, dentists, and activists, who acknowledge that it is reasonable to believe the dose of mercury released is a poison, are reaching out and disclosing what has been discovered. Many patients, however, have amalgams in their teeth. They are unknowingly becoming ill from these existing amalgams. The problem of removing existing amalgams for health reasons is becoming more important than ending amalgam installation.

To succeed at ending amalgam installation, the focus of action needs to capitalize on the traditions of our culture and ways of our government. The federal government regulates distribution of health care products, whereas state governments regulate health care services. The federal government has a system to enforce regulations pertaining to the distribution of dental products. Federal regulation can effectively ban the distribution of dental mercury and amalgam alloy and, thus, end amalgam installation. Amalgam removal is a service, therefore state policies or statutes need to address it; federal regulation never will because existing amalgams are a product that has already been distributed and installed in patients. Synergistic federal and state government beneficent action can, therefore, be obtained with: 1) federal regulation that bans the distribution of dental mercury and amalgam alloy for any reason, and 2) state action that encourages proper amalgam removal.

> When you run alone you run fast but when you run together you run far. African Proverb

State governments have boards that regulate dental services. These boards get their authority from state statutes. Most, if not all, state dental statutes allow their boards to adopt the ADA Code, with its veracity aspect, as an ethical standard. That code restricts dentists, who believe the dose of mercury released from an amalgam is a poison, to discuss with patients the health hazard they believe exists. That allows: 1) an organizational consensus, which mandates that the dose is not a poison, to prevail over individual autonomy in dentistry, and consequently 2) the ADA to maintain an organizational grip in dentistry concerning the dental amalgam issue. When organizational consensus prevails over individual autonomy you do not have professionalism.

> Where all think alike, no one thinks much. Walter Lippmann

> …I will use regimens for the benefit of the ill in accordance with my ability and my judgment, but from [what is] to their harm or injustice I will keep [them]… Oath of Hypocrites, circa 400 BC

The ADA will lose their organizational grip when 1) the veracity aspect of the ADA Code is removed and replaced or pre-empted, and 2) the biomedical ethics aspects of autonomy,

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beneficence, and justice that are not addressed by the ADA Code legally become available to dentists. Then dentists will not be restricted from discussing with patients health hazards associated with existing restorations such as the amalgam. Dentists will also be able to remove amalgams, in a professional manner if the patient concurs (i.e. professional outreach).

> The transfer of concepts as models from one field to another requires intimacy, informality, and friendliness because the transfer usually is not a conscious process. Edwin Land

Amalgam poisoning is a sustained and not an immediate problem. To succeed in putting an end to amalgam installation, a persistent message about its associated hazards needs to be available. Allowing for professional outreach through dentists can disperse that message. As professional outreach grows, a dentist will less likely install amalgams and more likely properly remove them. Replacing the ADA Code's veracity aspects with the following suggested dental amalgam removal policy provided below will encourage professional outreach.

Suggested Dental Amalgam Removal Policy

- A dentist may inform patients of research pertaining to amalgam restorations.
- Before removing amalgam restorations, a dentist should inquire about medical conditions that a patient might have, and if necessary, advise the patient to consult with a medical doctor knowledgeable about the amalgam removal process. The patient should receive medical advice from the doctor regarding preparation for the removal process.
- A dentist should remove amalgams in accordance with recognized techniques.
- A dentist may choose not to remove a patient's amalgams.

If a state dental board is not willing to remove the ADA Code's veracity aspects and replace them with an amalgam removal policy, then a state statute that pre-empts them will be needed in order to move the amalgam issue into the dental profession. The suggested dental peer-review statute will: 1) provide for biomedical ethics aspects of autonomy, beneficence, and justice that are not addressed by the ADA Code (bridge the ethics-gap), 2) pre-empt the ADA Code's veracity aspects (over ride the gag-rule), 3) prevent an organizational grip from forming in dentistry, and 4) discourage harmful restorative products that dentists can assemble in their office from entering the market place. That statute will allow a dentist to legally peer-review restorative material installed by another dentist and inform the patient that (based on his/her belief) a hazard is present, then properly replace it if the patient concurs.

> Suggested Dental Peer-Review Statute A patient may be informed of research pertaining to dental restorative material. A patient may have dental restorative material replaced in accordance with recognized techniques.

The federal government will ban the distribution of dental mercury and amalgam alloy when: 1) enough dentists believe that the dose of mercury released from an amalgam is a poison (jurors on the amalgam are dentists), 2) the FDA looks as if they have made an unconservative decision, or 3) Congress passes a prohibition act. A state policy or a statute, which encourages amalgam removal through professional outreach, will: 1) increase the number of dentists who believe that the amalgam should be banned, and 2) send a circuitous message, which is compatible with the *first do no harm* tradition, to the FDA that does not pre-empt their authority and makes them look as if they have made an unconservative decision. Also, a federal ban will be more effective and lasting if professional outreach is present.

> An important scientific innovation rarely makes its way by gradually winning over and converting its opponents.... What does happen is that its opponents gradually die out and the growing generation is familiarized with the idea from the beginning. Max Planck, German Physicist 1936

6. Closing

More than two centuries ago, Benjamin Rush foresaw the calamity that would be caused by restricting the art of healing to one class of men. That calamity has occurred by restricting the practice of dentistry solely to policies established by the ADA. Today, there is a growing body of scientific research that indicates mercury released from the dental amalgam, which the ADA has claimed to be safe for more than 170 years, causes harm to every exposed person and developing fetus. To discourage the amalgam and other products like it from entering the market place, state policies or statutes that allow for dental restoration removal for health reasons are needed. The policies or statutes need to allow for aspects of autonomy, beneficence, and justice that are not addressed by the present ADA Code. When these become available to dentists, then individual autonomy will prevail over organizational consensus in dentistry. That will inspire enterprise and result in a phase out and eventually the ban of the amalgam. That will also keep products like the amalgam from entering the market place.

> An army marches on its stomach. Napoleon Bonaparte

> Unless we put medical freedom into the constitution, the time will come when medicine will organize itself into an undercover dictatorship. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic. Benjamin Rush, Revolutionary War hero, physician, and signer of the Declaration of Independence

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