

TESTIMONY OF
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FOR THE
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS
OF THE
COMMITTEE ON GOVERNMENT REFORM

HEARING ENTITLED
"CALIFORNIA'S COMPLIANCE WITH DENTAL AMALGAM DISCLOSURE POLICIES"

UNIVERSITY OF SOUTHERN CALIFORNIA
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I am speaking today as an individual dentist. I am a member of the Dental Board of California. I do not speak for the Dental Board and I am giving my opinions only.

I come today to tell you about an extremely disappointing turn of events. This turn of events directly applies to the subject of "California's Compliance with the Dental Amalgam Disclosure Policies." As you are well aware, California Law required the Dental Board to produce a fact sheet on the risks and efficacies of filling materials. A second law mandated that these facts be given to every patient. This would disclose the health risks of mercury in dental amalgam to the public. To this end I have given my time and energy.

I have been proud to serve as the Chairman of the Dental Materials Fact Sheet Committee. When I approached the existing document, I quickly realized that it contained several statements that seemed to be incorrect. I called for a hearing on the scientific evidence of health risk from mercury in the amalgam. We learned that there are scientists with relevant scientific studies and publishing in relevant scientific journals. When I found there was evidence of a substantial health risk to members of our California population, I felt it was my duty to give a clear warning concerning that risk. It is a risk of exposure to a chemical known to the state of California to cause birth defects and reproductive harm. A risk that is a fact in California Law known as Prop 65. As chairman of the Dental Materials Fact Sheet Committee, I was able to develop a document that included this warning. I developed this document over a period of time. There were many meetings, emails, phone calls and discussions. There was stakeholder input. Dentists gave their opinions. There was public debate. The Dental Board had a hearing and in public view discussed the contents of the draft fact sheet multiple times. I dotted all my I's and crossed all my T's. . This process was done by the book, step by step. So why am I so extremely disappointed? I shall explain further. Last year at the July Board Meeting this draft document was brought to the Board and it was voted 7to1 to approve the idea of including the warning I spoke of and a message to pregnant women and parents. The Board then requested that the Department of Consumer Affairs make this document into a brochure and make sure that the language was consumer-friendly. It

was agreed upon by the Board that at the next meeting in Nov. 2003 the Board would take the final vote.

Just before the meeting in Nov. the California Dental Association (CDA) sent out a letter to each Board member saying that the Prop 65 warning, the warning about the exposure to mercury and it's connection with birth defects and reproductive harm, was false and misleading. It must be said here that it was the same CDA that sent out the same warning to dentists. That warning stated "Dental Amalgam...exposes you to mercury, a substance known to the state of California to cause birth defects and reproductive harm." The letter sent to the Board Members had an opinion from their expert that this statement was false and misleading. A very odd chain of events, not easily explained. Never the less, this is a matter for the Cal-EPA scientists to be notified of; because this warning is a matter of law in the state of California.

Even with this strange letter, Dental Board had it's meeting in Nov. and after deliberations, again voted to approve the brochure, 8to0. The Board agreed that it was the right format and "95% complete." The committee was asked to make minor changes and bring it back in one month for a final vote. That vote was to occur by the end of the year 2003. I quickly did the Board requested editing and sent the changes off to the other member of the committee for her approval. The other committee member was initially too busy. I waited an appropriate amount of time and re-requested her answer. To my surprise, she sent me a completely new draft fact sheet. This was laid out professionally and was complete, in brochure form already. Several questions were in my mind. Where did this new version come from? Why did the President not ask for an explanation? Why did the President not direct us to work with the twice-approved document that was clearly what the Board expected? Then there was no Dec meeting.

I was upset by these developments. Then came the most disturbing turn of events. At the beginning of the year, I was sent an email that said that I was no longer the committee chair and that there was an entirely new committee and a new agenda. My attempts to comply with the California Dental Amalgam Disclosure Policies had been side tracked. I hope that you will urge the Dental Board to push forward for full disclosure.

While working on this committee I found several facts that make it even more important that the Dental Board continue on it's quest for full disclosure of health risks in order to protect the people of Calif. First, to depend on the FDA as the source of safety of dental amalgam is invalid. It is often assumed that the FDA has studied this health risk carefully. For that matter it is often said that the FDA has approved dental amalgam as safe. I found quite the contrary. The FDA claims no jurisdiction over mixed dental amalgam because it is mixed by the dentist. The dentist is the manufacturer, mixing the mercury and silver particles in the office and there by manufacturing the final mixed product that goes into the teeth. The FDA therefore has made no classification, does not regulate, has not studied and does not approve the mixed amalgam. The FDA also did not

study or demand studies to classify the separate ingredients. The separate ingredients were simply “grand fathered” in. As late as Jan 15th, 2004, the head of the Dental Devices Division of the FDA has said that “...the agency did propose to classify (approve) the encapsulated form of amalgam approximately 1 year ago and at the present time that process is on hold.” When asked why, she said, “The status of the classification as being on hold is awaiting additional information from a third review of the literature on dental amalgam that is being conducted.” So even the encapsulated form, which would be the closest to the actual substance that dentists use to fill teeth is not classified, and therefore not approved.

The Second realization was that the ADA/CDA has argued successful in California courts that “The 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.” This puts the burden squarely on the shoulders of the individual dentist who is “manufacturing” the amalgam and therefore responsible.

There were three important questions:

- 1) Has the FDA approved dental amalgam for safety? NO.
- 2) Does the ADA/CDA owe a duty of care to protect the patient from health risks from dental amalgam? NO.
- 3) Does the Dental Board have the responsibility to protect the public from known sources of health risk? YES.

Then it logically follows that:

- 1) Amalgam is 50% Hg. YES
- 2) Hg vapor constantly is emitted and goes to the organs of the body. YES
- 3) Amalgam is the predominant source of Hg exposure in people who have amalgam filling. YES.
- 4) Dental amalgam exposes you to Hg a substance known to the state of California to cause birth defects and reproductive harm. YES.
- 4) Therefore, dental amalgam is unsuitable for use in pregnant women and pregnant women should be clearly warned.

I shall continue to press for full disclosure of the risks of dental amalgam to patients, in order to better enable them to make informed choices.