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**Of 464 pages of Documentation presented by
Florida Dental Association to Dental Board
September 29, 2001**

List of Contents

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7. Advances in Dental Research,
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-Science on Safety of amalgam challenged. Twin law suits filed in California against the American Dental Association and the California Dental Association over failure to inform patients of presence of mercury in dental amalgams and seeks to bar the ADA and CDA from disseminating "false, misleading and inaccurate" information of the existence and toxicity of mercury in amalgam.

California dental board disbanded?

Citing frustration with the state dental board's unresponsiveness in revising a fact sheet on dental materials, including mercury, a state Senator wants to pull the board's funding.

"The dental board has blatantly and continually failed to carry out its duties in an effective and efficient manner the Senator testified.

Maryland lawsuit charges dental board.

Another lawsuit involving dental amalgam was filed May 9 (2001) against the Maryland state board of dental examiners, charging the board, individually and as a representative of a class of defendants, with violating dentists' freedom of speech, civil rights, due process and equal protection.

The suit seeks to “allow” dentists to disclose the risks of mercury-based dental fillings and health warnings which manufacturers of dental amalgam include with their product.

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Maine passes trio of mercury laws

New laws restrict sale of mercury added products.

Another law will require dentists who use amalgam to give each patient a brochure on the advantages and disadvantages of mercury.

Dentists must also display a poster in the waiting room indicating the brochure is available.

12. National Multiple Sclerosis Society Letter,

March 12, 1991

009317-009318

(pg.009317 – No proper clinical study has been done to address the question of whether removal of dental amalgam fillings benefits people with multiple sclerosis.)

TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available. Talk Papers are not intended for general distribution outside FDA, but all information in them is public, and full texts are releasable upon request.

T91-15
March 20, 1991

Susan Cruzan
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FDA Panel Considers Safety of Dental Amalgams

FDA's Dental Devices Panel met today to discuss recent research and patient case reports related to the possible hazards associated with dental amalgam fillings. The panel was asked to address whether the mercury in amalgam fillings can pose a risk to patients and to advise the agency on the types of studies needed to further assess the safety of these devices.

The following may be used to respond to questions.

Several clinicians, patients, researchers, manufacturers and organizations, including the American Dental Association and the National Institute for Dental Research, expressed their views on possible hazards and research needs in this area. The panel reviewed recent animal studies and human case reports which have raised questions about the continued use of these devices.

The panel concluded that none of the data presented shows a direct hazard to humans from dental amalgams. However, the panel agreed that the studies presented did raise questions that warrant further research. The panel recommended that FDA establish a special working group to identify the kinds of animal and human studies needed to answer the question of amalgam safety. This group would work in collaboration with other research organizations such as the National Institute for Dental Research.

The panel's recommendations are not binding, but FDA will take them under consideration. FDA agrees with the panel that additional research is

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needed to resolve unanswered questions about amalgam safety. In the months to come, FDA will decide on the best means of assuring that this research is undertaken.

In the meantime, FDA does not advise that individuals ask dentists to remove their amalgams. FDA agrees with the advisory panel that there is no valid data to demonstrate clinical harm to patients from amalgams, or that having them removed will prevent adverse health effects or reverse the course of existing diseases.

Dental amalgams, a mixture of silver and mercury, have been used for over 150 years. The mercury allows the amalgam to flow smoothly into the dental cavity. This material is ideal for cavities because it adheres tightly to the cavity, sets up hard and resists abrasion.

~~###~~

mechanisms. "Improvement" after removal of dental amalgam may be coincidental, especially when the complete exposure situation has not been determined.

Not all sources of mercury and their exposure durations that contribute to the total body burden are identified routinely. Mercury exposure from dental amalgam must be put into perspective with respect to total mercury intake from the diet, ambient air, water, cosmetics, and drug therapy.

Other factors can influence the dose of amalgam constituents available to interact with the central nervous system (CNS) (e.g., alcohol consumption, use of tobacco, bruxism, oral vs. nasal breathing, gum chewing, iron-deficiency anemia and other dietary deficiencies, acatalasia, and drug therapies).

Susceptibility of the CNS can vary with critical periods of brain development. Experience with other agents damaging the nervous system (e.g., lead, radiation, alcohol, etc.) has demonstrated that we might expect a wide range of potential CNS dysfunction, depending on the stage of development at the time of exposure.

Mercury can be neurotoxic to dental personnel if it is repeatedly mishandled during trituration, placement, or removal of amalgams. The brain is considered the critical target organ. Chronic exposure to high levels of elemental mercury vapor (the form of mercury most likely encountered when dental restorative materials are being handled) can affect the nervous system, but the variety of symptoms induced by severe exposures can be prevented when even simple handling precautions are heeded.

The kidney has also been identified as a major organ for sharing the body burden of mercury. Studies of individuals with long-term low-level occupational exposure to mercury vapor have not demonstrated any significant renal functional abnormalities. At present, no scientific evidence exists that mercury from dental amalgam contributes to renal disease in dental workers or their patients.

QUESTION 4. WHAT ARE THE BENEFIT/RISK RATIOS OF DIFFERENT TOOTH RESTORATIVE MATERIALS?

Benefits include ease of placement of the material for both the patient and dental personnel involved, cost, longevity, ability to maintain and improve such functions as eating and speaking, freedom from pain, esthetics, and effect on tooth life expectancy. All these benefits should be assessed in light of their contribution to dental, oral, and general health and well-being. ~~The risks associated with these materials may be short- or long-term or localized or systemic and may pertain to special population groups such as pregnant women, young children, dental personnel, or individuals with particular immunological predispositions.~~

Lack of reliable quantitative estimates of the risks and benefits of the various dental materials discussed at this conference precludes calculation of benefit/risk ratios. The paucity of data concerning predictable risks associated with

restorative dental materials was striking. As a result, benefits and risks can be compared in only qualitative rather than quantitative terms.

Different clinical conditions require restorative materials with particular qualities and characteristics, including malleability, strength, and esthetics. Although for some restorative needs, more than one material fulfills the requirements, for others, only one is appropriate. However, the benefits of single tooth restorative materials are similar when the materials are selected properly. Composites, glass-ionomer cements, and ceramics provide excellent esthetics and, as technological developments progress, improved longevity. Amalgams, cast alloys, and ceramics, however, offer additional strength and durability.

All materials introduced into the oral cavity may present some risk to the general population. Selected individuals and groups may experience greater risks because of heredity or unusual clinical characteristics. Taking all the evidence that is presently available, the benefits of existing dental restorative procedures far outweigh the currently documented risks.

QUESTION 5. WHAT SHOULD BE THE FUTURE DIRECTIONS FOR RESEARCH ON MATERIALS FOR TOOTH RESTORATIONS?

- (1) Carry out long-term epidemiological and multidisciplinary studies to determine whether there is a link between restorative materials and the incidence of local and/or systemic effects and establish the benefit/risk ratios of these materials.
- (2) Determine the long-term effects of dental restorative materials on the developing organism.
- (3) Develop new methods and materials for restoring teeth, such as utilizing bonding agents with improved composites, amalgams, and new biocompatible materials that minimize removal of healthy tooth structure, release cariostatic agents, and reduce the risk of side-effects.
- (4) Determine the composition, degradation, release pattern, and pharmacokinetics of all restorative materials and their components under a variety of conditions. The effects of such materials and their components on cells, tissues, and organs should be established.
- (5) Investigate the cellular and molecular mechanisms by which mercury at different concentrations damages different types of cells (e.g., CNS, kidney, oral epithelium, etc.).

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Current dental restorative materials can be used effectively for restoring teeth for functional or esthetic reasons. Virtually all restorative materials have components with potential health risks. However, there is no scientific evidence that currently used restorative materials cause significant side-effects. Available data do not justify discontinuing the use of any currently available dental restorative materials or recommending their replacement.

Although mercury vapor is released from dental amalgam, the quantities released are very small and do not cause verifiable adverse effects on human beings. While the current evidence supports the concept that existing dental restorative materials are safe, it must be recognized that the supporting data are incomplete.

Recommendations

(1) Manufacturers of all restorative materials should provide

an insert or "stickers" listing the constituents used to formulate each material. This information should be referenced in each patient's chart.

(2) Dentists should install devices to recover waste amalgam residues in their offices for recycling to reduce environmental contamination.

(3) A specific Food and Drug Administration program should be established for reporting and investigating adverse reactions to dental restorative materials.

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"Biodegradability of Dental Ceramics"

Stephen C. Bayne, MS, PhD
"Dental Composites/Glass Ionomers: Clinical Reports"

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"Dental Amalgam: Environmental Aspects"

Rafael L. Bowen, DDS
"Dental Composites/Glass Ionomers: The Materials"

Thomas W. Clarkson, PhD, MD
"Principles of Risk Assessment"

Chester W. Douglass, DMD, PhD
"Future Needs for Dental Restorative Materials"

Carl W. Fairhurst, PhD
"Dental Ceramics: The State of the Science"

Palle Holmstrup, Dr. Odont., DDS, PhD
"Oral Mucosa and Skin Reactions Related to Amalgam"

K. Sune Larsson, DDS, PhD
"Teratological Aspects of Dental Amalgam"

Linda C. Lucas, PhD
"Biodegradation of Restorative Metallic Systems"

J. Rodway Mackert, Jr., DMD, PhD
"Side-effects of Dental Ceramics"

Miroslav Marek, PhD
"Interactions Between Dental Amalgams and the Oral Environment"

Sally J. Marshall, PhD
"Dental Amalgam: The Materials"

Ivar A. Mjor, BDS, MSD, MS, Dr.odont.
"Problems and Benefits Associated with Restorative Materials: Side-effects and Cost-Benefit Analysis"

Harold F. Morris, DDS, MS
"Casting Alloys: The Materials and the Clinical Effects"

Erk Christian Munksgaard, PhD, Dr.odont.
"Toxic and Allergic Reactions Induced by Dental Restorative Materials"

Gudbrand Øilo, Dr.odont.
"Biodegradation of Dental Composites/Glass-ionomer Cements"

Research

It was clear from the findings of the CCEHRP Subcommittee on Risk Assessment that additional research is needed to resolve the question of whether the mercury in dental amalgam poses any significant health risk to patients. The answer to this question would resolve the two basic public health policy issues regarding dental amalgam: whether amalgam restorations should continue to be used in the future, and whether existing restorations should be removed and replaced with other materials.

The Subcommittee on Risk Management (through an interagency Research Work Group) was charged with looking into several aspects of research on the health effects of dental amalgam. These are the group's conclusions:

- Research is needed on the specific health effects of low-level mercury exposure; on the absorption, distribution, metabolism and elimination of this material; on potential biological markers for exposure and effect; on the medical significance of such markers; and on the significance of various blood, urine or tissue levels of mercury.
- Among the issues high on any dental amalgam research agenda would be the following: whether low-level mercury effects are prevalent in the general population, and whether these can be attributed to amalgam; which special population groups, if any (e.g., children, pregnant women, or those with renal disease), might be especially sensitive to mercury effects; how human studies could be designed to assess the potential effects of dental amalgam; whether existing amalgam should be replaced and, if so, under what circumstances; how the mercury in amalgam might be stabilized to minimize release into the body; and, how safe and effective are the existing alternatives to amalgam.

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Education

Over the past decade, the use of amalgam has declined because of a decrease in dental caries and improvement in alternative materials. Nevertheless, dental amalgam continues to play an important role in the dental restorative process. Recently, a number of public health concerns regarding mercury in dental amalgam have been raised. Although no controlled clinical studies have shown adverse human health consequences associated with chronic low-dose exposure to mercury, public concern has been seen. For example, in a 1991 survey commissioned by the American Dental Association, 20 percent of those responding had considered having their amalgam restorations removed or had actually had them removed because of concern over the potential health risks. The lack of a definitive educational initiative by Federal health agencies may be a contributory factor in the anxiety experienced by the public.

The CCEHRP Subcommittee on Risk Management charged the Education Work Group to consider whether new consumer and professional educational efforts were needed. The Work Group reached the following conclusions:

- ~~The public and the health care community must be properly informed about the risks and benefits of dental amalgam.~~ However, this will be difficult in view of the diverse nature of the intended audiences and their varying perceptions of risk.
- Dentists, physicians and other health professionals need accurate information about the risks and benefits of all dental restorative materials in order to provide patients with the information necessary to make informed and intelligent choices in regard to dental restorative material selection or removal. (At present, available scientific data do not support the need for removal of otherwise sound dental amalgam restorations.)
- Third party payers should be educated on relevant topics of tooth conservation techniques and materials such as sealants and preventive resin and appropriateness of restoration repair in specific cases to assure reimbursement.

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people may develop mild reactions such as irritation or redness near the restored tooth, but most patients are not at risk," said panel chairman Dr. William McHugh, director of the Eastman Dental Center at the University of Rochester. "In reviewing the available data, however, we found no evidence that dental restorations are related to the development of disease."

While silver amalgam has received considerable attention because of its mercury content, its potential to cause side effects is no greater than that of any other restorative material, the panel concluded.

In addition to silver amalgam, the panel reviewed data on other materials including metal alloys, ceramics, tooth-colored plastic composites, and glass ionomers. The group noted that selection of the most appropriate material depends on the type of restoration required, the condition of the mouth, the resulting aesthetics, and cost factors.

The 14-member panel called for studies to verify the safety of restorative materials and to detect any adverse effects, however minimal. Future research also should focus on developing new methods and materials for tooth restoration that would minimize the removal of healthy tooth structure and reduce the risk of potential side effects, the panel said.

This 3-day technology assessment conference on the effects and side effects of dental restorative materials was sponsored by the National Institute of Dental Research and the NIH Office of Medical Applications of Research.

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Today's News

July 16, 2001

Stories

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San Francisco — The American Dental Association and the California Dental Association both view as without merit two lawsuits alleging the associations deceive patients about the presence of mercury in dental amalgams.

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The twin suits filed in Los Angeles and then in San Francisco seek injunctive relief that would bar the ADA and CDA from disseminating "false, misleading and inaccurate" information on the existence and toxicity of mercury in amalgam.

The suits also seek monetary restitution from the associations for making representations "deliberately intended to disguise mercury amalgam fillings as silver," for conspiring to "assure that consumers ... remain oblivious" to amalgam dangers, and for "continuous efforts to 'gag' any opposition" from dentists so the ADA could continue to "profit" from sales of pro-amalgam literature.

"This litigation appears to be an effort to 'gag' scientific debate," countered ADA president Dr. Robert M. Anderton. "This complaint is without merit, and the ADA and CDA will mount a vigorous defense."

The ADA does not conceal that dental amalgam contains mercury and has long held the view that dentists should offer treatment based on the best scientific evidence — including the scientific fact that mercury in dental amalgam binds with other components to form a hard, stable restorative material.

"Based on studies to date, there is no sound scientific evidence supporting a link between amalgam fillings and systemic diseases or chronic illness," says Peter Sfikas, ADA general counsel. "It simply has not been shown that dental amalgam causes systemic toxicity. This position is shared by all major U.S. public health agencies."

"If the plaintiffs are successful," Dr. Anderton added, "it would establish the precedent that professional associations cannot form scientific opinions and communicate those opinions to the public and the profession without fear of being sued by those who do not share their views."

The plaintiffs in one of the twin lawsuits are Kids Against Pollution and other anti-amalgam groups; the other seeks class-action status.

Other state legislative activity related to mercury in amalgam includes:

California dental board disbanded?

Sacramento, Calif. — Citing frustration with the state dental board's

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unresponsiveness in revising a fact sheet on dental materials, including mercury, state Sen. Liz Figueroa wants to pull the board's funding.

"The dental board has blatantly and continually failed to carry out its duties in an effective and efficient manner," Sen. Figueroa (D-Fremont) testified June 26 before the state senate, hoping to convince legislators to "transfer funds from the dental board to the [California] Dept. of Consumer Affairs, for the purpose of performing the board's duties until a new dental board is created on Jan. 1, 2002."

"We are very displeased," added Lynn Morris, director of the state Dept. of Consumer Affairs. "The members of the board do not understand the gravity of this situation."

But according to Dr. Kit Neacy, director of the California dental board, "the very obvious issue is that special interests, namely anti-amalgam people, are in bed with the current administration and has its ear," she counters.

Earlier this year, the board contracted with a dental materials expert to revise the fact sheet, Dr. Neacy explains, but the board found this revision to be incomplete, and the anti-amalgam group Consumers for Dental Choice also had objections.

The fact sheet was then further revised and the board planned to review this version June 14, but canceled the meeting due to lack of a quorum, says Dr. Neacy. This angered amalgam opponents and Sen. Figueroa, who introduced emergency legislation (SB 26) to stop funding and dissolve the board as soon as Gov. Gray Davis can sign it.

"We have a meeting planned for July 19 and will review the fact sheet — if we [as a board] still exist," says Dr. Neacy.

The fact sheet, mandated by law for use by dentists in patient discussions, is "long overdue," the California Dental Association stated in its response to SB 26.

"The CDA is sorry the board has come to this circumstance," says Tim Comstock, executive director of the CDA. "We will work diligently with Sen. Figueroa to build a better dental board — one that will align more clearly the interests of consumers and providers of oral health care."

"It is incumbent upon all communities of interest," Mr. Comstock added, "to help make the new dental board as responsive and as effective as it can be."

Maryland lawsuit charges dental board

Baltimore — Another lawsuit involving dental amalgam was filed May 9 against the Maryland state board of dental examiners.

According to the suit, the board is charged "individually and as a representative of a class of defendants which includes 48 of the 50 state boards of dental examiners" with violating dentists' freedom of speech, civil rights, due process and equal protection.

The suit seeks to "allow" dentists to disclose the "risks of mercury-based dental fillings" and "health warnings which manufacturers of dental amalgam include

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with their product," the complaint reads.

Due to the pending litigation, the board was not at liberty to comment, but has proposed a regulation that unprofessional conduct includes removing sound or serviceable mercury amalgam restorations without appropriate informed consent from the patient.

Maine passes trio of mercury laws

Augusta, Maine — New laws restrict the sale of mercury-added products, require dentists to store and dispose of it properly and give wastewater treatment facilities authority to limit mercury discharge.

Another law will require dentists who use amalgam to give each patient a brochure — designed by the state Bureau of Health — on the health and environmental advantages and disadvantages of mercury amalgam and its alternatives.

The brochure "may also include other information that contributes to the patient's ability to make an informed decision when choosing between the use of mercury amalgam or an alternative material," the law reads.

Dentists must also display a poster in the public waiting area indicating the brochure is available. "While we certainly hoped that nothing be passed and the bill defeated, this law is much more workable than the original, which was very onerous and which we fought vigorously," says Frances Miliano, executive director of the Maine Dental Association. "We look forward to seeing what [kind of brochure] the Bureau of Health will develop over the next few months."

Document address: <http://www.ada.org/prof/pubs/daily/0107/0716amal.html>

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March 12, 1991

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Dear Dr. Duncanson:

The National Multiple Sclerosis Society is pleased to have the opportunity to provide testimony to the Dental Products Panel of the Medical Devices Advisory Committee of the Food and Drug Administration. This testimony does not relate to the overall question of the safety of dental amalgam fillings. Rather, our interest in this issue stems from the extraordinary attention drawn to multiple sclerosis as a consequence of recent publicity in the popular news media concerning anecdotal reports that removal of amalgam fillings may have a therapeutic role in multiple sclerosis.

The Medical Advisory Board of the National Multiple Sclerosis Society has followed the controversy about an alleged relationship between dental mercury amalgam fillings and multiple sclerosis for a number of years. No proper clinical study has been done to address the question of whether removal of dental amalgam fillings benefits people with multiple sclerosis. There are anecdotal case reports of people whose conditions have improved, remained the same, or worsened after the removal of dental amalgam fillings.

Anecdotal reports do not address the real issue of natural variation in the disease process. It is well known that multiple sclerosis follows an unpredictable clinical course and that considerable improvement or remission of the disease can occur at times that are unpredictable. In addition, a significant placebo response by people with multiple sclerosis has been documented in numerous controlled clinical trials with a variety of therapeutic agents. Finally, in none of the anecdotal reports can the accuracy of the diagnosis of multiple sclerosis be determined with certainty. These problems, individually or together, could provide alternative explanations to the claims made for improvement of multiple sclerosis after removal of amalgam fillings.

The National Multiple Sclerosis Society is proud to be a source of information about multiple sclerosis. Our comments are based on professional advice, published experience and expert opinion, but do not represent therapeutic recommendation or prescription. For specific information and advice, consult your personal physician.

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