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CALIFORNIA'S COMPLIANCE WITH DENTAL AMALGAM DISCLOSURE POLICIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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CONTENTS

	Page
Hearing held on January 26, 2004	1
Statement of:	
Johnson, Karen, State representative	16
Yokoyama, Dr. Chester, DDS, California Dental Board and former Chair Dental Materials Fact Sheet Commission; Shawn Khorrami, Esq.; Parin Shah, executive director, Community Toolbox for Children's Environmental Health and past president, San Francisco's Commission on the Environment; and Dr. Harold Slavkin, DDS, dean, University of Southern California School of Dentistry	21
Letters, statements, etc., submitted for the record by:	
Burton, Hon. Dan, a Representative in Congress from the State of Indiana, prepared statement of	6
Khorrami, Shawn, esq., prepared statement of	31
Shah, Parin, executive director, Community Toolbox for Children's Environmental Health and past president, San Francisco's Commission on the Environment, prepared statement of	44
Slavkin, Dr. Harold, DDS, dean, University of Southern California School of Dentistry, prepared statement of	40
Watson, Hon. Diane E., a Representative in Congress from the State of California, prepared statement of	12
Yokoyama, Dr. Chester, DDS, California Dental Board and former Chair Dental Materials Fact Sheet Commission, prepared statement of	25

CALIFORNIA'S COMPLIANCE WITH DENTAL AMALGAM DISCLOSURE POLICIES

MONDAY, JANUARY 26, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Los Angeles, CA.

The subcommittee met, pursuant to notice, at 2 p.m., in the Town and Gown Road, USC Campus, Los Angeles, CA, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton and Watson.

Staff present: Nick Mutton, press secretary; Danielle Perraut, clerk; and Richard Butcher, minority professional staff member.

Mr. BURTON. Good afternoon. A quorum being present, the Subcommittee on Human Rights and Wellness will come to order. And we're very happy that Congresswoman Watson is here with us today. I like those blue glasses, too.

Ms. WATSON. 99 cent store.

Mr. BURTON. Just goes to show you do not have to spend a lot of money.

I ask unanimous consent that all Members and witnesses written and opening statements be included in the record, and without objection so ordered.

I ask unanimous consent that all articles, exhibits and extraneous material referred to by Members or witnesses be included in the record, and without objection so ordered.

Before we start our opening statements, Congresswoman Watson and I have a couple of opening statements that will take some time.

There has been some question about scientific evidence about whether or not amalgams in teeth give off any kind of a residue or invisible smoke, if you will, that could effect the neurological system of human beings. So we have a very brief scientific film here, it's about 3 or 4 minutes long, and I hope everybody will take a hard look at that at the beginning, and then we will go to our opening statements.

[Video shown.]

Mr. BURTON. I think that's all we need to hear. That was showing that one picture is worth 1,000 words.

I would like to start off my opening statement by thanking the University of Southern California, especially Michael Klaus and Susan Lynch for their assistance in putting together today's hearing. We really appreciate their efforts. And as chairman of the House Committee on Government Reform and now chairman of the

Subcommittee on Human Rights and Wellness, I have along with Representative Watson led a 2-year long effort to bring to the public's attention, as well as the attention of my colleagues in Congress, the dangers posed by mercury containing medical and dental devices.

At previous hearings we have reviewed the concerns about thimerosal which contains mercury in vaccines and mercury containing dental amalgams. In each case, credible witnesses provided testimony that links mercury in the human body to a variety of developmental and neurological disorders.

Mercury is a base element and the most toxic substance known in science outside of radioactive elements. It remains a base element even when mixed with other materials. Mercury is a substance that human beings were not designed to ingest, so the body does not have an effective filter or elimination system for it.

Some of the mercury we ingest is eliminated through normal bodily functions, but much of it accumulates in the body's tissue including vital organs such as the brain. The developing neurological systems of fetuses and young children are especially susceptible to damage by even the slightest trace amounts of mercury. And you saw how much mercury comes off of those teeth at various temperatures.

An ever increasing body of scientific evidence points to mercury toxicity as a source of neurological problems including but not limiting to, modest declines in intelligence quotient, tremors, attention deficit disorder, attention deficit hyperactivity disorder [ADHD], Alzheimer's Disease and autism. No one has ever identified a positive health benefit to mercury in the human body, thus it was sound public policy to eliminate mercury from thermometers, blood pressure gauges, light switches, cosmetics, teething powder, horse liniment, hat making materials, smokestack emissions and mining operations. In fact, virtually every industry has either reduced or banned the use of mercury with the exceptions of dentistry and the pharmaceutical industry.

The amalgam fillings the American Dental Association so wrongly calls silver are mainly mercury, not silver at all. Mercury is the single largest ingredient in each filling, representing about 40 to 50 percent of the mercury by weight or about one half a gram per filling. That is a colossal amount of mercury in scientific terms, as much as is in an old fashioned thermometer.

For example, a young child with six amalgam fillings has the equivalent of six mercury thermometers worth of mercury in his or her mouth. And dentists cannot honestly claim that they were not aware of the dangers of mercury. In fact, dentists take routine precautions against this potent neurotoxin. According to protocol, mercury containing amalgam scraps and extracted teeth with amalgam fillings must be stored in sealed jars under liquid until special hazardous materials recycler pick them up for safe disposal. So if dentists are aware of the dangers of mercury, then why is this toxic material still being used at all?

The answer is that the dental establishment continues to hold to the scientific fiction that a material that is hazardous before it goes into the mouth and hazardous after it comes out of the mouth is

somehow perfectly safe while it is in the mouth. The truth is that it is not.

A scientific review of mercury amalgams in 1993 conducted by the U.S. Public Health Service demonstrated that mercury amalgams continuously vaporize and mercury vapor is then absorbed into the blood stream and distributed throughout the human body as you just saw in that brief film.

In addition, particles can and do chip off with regular chewing, grinding and toothbrushing, further adding to a person's mercury load.

The PHS study conclusively showed that people with amalgam fillings have higher concentrations of mercury in their blood, in their urine, kidneys and brains then those without amalgams. If that is the case, how can anyone believe that dental amalgams are harmless.

There are readily available alternatives to mercury containing fillings, and every dentist knows about them. Yet organized dentistry will not act to eliminate this dangerous substance, thus it is left up to the patients to take the initiative.

And one of the things that kind of disturbs me about this hearing today is that there are millions and millions and millions of people in California and across this country that have mercury in their mouths and we do not have one television station here covering this today. And it is something that should be brought to the attention of everybody; every man, woman and child in the country ought to know about this. Unfortunately, most patients are still uninformed about the materials used to restore their teeth and the benefits and risks of each. And, again, I believe the blame has to be laid at the feet of organized dentistry.

And there is no better proof of that than what has been happening here in California. In 1986 the voters of California enacted Proposition 65 requiring posting of notices of toxins in the workplace or office. Soon therefore, the then Governor Deukmajian with his administration listed mercury as a toxic substance which required Proposition 65 postings. Nothing happened until 1992 when the California legislature passed the Watson law, my good colleague's law, requiring the California Dental Board to produce a facts sheet to comply with Proposition 65 spelling out the risks and benefits of various filling materials.

Named after my good friend and the ranking minority member of this subcommittee, Ms. Diane Watson who was a California State Senator at the time, the Watson law was a simple common sense effort to ensure that the public could make an informed choice about their dental care. Ms. Watson has been a tireless advocate on this issue for many years and a staunch ally in the Congress as the subcommittee works to eliminate this dangerous threat to our public health. And I really want to thank you for your hard work. And I thank you for being here.

However today despite the passage of Proposition 65 and the Watson law, Californians still are not able to get information from their dentists about the dangers of mercury amalgams. So far as the subcommittee has been able to determine, the California Dental Board's only attempt thus far to actually issue a facts sheet occurred in 1993, and the effort was deemed by the California De-

partment of Consumer Affairs to be probably misleading. Regrettably, the board has never corrected the problem.

In fact, the board's refusal to implement the Watson law lead California State Senator Liz Figueroa to sponsor legislation to dissolve the board completely and constitute a new dental board. The law also mandated the Watson fact sheet must be given to every dental patient. And we are going to put that in the record. We have a copy of this which we will put in the record today, so at least it will be on the Congressional Record in case anybody wants to know about it.

Yet, under pressure from the California Dental Association the new dental board has not been any more capable of producing a fact sheet than the old one. That two dental boards have yet to create a simple consumer friendly fact sheet in more than 17 years after the implementation of Proposition 65 and 11 years after the passage of the Watson law is a grave disservice to the residents of California.

I personally believe that there is no more important function of government than doing everything in its power to protect the health and well being of its citizens. When controversy and uncertainty exists, such as in this case, the least we should do is ensure that the public is adequately and objectively informed and given the option of choosing what materials are used to restore their teeth.

Today's hearing will focus on the lessons learned from and the progress still being made here in California to implement full disclosure of adequate information to dental patients.

Dr. Chet Yokoyama, a member of the California Dental Board, former Chair of the California Dental Board Fact Sheet Committee and a supporter of the Watson law is here this afternoon to testify about why the dental board has had such trouble complying with the Watson law. Although Dr. Yokoyama is not speaking on behalf of the board nor has he been authorized to speak on behalf of the board, I look forward to hearing his personal perspective on this issue. And he testified in Washington, and I want to thank you once again for being here, Doctor.

I also look forward to hearing from Mr. Shawn Khorrami, an attorney who led the recently successful fight in the California court system to force dentists to post a Proposition 65 warning in their offices. While not as comprehensive as the fact sheet required by the Watson law, the Proposition 65 warning is at least an important step in the right direction.

And, unfortunately, we have learned recently that the California Dental Association has tried to stymie even the modest level of public disclosure by lobbying against the warning on the grounds that it is deceptive. We asked the California Dental Association to be here today to participate, but they declined to send a representative preferring to send a written statement for the record instead. And it is disappointing that they choose not to appear today to defend their record on this issue.

However, we will hear from Dr. Harold Slavkin, Dean of the School of Dentistry here at the University of Southern California who can perhaps helps us better under the organized dentistry's opposition to the elimination of mercury containing amalgams.

California's population represents approximately one out of every eight people in the United States. So it is not surprising that events here can have a ripple effect on similar activities and movements in other parts of the country. The Honorable Karen Johnson, a State Representative from Arizona—I am glad you are here today—is here to talk about her efforts to pass legislation in Arizona similar to the Watson law here in California. And we appreciate your hard work on that.

And last but not least, we will hear today from Mr. Parin Shah, executive director of Community Toolbox for Children's Environmental Health concerning the environmental impact of dental amalgams.

When scraps of amalgam or old fillings are washed down the drain, and I know they are because I have seen it out of my own mouth, they can end up in our rivers, lakes and oceans and eventually into our drinking water. If the fillings do get caught in our waste water treatment plants, they settle in the treatment plant's sludge which either gets incinerated releasing the mercury directly into the atmosphere or it gets spread out onto our agricultural fields as fertilizer contaminating the food chain. So mercury amalgams are not just a public health hazard, but an environmental one as well.

I want to thank all of our witnesses for being here this afternoon.

And I now yield to Ms. Watson.

[The prepared statement of Hon. Dan Burton follows:]

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BERNARD SANDERS, VERMONT,
INDEPENDENT

Opening Statement
Chairman Dan Burton
Subcommittee on Human Rights and Wellness
Committee on Government Reform
Title: *"California's Compliance with Dental Amalgam Disclosure Policies."*
Date: January 26, 2004

Good Afternoon. I would like to start off by thanking the University of Southern California, especially Michael Kloss and Susan Lynch, for their assistance in putting together today's hearing. We appreciate their efforts.

As Chairman of the House Committee on Government Reform and now Chairman of the Subcommittee on Human Rights and Wellness, I have led a two-year long effort to bring to the public's attention as well as the attention of my colleagues in Congress, to the dangers posed by mercury-containing medical and dental devices.

At previous hearings we have reviewed concerns about thimerosal in vaccines, and mercury-containing dental amalgams. In each case, credible witnesses provided testimony that links mercury in the human body to a variety of developmental and neurological disorders.

Mercury is a base element and the most toxic substance known to science outside of radioactive elements. It remains a base element even when mixed with other materials. Mercury is a substance that human beings were not designed to ingest, so the body does not have an effective filter or elimination system for it. Some of the mercury we ingest is eliminated through normal bodily functions, but much of it accumulates in the human body's tissue, including vital organs such as the brain.

The developing neurological systems of fetuses and young children are especially susceptible to damage by even the slightest trace amounts of mercury. And an increasing body of scientific evidence points to mercury toxicity as a source of neurological problems including, but not limited to, modest declines in intelligence quotient (IQ), tremors, attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD), Alzheimer's disease and autism.

No one has ever identified a positive health benefit to mercury in the human body. Thus it was sound public health policy to eliminate mercury from thermometers, blood pressure gauges, light switches, cosmetics, teething powder, horse liniment, hat-making materials, smokestack emission, and mining operations. In fact, virtually every industry has either reduced or banned the use of mercury, with the exception of dentistry.

The amalgam fillings the American Dental Association so wrongly calls "silver" are mainly mercury, not silver at all. Mercury is the single largest ingredient in each filling, representing about 45 to 50-percent of the mercury by weight, or about one-half a gram per filling.

That is a colossal amount of mercury in scientific terms – as much as is in an old fashioned thermometer. For example, a young child with six amalgam fillings has the equivalent of six mercury thermometers worth of mercury in their mouth.

And dentists cannot honestly claim that they are not aware of the dangers of mercury. In fact, dentists take routine precautions against this potent neurotoxin. According to protocol, Mercury-containing amalgam scraps, and extracted teeth with amalgam fillings, must be stored in sealed jars under liquid until special hazardous materials recycler picks them up for safe disposal.

So, if dentists are aware of the dangers of mercury, then why is this toxic material still being used? The answer is that the dental establishment continues to hold to the scientific fiction that a material that is hazardous before it goes into the mouth, and hazardous after it comes back out of the mouth, is somehow perfectly safe while contained in the mouth.

The truth is that it is not. A scientific review of mercury-amalgams in 1993 conducted by the United States Public Health Service (PHS) demonstrated that mercury –amalgams continuously vaporize, and mercury vapor is then absorbed into the bloodstream and distributed throughout the human body. In addition, particles can and do chip off with regular chewing, grinding, and tooth-brushing, further adding to a person's mercury load.

The PHS study conclusively showed that people with amalgam filings have higher concentrations of mercury in their blood, urine, kidneys and brain than those without amalgams. If that is the case, how can anyone believe that dental amalgams are harmless?

There are readily available alternatives to mercury-containing fillings, and every dentist knows about them. Yet organized dentistry won't act to eliminate this dangerous substance, this it is left to the patients to take the initiative Unfortunately, most patients are still largely uninformed about the materials used to restore their teeth and the benefits and risks of each. And again, I believe the blame has to be laid at the feet of organized dentistry.

And there is no better proof of that than what has been happening here in California.

In 1986, the voters of California enacted Proposition 65, requiring posting of notices of toxins in a workplace or office. Soon thereafter, then Governor Deukmejian's [duke may gee an] Administration listed mercury as a toxic substance which required Prop 65 postings.

Nothing happen until 1992, when the California Legislature passed the Watson Law, requiring the California Dental Board to produce a fact sheet to comply with Proposition 65 spelling out the risks and benefits of various filling materials.

Named after my good friend and the Ranking Minority Member of the Subcommittee, Ms. Diane Watson, who was a California State Senator at the time, the Watson Law was a simple, common-sense effort to ensure the public could make informed choices about their dental care. Ms. Watson has been a tireless advocate on this issue for many years and a staunch ally in Congress as this Subcommittee works to eliminate this dangerous threat to our public health and I thank her for all of her hard work

However, today, despite passage of Prop 65 and the Watson Law, Californians still are not able to get information from their dentist about the dangers of mercury amalgams. So far as the Subcommittee has been able to determine, the California Dental Board's only attempt thus far to actually issue a fact sheet occurred in 1993 and the effort was deemed by the California Department of Consumer Affairs to be "probably misleading." Regrettably, the Board has never corrected the problem.

In fact, the Board's refusal to implement the Watson Law led California State Senator Liz Figueroa [fig O row A] to sponsor legislation to dissolve the Board completely and constitute a new Dental Board. The law also mandated that the Watson Fact Sheet must be given to every dental patient.

Yet, under pressure from the California Dental Association, the new Dental Board has not been any more capable of producing a fact sheet than the old one.

That two Dental Boards have yet to create a simple consumer friendly fact sheet more than 17 years after implementation of Proposition 65 and 11 years passage of the Watson Law, is a grave disservice to the residents of California.

I personally believe that there is no more important function of government than doing everything in its power to protect the health and well-being of its citizens. When controversy and uncertainty exist, such as in this case, the least we should do is ensure that the public is adequately and objectively informed and given the option of choosing what materials are used to restore their teeth.

Today's hearing will focus on the lessons learned from, and the progress still being made here in California to implement full disclosure of adequate information to dental patients.

Dr. Chet Yokoyama, a member of the California Dental Board, former Chair of the California Dental Board Fact Sheet Committee, and a supporter of the Watson Law, is here this afternoon to testify about why the Dental Board has had such trouble complying with the Watson Law. Although Dr. Yokoyama is not speaking on behalf of the Board, nor has he been authorized to speak on behalf of the Board, I look forward to hearing his personal perspective on this issue.

I also look forward to hearing from Mr. Shawn Khorrami [core ra me], an attorney who led the recently successful fight in the California court system to force dentists to post a Proposition 65 warning in

their offices. While not as comprehensive as the fact sheet required by the Watson Law the Prop. 65 warning is at least an important step in the right direction.

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However, we will hear from Dr. Harold Slavkin [slav kin], Dean of the School of Dentistry here at the University of Southern California who can perhaps help us better understand organized dentistry's opposition to the elimination of mercury-containing amalgams.

California's population represents approximately one-eighth of the population of the United States. So, it not surprising that events here tend to have a ripple affect on similar activities and movements in other States throughout the country.

The Honorable Karen Johnson, a State Representative from Arizona is here today to talk about her efforts to pass legislation in Arizona similar to the Watson Law here in California. We appreciate her hard work and admire her efforts.

And last but not least, we will hear today from Mr. Parin [Pear in] Shah, Executive Director of Community Toolbox for Children's Environmental Health, concerning the environmental impact of dental amalgams.

When scraps of amalgam or old fillings are washed down the drain they can end up in our rivers, lakes and oceans and eventually into our drinking water. If the fillings do get caught in our wastewater treatment plants they settle into treatment plant sludge which either gets incinerated releasing the mercury directly into the atmosphere, or it gets spread out onto agricultural fields as fertilizer, contaminating the food chain. So, mercury amalgams are not just a public health hazard but an environmental one as well.

I want to thank all of our witnesses for being here this afternoon.

Ms. WATSON. Thank you so much, Mr. Chairman. And a special thanks for coming all the way out to California and appearing in my District. And this great University of Southern California that has been touted in the last few days of having four major trophies. We won the Rose Bowl game.

Mr. BURTON. I know. Indiana was way down the list.

Ms. WATSON. And we are so very pleased. And I would like to thank the Government Relations Department, particularly Carolyn deMacias and President Sample for working to make this special field hearing possible and all of you that have come out this afternoon.

The Human Rights and Wellness hearing today is a very important activity for Californians and the rest of the Nation. The subcommittee seeks to obtain information about the noncompliance, and I want you to focus on why we are here today.

We are focusing on the noncompliance by the California Dental Board regarding public disclosure of elemental mercury and its use in dental fillings. In previous Government Reform hearings we have discussed different aspects about the last remaining use of mercury inside the human body. But, the 12 year failure—the 12 year failure to inform Californians and Americans about the risk and the efficacies of mercury is very disturbing to me.

This hearing will focus primarily upon disclosing relevant information to patients which will enable patients to make informed choices about the type of dental restorative material that is used in their treatment.

What we're trying to do, everyone in this room that hears my voice, is trying to make Americans, particularly Californians, partners in their own wellness and in their own health care. Keep that in mind.

In 1992 I wrote a law. It is Section 1648.10 of the California Business and Professions Code which mandated—1992 it mandated a fact sheet to be produced by the California State Dental Board stating the risk and efficacies of dental materials. Over the following 9 years the board has not been in compliance. I want to know why. However, I am pleased to report that the last administration installed a new dental board, because I saw that the dental board of California did not want to comply with the law. So, there was a new dental board appointed. The new board held hearings on the safety of mercury fillings in 2002, but has again failed to fully comply with the mandate. Why did it take 12 years? These are intelligent professionals. I am appalled that in 12 years they have not produced a fact sheet. Why?

The dental board was required to take into account what would be in the best interest of the patient and the public. I need to know why a consumer friendly fact sheet, which in July 2003, that's just a few months back, was approved seven to one. And then again eight to zero in November 2003. And it is not ready, Congressman, for circulation.

I am especially disappointed after receiving assurances from the president of the board that the fact sheet would be in the hands of patients before December 31, 2003, a few days ago. I do not understand why the fact sheet should not be released today. And I am

terribly disappointed that—is there anyone from the dental board except Dr. Yokoyama? Anyone else?

And then they all declined, and I got a letter, a polite letter from the CEO of the board declining to appear. Now, what does that tell you? Intelligent thinking people can figure it out. Not one, except the person who was the former Chair of the committee to do the fact sheet, showed up today.

The fact sheet was produced by a fact sheet committee of the dental board and approved by the majority. I want to know why the committee Chair who has worked on the fact sheet for the last 2 years was suddenly dismissed.

The efforts by Dr. Chet Yokoyama, a mercury free dentist and a member of the California Dental Board, led to the production of this fact sheet, which was voted on by the majority.

So, Mr. Chairman, I hope that we can be enlightened today by the testimony that is presented here as to why it has taken 12 years to comply with the mandate. There is a violation in the law going on with the dental board. And I don't think anyone who sits on that board who does not comply with the law ought to remain a member of the board. And if anyone in this room thinks that I'm not going to followup, you do not know how tenacious I am. I have a partner here who has traveled across this country to join me. I resent the fact that it has taken 12 years. This was already voted on, it should be in the public's hands.

So, I would like to thank all of you for your efforts to come to this hearing, and to provide us with the information we were seeking on the beautiful campus of the University of Southern California. Visit South Central Los Angeles again. This is it.

So, I yield back my time, Mr. Chairman.

[The prepared statement of Hon. Diane E. Watson follows:]

Government Reform Subcommittee
Human Rights and Wellness

Opening Remarks of Diane E. Watson, M.C.
Human Rights and Wellness Field Hearing January 26, 2004
"Consumer Choice and Implementing Full Disclosure in Dentistry"

****

Thank You Mr. Chairman. I would like to also thank the Government Relations Department of the University of Southern California, Carolyn Webb-deMacias, and USC President Steven Sample, for working to make this special field hearing possible.

The Human Rights and Wellness hearing today is very important for Californians and the rest of the nation. This Subcommittee seeks to obtain information about non-compliance by the California Dental Board regarding public disclosure of elemental mercury and its use in dental fillings. In previous Government Reform hearings we have discussed

different aspects about the last remaining use of mercury inside the human body, but the 12 year failure to inform Americans about the risks and efficacies of mercury is very disturbing. This hearing will focus primarily upon disclosing relevant information to patients which will enable patients to make informed choices about the type of dental restorative material that is used in their treatment.

In 1992 I wrote a law, Section 1648.10 of the California State Business and Professions Code, which mandates a fact sheet be produced by the California State Dental Board stating the risks and efficacies of dental materials. Over the following 9 years the Board was not in compliance. However, I am pleased to report that Governor Davis installed a new California Dental Board. The new board held hearings on the safety of mercury fillings in 2002, but

has again has not met the full mandate.

Why did it take 12 years to produce a fact sheet? The Dental Board was required to take into account what would be in the best interest of the public. I need to know why a consumer friendly fact sheet, which in July 2003 was approved 7-1, and then again 8-0 in November 2003, is not ready for circulation? I am especially disappointed after receiving assurances, from the president of the Board, that the fact sheet would be in the hands of patients before December 31, 2003. I do not understand why the fact sheet should not be released today.

The fact sheet was produced by the Fact Sheet Committee of the Dental Board, and approved by the majority. I want to know why the committee chair, who had worked on the fact sheet for the last two

years, was suddenly dismissed. The efforts of Dr. Chet Yokoyama, a mercury free dentist and member of the California Dental Board, led to the production of this consumer friendly fact sheet.

So, Mr. Chairman, I look forward to today's testimony, and I like to thank you for your efforts to provide this hearing in the 33rd Congressional District, on the beautiful campus of the University of Southern California.

I yield back my time.

Mr. BURTON. Well, thank you, Ms. Watson.

We have a video of that—we do not need to show it. I think—unless you feel you—you want to see it. OK. Well, we have a video we want to show. This is the last meeting of the board?

PARTICIPANT. Actually it is a little culmination of the——

Mr. BURTON. I think it is self-explanatory. Could you turn the sound up so we could be sure to hear it.

Ms. WATSON. Can everyone see?

[Video shown.]

Mr. BURTON. The last clip is Dr. Alan Kaye, he's the immediate past president of the California Dental Board.

Ms. WATSON. Yes.

Mr. BURTON. I see. OK. I see. OK. Thank you very much.

OK. We'll now go to our first panel.

And do you have anything else right now, Ms. Watson?

Ms. WATSON. I do not think so.

Mr. BURTON. Representative Johnson, would you stand to be sworn, please.

[Witness sworn.]

Mr. BURTON.

STATEMENT OF STATE REPRESENTATIVE KAREN JOHNSON

Ms. JOHNSON. Thank you so much. That is a very hard act to follow.

Mr. BURTON. And I am not even in vaudeville.

Ms. JOHNSON. Well, my name is Representative Karen Johnson. I serve in the Arizona House of Representatives.

Ms. WATSON. And welcome.

Mr. BURTON. Welcome.

Ms. JOHNSON. Thank you so much. I feel very, very privileged to be able to come here today. And I thank you so much, both Chairman Dan Burton and Ranking Member Diane Watson for allowing me to speak with your committee.

Chairman Burton, you lead the way in getting mercury preservatives removed from childhood vaccines, and you have a national reputation for making government agencies accountable to the people.

You are now spotlighting mercury in dental fillings, and those of us from Arizona are deeply appreciative of your work.

Congresswoman Watson, you are the lead sponsor by the bipartisan Watson-Burton Bill to ban mercury fillings for children, pregnant women and nursing mothers and for eventually phaseout their use entirely. We used your bill as a prototype in Arizona, and I understand lawmakers all over the country are doing the same.

I am pleased to report that the legislation that I sponsored last year requiring full disclosure cleared both relevant committees and got to the floor for a vote. Because of strong lobbying opposition from the Arizona Dental Association, the bill was referred back to a third committee from the floor it hopes that it would die in that committee.

Once again we got the bill to the floor, but the time that was incurred in all of this allowed the opposition to pull off several supporters from the floor vote, and we nearly lost the battle. However, we did get to raise the issue of mercury fillings as never before.

The State's newspaper editorialized twice for disclosure. We have been able to bring together a citizens brigade that ultimately will prevail.

Congresswoman Watson, I also understand that as a State legislator, as you spoke of here recently, you wrote the State Watson law requiring the California Dental Board to disclose the risks of mercury fillings. I believe you are focusing today on the fact that the California Dental Board will not enforce the law, and I have a similar story from Arizona.

I represent a district in Mesa, AZ, and I entered the legislature in 1997. Because of the great interest in the health of our children and the increased problems in childhood immunizations, I began research into the mercury issue which ultimately led me to the Arizona Dental Board and their harassment of mercury free dentists.

One of my concerns is that our regulatory agencies, Federal and State, are not enforcing the law and they are restricting choices. In the area of dentistry, I was shocked to see the State dental board trying to shutdown a dentist because he offered mercury free dentistry and other cutting edge techniques that were not against the law, always with full disclosure and always based on consumer choice.

As I attended some of the board hearings and alerted other legislators about what was happening, the dental board backed off their efforts at that time. Unfortunately, the dental board did not give up persecuting dentists and continued this harassment because some dentists offer alternatives to traditional dentistry.

No profession can change if every member must do what every other member is doing. It is fair to debate the cutting edge issues in dentistry, such as the advisability of root canals or the efficacy of cavitation surgery. The State has no business taking sides in issues the marketplace can decide. However, organized dentistry seems to feel otherwise.

One issue of concern is that the American Dental Association has a gag rule—yes, a gag rule telling dentists not to give warnings about the toxic effects mercury might have on the body. Studies now show that mercury does indeed emanate from the teeth to the rest of the body and it is important that consumers know it. But the ADA thinks otherwise.

A few years back a scholar at the Arizona based Goldwater Institute, Mark Genrich, he wrote several articles about the first amendment rights of dentists to advocate an end to mercury fillings.

One of the major changes we need, and we may be close to getting in Arizona, is to give low income families a choice not to get mercury fillings. AHCCS or the Arizona Health Care Cost Containment System in Arizona is our Medi-cal. AHCCS simply told dentists to put in mercury fillings. Our assistant minority leader and Arizona's only African-American lawmaker, Leah Landrum Taylor and myself have co-authored a letter that we sent to Governor Napolitano asking that this program be changed to include informed choice for our constituents in the AHCCS program. We have identified the problem and are currently winding it through the bureaucracy step-by-step to secure a change, and this is a change that I hope will occur anywhere.

Now if I might quickly address the problem of our State dental board which ignores the law.

Four years ago, not nearly as long as you folks have gone through this, but 4 years in Senate bill 1155 we enacted a statute in Arizona stating it is unprofessional conduct: "To fail to inform a patient of the type of material the dentist will use in the patient's dental filling, and the reason why the dentist is using that particular filling."

Now, one would think that every parent and every pregnant woman would learn in advance that mercury is the major component of amalgam fillings and would also learn the rational for and/or against the use of that particular type of filling. Not so. In the past 4 years the Arizona Dental Board has turned a deaf ear to enforcing this simple statute. A consumer group filed a petition. I even appeared personally before the board and asked for its adoption.

As the Chair of the subcommittee overseeing the dental board's budget, I have raised this question year after year. Promises are made and promises are broken. This year I am proceeding with my House bill to ensure the dental board follows the law or we have the Governor replace the members of the board. I believe that this is what you have done in California.

This legislation will require that the Arizona Dental Board send a disclosure to every dentist who will then be required to hand to every patient who gets fillings the following information: "You have a choice in dental materials. Amalgam filling are 50 percent mercury so the term silver is not an accurate term. Notice to parents and pregnant women as follows: Because amalgam fillings are 50 percent mercury, the use of amalgam fillings is increasingly a matter of public controversy." Pretty benign.

My bill would also require neutrality in enforcement where informed choice, not the economic policies of the Arizona Dental Association govern. The board would be required to post such an enforcement policy.

I would be happy to work with this subcommittee in any way that would be useful. And I look forward to the day when no child, pregnant woman or nursing mother is subjected to mercury fillings simply because dentists in this country refuse to inform them of the toxic dangers associated with mercury.

Thank you so much for your attention to this imperative issue.

Mr. BURTON. Thank you, Representative Johnson. I have just a few questions I would like to ask you.

I think you pretty much told us a little bit about your experiences there in the Arizona Legislature. And you have had a lot of resistance from the State dental board there.

Ms. JOHNSON. Absolutely. In fact, Chairman Burton, I guess it is OK to say because it is true; they actually have lied in their monthly magazine that came out shortly after the legislation was defeated in the last session.

Mr. BURTON. And to your knowledge do the dental schools in Arizona educate their students about the toxicity of mercury in the filling?

Ms. JOHNSON. Chairman Burton, we have not had any dental schools in Arizona until about 8 months ago. And we have our first

one actually in Mesa, AZ, whose opening I attended. I am not sure they were real happy to see me there. But I do not believe that is taught in that school.

Mr. BURTON. Are there many dentists in Arizona that are using alternative materials in fillings there because they are concerned about the amalgam? Have any of them come and talked to you about this?

Ms. JOHNSON. Absolutely. Many, many of them have. I have had the privilege of talking to them. I would say that between 25 and 30 percent of the dentists in Arizona are what you would call mercury free. And one of the problems we face is that they want to advertise as mercury free dentists and our dental board has given them a great amount of harassment because of that.

Mr. BURTON. We had a number of hearings on this issue in Washington, and the American Dental Association has told some of our Members of Congress who are dentists that this is all a bunch poppycock, that the mercury is frozen in the amalgam and cannot cause any damage. And because of that, some of my colleagues who are dentists have been very vociferous in their opposition to us doing anything to get the mercury out of dental fillings. And it is because it is coming straight from their main authority.

Ms. JOHNSON. Right.

Mr. BURTON. Doctors listen to the Food and Drug Administration and the AMA. Dentists listen to the Food and Drug Administration, whom you saw on the television there who said, yes, there is a vapor that escapes; that was the FDA speaking. And the American Dental Association.

And so I think the main thing we have to do is just keep pounding on this wall until it comes down like the walls of Jericho. And I know Diane Watson and I are committed to that, and you are as well. And we really appreciate what you do in Arizona.

Ms. Watson.

Ms. JOHNSON. Thank you.

Ms. WATSON. I thank you for your courageous work you have done.

When we make public policy, as you know so well, it takes years. We try to make public policy that does no harm. So you are courageous and you are tenacious.

And as I was listening very intently to your testimony I was wondering what kind of strategy have you put together to come back again at this? Can you share it with us, and maybe we could pick up some pointers from you. It has taken me 12 years.

Ms. JOHNSON. Oh, Congresswoman Watson, no, I was so honored to be able to come here to find out more from you what I can do, what we can do.

The sad thing of it is in Arizona this is an issue that is really looked down upon. I mean, it is not something that has any kind of a priority with other legislators. I have been very appreciative of Representative Leah Landrum who has been a good friend. We came into the legislature at the same time. And she has a great concern for the minority children in our State that have no choice but to have the mercury put in their mouth. So she has been a great ally in this and has helped rally some of her party to this.

And, unfortunately, I would say that perhaps members of her party are more receptive to this than mine. And I would give that charge to the fact that the Arizona Dental Association lobby appears to give a lot of donations to members of my party in a large amount. And when they speak, the members of my party just follow.

Ms. WATSON. There has been a gag order placed on dentists here in California. And I think you mentioned something about them being gagged in Arizona as well. But, the first amendment allows them to advertise as mercury free dentists.

My dentist is sitting in the room right now. He had to go to Mexico to practice his craft because he refused to work on patients when he was in dental school and to put the silver fillings. So his practice is down in Mexico.

Now, what this says to me is that we are depriving our citizens of the knowledge of what effects their bodies. No professional can come to me and argue that the most toxic substance on the Earth ought to be in amalgam, but that is the kind of foolish argument. They ought to know by now that it does not work with me.

And so I really appreciate you coming and talking about your struggle. I want you to hold on. Because as you know, California is always on the cutting edge and when we start something, it moves across the country.

I am reminded of the smoking policy. It took us 14 years, and we were the first State that prohibited smoking on airplanes in California air space. Now it is nationwide and almost worldwide.

Do not give up. You are on the right side and history will reward you. Be tenacious and remember what you do will improve the quality of health for the voiceless and the toothless and those that have teeth and they think that they are saving their teeth.

I had a discussion with my dentist. And you know what it boiled down to, and my dentist is an African-American practicing just a few blocks away from here. He said it is a matter of cost.

How does a professional tell me they are willing to put a toxic substance, I do not care how well it fills. You crack a nut and your tooth cracks and then the vapors come out. And chew gum and the vapors come out. You get a tooth knocked out, and the vapors come out.

So at my age, I went across the border to get all the mercury taken out of my tooth. I want everyone to have that same opportunity. I want people to be knowledgeable. And I do not tolerate professionals coming to me saying that we need to block the information.

So, I want to encourage you to continue to do what you are doing. We will prevail.

Thank you so much.

Ms. JOHNSON. Thank you. And I applaud both of you, and we will not quit.

Mr. BURTON. Well, we have a mutual admiration society. So, thank you.

Ms. WATSON. See, I know who to team up with.

Mr. BURTON. We would like our next panel to come forward now. It is Dr. Yokoyama, he is with the California Dental Board; Mr.

Shawn Khorrami; Mr. Parin Shah and Dr. Harold Slavkin, who is the dean of the School of Dentistry here.

You know, while they are coming up, I would just like to say Abraham Lincoln said "Let the people know the facts and the country will be saved." About the same thing we are talking about here. Just let the people know the facts and they will do the right thing.

Would you please stand, please?

[Witnesses sworn.]

Mr. BURTON. Be seated.

OK. Since you have been with us before, Dr. Yokoyama, why do we not start with you. Do you have an opening statement?

STATEMENTS OF DR. CHESTER YOKOYAMA, DDS, CALIFORNIA DENTAL BOARD AND FORMER CHAIR DENTAL MATERIALS FACT SHEET COMMISSION; SHAWN KHORRAMI, ESQ.; PARIN SHAH, EXECUTIVE DIRECTOR, COMMUNITY TOOLBOX FOR CHILDREN'S ENVIRONMENTAL HEALTH AND PAST PRESIDENT, SAN FRANCISCO'S COMMISSION ON THE ENVIRONMENT; AND DR. HAROLD SLAVKIN, DDS, DEAN, UNIVERSITY OF SOUTHERN CALIFORNIA SCHOOL OF DENTISTRY

Mr. YOKOYAMA. Yes, I do.

Chairman Burton and Ranking Member Diane Watson, thank you very much for giving me the opportunity to speak here today.

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.

So 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, the 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. And this would, of course, disclose the health risks of mercury in dental amalgam to the public. And to this end I have given my time and my energy.

I have been proud to serve as the chairman of the Dental Materials Fact Sheet Committee. And 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 Proposition 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 con-

tents 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 7 to l 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 November 2003 the board would take the final vote.

Well just before the meeting in November the California Dental Association sent out a letter to each board member saying that the Prop 65 warning, the warning about the exposure to mercury and its connection with birth defects and reproductive harm, was false and misleading. And 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. Nevertheless, 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.

So even with this strange letter, the dental board had its meeting in November and after deliberations, again voted to approve the brochure, 8 to zero. The board agreed that it was the right format and "95 percent complete." The committee was asked to make minor changes and bring it back in 1 month for a final vote. That vote was to occur by the end of the year 2003. So 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 period 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 from the twice-approved document that was clearly what the board expected? Then there was no meeting in December.

I was upset by these developments. And 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 chairman of the committee, 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.

And I'd like to mention just a couple of things while I was working on this committee that I found. I found several facts that make it even more important that the dental board continue on its quest to bring full disclosure of health risks in order to protect the people of California.

First, to depend on the FDA as the source of safety of dental amalgam is invalid. These are things I learned along the way in my opinion. 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 thereby 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, which they have classified the separate mercury and the separate silver filings. The separate ingredients were simply "grandfathered" in.

As late as January 15, 2004, the head of the Dental Devices Division of the FDA has said that "the agency did propose to classify" in other words approve, and I'm putting that word in there to help you out. "The agency did propose to classify 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.

So the second realization was that the ADA/CDA, the ADA and by extension the 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."

So this puts the burden squarely on the shoulders of the individual dentist who is "manufacturing" the amalgam and therefore responsible.

So I found three important questions: One, has the FDA approved dental amalgam for safety? My opinion is no. Two, does the ADA/CDA owe a duty of care to protect the patient from health risks from dental amalgam? In my opinion no. Three, does the dental board have the responsibility to protect the public from known sources of health risk? Yes.

Then it logically follows that: One, amalgam is 50 percent mercury? Yes. Two, mercury vapor constantly is emitted and goes to the organs of the body? Yes. Three, amalgam is the predominant source of mercury exposure in people who have amalgam filling? Yes. Four, dental amalgam exposes you to mercury, a substance known to the State of California to cause birth defects and reproductive harm. Yes. 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.

And I would just like to say that I am disappointed with the absence of the California Dental Association. We are trying to come to an agreement, but it is difficult if you do not come to the table. And I am disappointed with the absence of any of the board members or representatives of the board, I will just say that.

And I thank you for your time.

[The prepared statement of Dr. Yokoyama follows:]

TESTIMONY OF

CHESTER YOKOYAMA, DDS

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
LOS ANGELES, CALIFORNIA
JANUARY 29, 2004

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 developed 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 was 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.

Mr. BURTON. Thank you, Dr. Yokoyama. We will have some questions for you in just a few minutes.

Mr. Khorrami.

Mr. KHORRAMI. Thank you, Mr. Chairman. Thank you, Congresswoman Watson. And thank you for having me over here. I really appreciate your efforts on this issue, and the full issue of mercury in pharmaceutical use. It's surely a disaster.

I am an attorney. I practice mostly in the area of pharmaceuticals. I for the past 5 years have focused quite a bit on mercury. I have litigated cases, the environmental level in terms of waste water and discharge, and certainly in terms of exposure having to do with a variety of products, even florescent lamps, fish, vaccines. Currently I litigate vaccine cases with Thimerosal nationally. I am lead and liaison counsel both in California, and I sit on the board for the National Steering Committee for vaccine cases.

With respect to amalgam, I have litigated class cases, public interest cases, individual personal injury cases. One of my cases is actually pending in front of the California Supreme Court right now.

And I have also handled cases involving Proposition 65, again in the entire gambit of toxins that are out there, but particularly with respect to mercury.

Last year, about exactly a year ago, the Superior Court of San Francisco entered an order, and that order required dentists in this State to give warnings, warnings as to mercury exposure and specifically mercury expose. I know this because I was the attorney who handled it for over 2 years. I negotiated the settlement, and it was the California Dental Association that actually came and solicited the concept of settlement. I did not go to the California Dental Association. I was interested in dentists. And I will get into why I did that, but getting into Prop 65 and sort of looking at the background a bit.

Proposition 65 was a ballot initiative that the citizens of this State placed on the ballot. And one of the premises was, one of the geneses of this ballot initiative was the people's distrust of government and the failure of their government agencies to protect them with respect to toxic materials.

Proposition 65 then requires disclosure, and specifically warnings when the citizens of this State are being exposed to a toxic material. Mercury, of course, and all of the compounds, have been listed as Prop 65 chemical for ages.

Now, the manufacturers of amalgam have been under a continuing duty to warn, and they have settled cases requiring the warnings. This was one of the first situations I had ever seen, and I believe it is the only one I have ever seen, where you have a manufacturer that puts together a warning scheme and the reason for that warning scheme is for it to get to the ultimate consumer, the exposed individual. This industry was the only one that I saw where although manufacturers were providing these warnings, it never got to the ultimate individual. And who is there in the middle of the process but the dentist; the dentist, the dental association and perhaps the dental board.

This to me was also the only industry that I could find that when confronted with this issue of what are you doing with the mercury,

they just sat back and clung on to their current practice of keeping this in use. When you look fluorescent lamps, those guys have taken the mercury down even though there is really not much of a possibility of individual exposure. When you look at vaccines and you have been very involved in that process, there is at least been a reduction. A lot of manufacturers said OK, fine, we are going to take some of these out.

In dentistry there is not even the concept of reduction of this.

Now, going back to the Prop 65 settlement, the CDA after I went and sent out notices to the dentists that I was just going to sue them for not providing warnings to their patients, the CDA came to me and said that it wanted to settle the matter on a statewide basis, and here is the reason they gave me: Was that they wanted uniform warnings across the State, warnings that were accurate. And we held out and we made sure that the warnings included mercury and talked about exposure, not that amalgams contain mercury.

Now, when this was going on the court held three separate days of hearings. The court took in evidence. The court took in testimony. Well, not testimony. The position of the various side. The Attorney General of this State was present. The California Dental Association was present. Dentists were present. And the American Dental Association was present.

The American Dental Association vehemently disagree with the concept of giving warnings, but then also disagreed with the form of the warning. And after considering everything, the court said that the warnings were appropriate, that the settlement was appropriate and they were to be given.

Now mind you, there was no discretion given to the dentists in that situation. The warning has to be given. You can choose whether to give a warning or not to give a warning. It has to be given. And, in fact, that discretion was taken out of the hands of the dentists in the form that the warning took, which was a posted sign. It cannot be inside of an informed consent form. It is not going to be something that you just tell the patient. You first have to put it up and the patient has to see it, and the patient has to read it. So that is the way we did this.

Now, going to the Watson law, as I read the Watson law we talk about safety, and I know Dr. Yokoyama talked about safety, and I know Dr. Slavkin is going to be on the other side of the safety issue, for sure. But that is not the point of the law.

The law says risks and efficacies. Safety is irrelevant. It has nothing to do with it. We have millions of products in our safety that are considered safe yet go out with warnings because they have risks, because you have to have cautions, because we have precautions. OK. Pharmacueticals is a prime example of exactly what that is. That is why there is labeling requirements. That is why we have this.

So safety, forget about. Information, disclosure; that's the point.

Now, when the dental board comes in and decides well we do not feel like giving that warning, and this one is OK, and this way it is beneficial and the other way it is not; that is not the discretion that the Watson law gave. That is not a discretion that any of us gave it. That was not what we gave the dental board when we

passed Proposition 65. We said we do not want them to have discretion. We do not trust them. And with this dental board, I don't think we should trust them.

But this is exactly what is going on: They are sitting there and saying well we choose what goes out and we choose what the patient gets. And let us put aside Proposition 65. Let us put aside the Watson law. What about informed consent? Is a profession entitled to decide what is a risk, what it will disclose, what it will not disclose? The California Supreme Court has said emphatically absolutely not. Informed consent is a legal standard. That means Dr. Slavkin cannot get together with his colleagues and then decide what is something that we disclose and what is something that we do not disclose.

Even if the dental board of California wanted to do a position statement on safety, that still does not do anything to the Watson law and the dentist's duties under informed consent. What we want is full disclosure to the patient. The concept of informed consent is full disclosure for the patient so that the patient, being the ultimate decisionmaker, can decide I want this stuff or I do not want this stuff. And also can be in a position to decide whether that safety position that the dental board took is a valid position or is not a valid position.

That is why not only it is what the dental board illegal, not only does it not have discretion to do what it is doing, but it is also against this State's public policy. It is also against, frankly, every State I have looked at, the public policy of that State.

With that, I am ready to answer questions, Mr. Chairman.

[The prepared statement of Mr. Khorrami follows:]

BEFORE THE SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS OF THE COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

Testimony of Shawn Khorrami, Law Offices of Shawn Khorrami

RE: California's Compliance with Dental Amalgam Disclosure Policies

January 26, 2004

Mr. Chairman and Members of the Committee:

I am pleased to appear before you to testify regarding this matter. My name is Shawn Khorrami. I am an attorney in California. My practice covers a broad range of issues, including pharmaceuticals, environmental law and toxic torts, consumer fraud, civil rights, product liability and municipal liability. My firm employs eight attorneys and a number of full time support staff.

I graduated with honors from Pepperdine University School of Law in 1995, after earning my undergraduate degrees in mathematics, economics and computer programming at UCLA.

For the past five years, mercury and its presence in various products has been a focal point of my practice. I have litigated cases involving various forms and compounds of mercury, whether it be organic, metallic, or in vapor form. I have brought them under California's Proposition 65, consumer protection statutes in a number of states, and tort theories of liability, both on behalf of individual clients and as class actions. I have litigated regarding a broad range of products, from fish to florescent lights, to vaccines, to – what I am going to testify about today – dental amalgam. Similarly, I have litigated against manufacturers of products, governmental entities, and professional associations.

Currently, I am the lead and liaison counsel in the coordinated cases relating to vaccines in California and Ohio, and sit on national steering committees on vaccine litigation, including those pending in the Federal Court of Claims in Washington DC. With respect to amalgam, I

have filed cases in no fewer than a half dozen states both on behalf of individuals – mostly autistic children – and as class actions. I also have filed and currently have pending lawsuits against governmental entities relating to amalgam, most notably the Dental Board of California.

The purpose of my testimony today is to provide some insight for this Committee on the importance of full disclosure of adequate information with respect to dental restorative materials, with particular emphasis on mercury dental amalgam. I will also provide a brief overview of my experience with the effects of citizen enforcement, the California Attorney General's involvement, along with possible preemption which has been visited by the Executive, Legislative, and Judicial branches of the Federal government at the request of one or more industry groups.

I. The Position of the Dental Board Is Contrary to that which Dentists throughout California Are Doing and Violates the Law

On January 9th, 2003, after over two years of negotiation and litigation, the San Francisco Superior Court entered a historic order. Through its order, the Court approved a consent judgment under California's Proposition 65 which embodied a settlement reached between an environmental organization, As You Sow, and the California Dental Association requiring all dentists in California who are subject to Proposition 65 – meaning have more than 10 employees – to warn regarding patient exposure to mercury. The text of the warning is as follows:

The warning is to be posted by the dentist at a location where it is likely to be seen and read by patients. This demonstrates clear and unmistakable intent that the warning is not discretionary, meaning the dentist cannot pick and choose who gets the warning and who does not.

I know the settlement well. I was the attorney representing the plaintiff and was the primary person present throughout the process. While the California Dental Association ("CDA") only appeared in the case as an intervener, it was the only entity with which I negotiated. Of course, the California Attorney General's office was instrumental in bringing the parties together and ultimately in getting the Court's approval for the settlement. Virtually every word of the consent judgment was the subject of intense negotiation.

It is noteworthy that although the CDA was supportive and, indeed, signed the consent judgment, the American Dental Association vehemently objected. It is safe to say that with the CDA, the Attorney General's office, myself, and the ADA, and three days of hearings, the Court

had before it able and complete representation of all sides of the issue.[1]

A. The Position of the Dental Board Violates the Law

Under Business & Professions Code §1648.10 (the "Watson Law"), the legislature demanded that the Dental Board of California "develop and distribute a fact sheet describing and comparing the risks and efficacy of the various types of dental restorative materials . . ." Obviously, this included the most popular dental restorative material – mercury dental amalgam. For over a decade, the Dental Board has ignored this duty and has in the process acted against California's consumers rather than serving their interest. So much so, that on July 12th, 2001, California's legislature took the unprecedented step of de-funding the Board prior to its sunset.

[1]The Court was already well familiar with dental amalgam and was in the process of considering expert scientific testimony on the matter on other cases on which I was counsel.

When considering compliance with Section 1648.10, it is important to differentiate between "safety" on the one hand and "risks" on the other. The statute clearly and unmistakably requires disclosure of "risks. It *does not* require a position statement on "safety." There are literally tens of thousands of products on the market which are considered safe for use, but which must be accompanied by warnings, contraindications, or cautions, disclosing *risks*.[2]

Amalgam fillings cause exposure to mercury. CDA found this exposure to be substantial enough that upon its members receiving notices that they were going to be sued, it began the process of negotiating a settlement which included warnings – warnings which were not discretionary, but mandatory. The settlement was negotiated under California's Proposition 65, an initiative that was approved by the People of the State of California by an overwhelming two to one margin. Proposition 65 requires anyone who causes exposures of individuals to certain reproductive toxins, including mercury, to provide warnings to those individuals.

Dentists throughout the state are required to provide warnings. Yet the Dental Board of California, an entity who is vested with the duty to protect California's consumers, refuses to provide the public with the very warnings that the professionals it governs are under court order to give. Not only does this violate the law, but it violates our sense of honesty and decency, and in the process undermines the public's confidence in this Board and the government.

B. The Position of the Dental Board Violates the Public Policy of the State of California

Proposition 65 represents the intent of the People of the State of California to be warned regarding exposures to certain dangerous toxins. It is also important to note that in passing Proposition 65, the People declared that "state government agencies have failed to provide them with adequate protection." Proposition 65 ballot initiative, Section 1. As such, not only did the People assert their right to know, but they stated that they are particularly concerned because state agencies – entities such as their Dental Board – have failed them in providing those disclosures.

Mercury and all of its compounds have been on Proposition 65's list for over a decade. Furthermore, there is virtual unanimity within the scientific community that mercury is one of, if not the most toxic, element known to man. The levels of exposure to mercury from dental amalgam clearly violate the standards of Proposition 65. In fact, my firm has presented scientific testimony from world renown scientists stating that amalgam is unsafe.

Any decision by the Dental Board not to provide California's consumers with information

[2]For the record, I want to be clear that my position along with the position of a growing number of individuals and scientists is that amalgam is *not* safe.

which they demanded through Proposition 65 would violate the public policy of this State and would feed into the very distrust which was the genesis of Proposition 65.

II. Dentistry Has Prevented Legally Mandated Warnings and Important Health Information from Reaching Patients

A. When It Comes to Amalgam, the Dental Establishment Does not Allow Disclosures

I am lead counsel in the case of Kids Against Pollution v. California Dental Association. The case centers around the American Dental Association and the California Dental Association's attempts at stopping any warnings regarding mercury from reaching the consuming public, and specifically dental patients.

The lawsuits allege that the associations have used ethical rules and their monopoly power over the dental industry to control what is and is not transmitted to the consuming public. Unbelievably, the associations have gag rules specific to amalgam. While the associations have come up with multiple purported reasons for the existence of such rules and have tried to show their applicability in very limited circumstances, their own pre-litigation interpretation of their gag rules show that, indeed, the rules are intended to silence any disclosure of the existence of mercury or the potential for toxicity.

Ironically, the dental associations have claimed as their primary defense that they have a First Amendment right to preclude vital information from reaching consumers. They also have claimed that they have no duty to be truthful with the public.

B. The Fact that any Settlement Was Necessary with Dentists Is Indicative of Dentistry's Disdain for Providing Warnings

As I mentioned above, the Consent Judgment which the Court entered last year was against *dentists*. What I did not mention is that most, if not all, manufacturers of amalgam already provide Proposition 65 warnings to dentists under a separate settlement agreement. In the hundreds of Proposition 65 actions that I have handled and the thousands that I have seen, this was the first situation of which I am aware, where downstream distributors and/or retailers required a separate lawsuit in order to get the warning to the consuming public. In virtually every other situation, once the manufacturer puts into place a proper warning mechanism, downstream purchasers will assure that the warnings reach the consuming public.

The dental profession was unique in that even though many manufacturers provided Proposition 65 warnings and even though the state of the science was clear that amalgam fillings violate Proposition 65's warning thresholds, dentists were for some reason not providing warnings to their patients. This points to a systemic problem. As we have alleged in our lawsuits against the American and California Dental Associations, this failure of the warning

system is a deliberate and direct result of the dental establishment's efforts to gag warnings and important health information relating to amalgam.

Dental boards are not only stacked with the very dentists who refuse to provide such warnings, but are also subject to an incredible amount of pressure by the American Dental Association and its web of constituents, such as the California Dental Association. In fact, it is my firm belief that it has been this pressure which has caused the Dental Board of California to introduce a fully drafted competing – and inaccurate – fact sheet, after the Board had approved a consumer-friendly fact sheet.

C. The Dental Board is not a Scientific Body and even if it Were, It Cannot Substitute Its Judgment for that of the Patient

The Dental Board is a regulatory body, *not* a scientific one. None of its members are qualified to make determinations as to the toxicology of dental restorative materials. Similarly, the Watson Law, perhaps recognizing this fact, did not require the Dental Board to interpret the science or to put out its opinion on safety. Instead, it required full disclosure of risks and efficacies, nothing more and nothing less.

Regardless, the doctrine of informed consent prevents a profession from setting its own standards when it comes to warnings and other health information. Indeed, informed consent is a legal standard and not subject to the discretion of the profession. Under this doctrine, patients are to be provided with all risk and warning information. The dental professional has no discretion to pick and choose which warnings to give and which not to give. Thereafter, the patient, being armed with full and complete information, is the ultimate decision-maker regarding his or her treatment options. The dental professional – the same as any medical professional – *cannot* substitute his or her judgment for that of the patient.

Based on the foregoing, while the Dental Board's position statement on safety may serve as interesting reading for the public, its determination as to safety is neither legally required nor relevant. Simply put, the Dental Board is not a scientific body and when it substitutes its opinion on safety for that of the patient, it is violating the legal and universally accepted doctrine of informed consent.

III. Conclusion

This Committee seeks testimony regarding the importance of fully disclosing adequate information to patients, in order to better enable them to make informed choices about the type of dental restorative material that is used in their treatment. I believe that the importance of such full disclosure is not be disputed. However, I think that the Dental Board – and actually dental boards around the country – do not understand the concept of full disclosure or alternatively are so stacked with dentists dependent on income from amalgam, that they pretend they do not understand the concept.

Their obligation to the consuming public – the dental patient – is full disclosure of risks and efficacies. That is what the doctrine of informed consent requires. We have recognized long ago, that a patient is the ultimate decision-maker and in order to make that decision, the patient is entitled to know *all* of the risks – there is no discretion on the part of the practitioner to decide which risks to disclose and which not to disclose. Simply put, the People do not want practitioners or dental boards substituting their judgment for that of the patient. Yet, when the Dental Board refuses to make full disclosure, and instead, provides repeated statements on safety, it is doing just that – it is substituting its conclusion for that of the patient and it is, in the process diluting whatever limited warning or risk information is being conveyed. While position statements on safety may be helpful to the dental patient, they are meaningless without full and complete disclosure.

This aside, when a government agency engages in such conduct, not only is it violating public policy, but it is feeding into the very distrust of the government which was the genesis of right to know laws such as Proposition 65. The People require transparency and honesty from their government officials, something the Dental Board seems to be loath to provide.

Mr. BURTON. Well, I will have a few questions for you in just a few moments, and I am sure Ms. Watson does as well.

Dr. Slavkin.

Mr. SLAVKIN. Thank you. And welcome to the University of Southern California. I am 1 of the 19 deans of the different colleges that make up USC, and I am very pleased that we are sitting in a room that we call Town and Gown, which is the opportunity of the university to engage with the larger society about issues of mutual importance.

One of the issues that I have heard today, and I know in the reputations of both of your distinguished records, that you are passionately and unconditionally interested in the health and well being of all Americans, not only in this District but across the country. I share that with you.

From 1995 to 2000 I served as the Director of the National Institute of Dental and Cranial Facial Research, one of the institutes that makes up the NIH, and it's the primary funder for research scientists not only in this country, but out of the country to work on problems related to dentistry and the cranial facial complex. In that capacity I had the opportunity to review thousands and thousands of papers and grants, and work closely with CDA and the Environmental Protection Agency, and the FDA and my colleagues in other institutes. And I would be more than happy to discuss from that perspective anything that you might be interested in.

I came here at the request of Steve Sample to join his leadership team 3 years ago. And began as dean of the USC School of Dentistry. We are 107 years old. We have almost 900 students in residence at any given time. And we have clearly been part of the education and training of dentists in the southern California region and beyond.

I wanted to mention to you that the Watson legislation, as I learned about it and as it became clear that I was a steward of dental education, of best practices, of standard of car, that I wanted to ensure that every faculty member, every student, every staff member, every alumni knew that there were risks whether they be potential or less than potential risks in the handling of mercury.

We immediately posted the signage throughout the School of Dentistry indicating the potential risk of mercury for pregnancy throughout the life span and in the elderly.

In 2001 when the board made available something called the Dental Materials Fact Sheet, we adopted it immediately. It is in the hands of every patient. We treat thousands and thousands and thousands of patients from Bakersfield to the San Diego border. Every patient receives this sheet. Every patient sees the signage in the school. Every patient is questioned do they understand, do they have questions and they can evaluate from their particular point of view the risk and benefit of all procedures that are done in a health care setting.

Now, at the same time I wanted to ask you if you would entertain in the spirit of the videos that we saw earlier, in the remarks that you both made and the testimony given, I would like to ask you if you would take a few moments. And I brought copies that might be inserted for you to take a look at.

There is a paper from Tom Clarkson, Laszlo Magos and Gary Myers that was published in the New England Journal of Medicine, and it came out on October 30, 2003. The title of the paper is "Current Concepts in the Toxicology of Mercury, Current Exposures and Clinical Manifestations." The paper goes into a critical analysis of the issue that are near and dear to your heart and mind. It evaluates the very critical references. It was supported by the National Institutes of Health. It is not affiliated with the dental school or the dental profession, or any of those implied self-interested communities. And I believe you would find it, that it talks to the grayness of the subject matter. It talks about the level of exposure per kilogram by day body weight. It talks about 0.1 micrograms being the ideal threshold from the EPA statements of 2001, from the WHO responses and analysis of 2002. And I think it is a very useful scientific peer reviewed presentation that would be of value to all of us in weighing the risks and the benefits of ethel mercury or methyl mercury, or mercury out of the ground and the applications in society.

From my background as a scientists working at the NIH and in my career as a scientist, I believe that the available peer reviewed scientific evidence clearly indicates that there are risks to the use of mercury. And, the scientific evidence clearly supports that there are many opportunities of utilizing mercury where the benefit significantly outweighs the risk.

Thank you for the opportunity to be with you, and of course I would be more than happy to entertain any question that you might have.

[The prepared statement of Dr. Slavkin follows:]

Statement of

Harold C. Slavkin, D.D.S.
G. Donald and Marian James Montgomery
Professor of Dentistry
Dean, USC School of Dentistry

For the Subcommittee on Human Rights and Wellness Hearing
"California's Compliance with Dental Amalgam Disclosure Policies"
January 26, 2004

My critical assessment of the available international scientific peer-reviewed literature, and previously published extensive reviews of the scientific reporting on studies designed to assess the effects and side effects of dental restorative materials, concludes that based upon available scientific evidence, currently used dental materials, specifically dental amalgam, does not cause harm to humans throughout the lifespan. Except for an exceedingly small number of people who have allergic reactions to dental amalgam, there was no scientific evidence that exposure to mercury as found in dental amalgam poses a health risk. This conclusion is derived from an assessment of scientific publications on mercury toxicity, biocompatibility of metals, toxicity and hypersensitivity, criteria for the placement and replacement of dental amalgam restorations, and possible systemic responses from dental amalgams. Based upon scientific peer-reviewed literature, there exists no science-based reason either to discontinue or to curtail the clinical use of dental amalgam or to recommend removal of existing amalgam fillings absent of clear evidence of allergy or intolerance in individual patients. Meanwhile, emerging science, technology and advances in clinical research studies are working to design and fabricate new biomaterials.

Mr. BURTON. We would like that. Thank you, Doctor. We would like to have your documents and we will put those in the record.

And I am sure Representative Watson and myself would like to ask you——

Mr. SLAVKIN. This is the signage throughout the School of Dentistry, the fact sheets that all patients receive and these are the copy.

Mr. BURTON. OK. Thank you very much.

Mr. SHAH. And thank you, Chairman Burton and Congresswoman Watson for allowing me to speak.

As you introduced me, I am the executive director for Community Toolbox for Children's Environmental Health and today I speak to you as a member of San Francisco's Commission on the Environment and past president of the Commission on the Environment for San Francisco.

Over the last 2 years we, as a Commission, have looked into the dental mercury issue as it relates to the citizens of San Francisco. And I am here today since, in part, fuller disclosure certainly but also to talk about an example of the solution to addressing mercury poisoning in our water and mercury contamination of fish.

As a policy body for San Francisco, we have decided to define the mercury issue as one, a right to know issue just as you have. Certainly the amalgams that dentists put in are not just silver. They rightfully should be known as mercury amalgams. And myself, I have four cavities from eating too many chocolates, I guess, as a child and not flossing which is about enough mercury in my mouth to contaminate a 20 acre lake and make it unfit for fishing. So, certainly I should know that and everyone should know that. And we support a brochure on the part of the California Dentists Association.

We also defined the mercury issue as a human rights issue or an environmental justice issue. All citizens in San Francisco and America have a right to clean air, safe water and ample food, access to open space which is free of toxins that could be harmful to their health. And so with that said, we decided to say you know we can go about the process of policymaking by saying there is science that says this, there is science that says that, here is a number that is safe and that number is four, here is a number that is safe and that number is seven. We chose to step back from that discourse a little bit and provide a cautionary approach to our policymaking with regard to this particular issue and try to implement the precautionary principle issues touched on earlier and which other speakers have talked about.

So what we did was we did a little bit of research. We held hearing. We got our information. We had dentists, the CDA, the ADA, environmental groups, activists come and talk to the Commission. And we did our own research. And we found that dentists are the largest contributor of mercury to our waste water facilities. And that, in fact, on our waste water facilities is an enormous financial impact on the citizens in San Francisco.

We evaluated the policies that we had enacted 10 years ago and 12 years ago. And we found that voluntary compliance on the part of dentists to reduce mercury in waste water systems just wasn't working. As of September 2003 there was less than 1 percent of the

dentists in San Francisco that were using amalgam separators to separate essentially when the filling comes out, to separate the mercury and the amalgam from what goes into the waste stream. That is less than 1 percent.

So we decided that we wanted to develop a mandatory permitting process. It is a very simple process whereby dentists, as a manufacturer, as to submit a permit for its discharge into the waste water system. The permitting process was developed in conjunction with the California Dental Association as well as the San Francisco Dental Society and activists, city workers, regulators. And we came to the solution of providing two options for dentists. They could either purchase amalgam separators so that the mercury would stay and it could be reused, recycled or disposed of appropriately at a cost of about $1,200, what the average has been, or they could go through a monitoring process and not purchase a processor or implement best management practices as they may have learned in their schooling or in their continuing education.

Since we have done that, which we began the education and the process for that in September 2003 when we had less than 1 percent of dentists that were using separators, we now have 76 percent of dentists in San Francisco who are using these amalgam separators. That reduces the amount of mercury that enters into our water system, into our fish and subsequently into our bodies, especially of bodies of low income individuals in the immigrant communities that live on the fish that they get, that they fish for everyday in the morning from the waters of San Francisco Bay. That reduces the amount of mercury by 90 percent. It is just enormous.

And as we talk about moving forward, as we talk about moving toward the elimination of mercury or amalgams in dentistry, you know we will have other issues which is what are we going to do with all this stuff now that we are going to make sure we collect. So California is paving the way in many ways. Hopefully, San Francisco is laying the seed for the next thing for California to do, which is in its waste water we certainly must mandate some way, a process where separators can collect the mercury before it gets into the environment and into our bodies.

I just wanted to rattle quick statistics off. Like I said, the two options of the 644 dentists office is 76 percent have chosen to install separators. We have offered and the process that really supported the engagement of the dentists was we offered small rebates through a bit of a local grant that we got from the California EPA.

We will continue to do education of the staff and the dentists so that they continue to use the best management practices. And we have developed various fact sheets which actually are part of the packet that I gave you all. We also have it on line. They are available.

And we also have an expo. And this is where we talk about the economy and we talk about stimulating the economy. This is where something that is good for public health and good for the environment can actually potentially spur economic growth.

What we did was we also engaged with producers of the amalgam separators and said we most likely are going to do this and there may be more dentists that come to purchase your equipment.

And they on their own started to educate the dentists about their products.

We held a vendor expo where we had folks come and talk about their wares. We have a list of vendors, which is also part of your packet, which meets certain criteria that we went through. So we sort of flushed that out.

And they are excited. They are engaged in this and they are helping support it because it helps their bottom line and they know that it helps the environment and it addresses human health issues.

So in closing, I say that as we move forward we certainly need to keep asking the CDA to do the right thing. Sometimes volunteerism, as I am sure you have learned Congresswoman Watson, does not always work. You know, sometimes it takes a little bit of a firmer hand and a little more tenancy that may twist a bit, right? And maybe a bit of a mandatory process, especially when it comes to the health of our children.

We have done this in San Francisco but we cannot keep the Bay free of mercury unless other jurisdictions who are in the Bay join us in this. And we hope for the State law that looks at permitting processes or even Federal regulations that looks at permitting processes. This came about because of, actually, a reduction in the amount of mercury that our waste water system was asked to put out.

So we look forward to working with you in any way and talking about how to implement it in local jurisdictions with State law and so on.

Thank you.

[The prepared statement of Mr. Shah follows:]

To: Chairman Dan Burton, Subcommittee on Human Right and Wellness
From: President Parin Shah, San Francisco Commission on the Environment

RE: San Francisco's Dental Mercury Pollution Prevention Program

The purpose of this document is to provide written testimony on dental mercury reduction efforts in San Francisco, CA an to describe the program implemented by the City and County of San Francisco's Department of the Environment and Public Utilities Commission. Below is the list of the topics covered in this document:

1.0 Text of oral testimony by Parin Shah
2.0 History of issue in SF
3.0 SF Permit Process – Nuts & Bolts
4.0 Success
5.0 Key Program Elements
- 5.1 EPA Grant Work-plan
- 5.2 ARE Rebate Program
- 5.3 Amalgam Waste Management Vendor Expo
- 5.4 Mercury Monitoring

6.0 Future Goals
7.0 Highlights

Attachments

A. Chronology
B. Program Overview Factsheet
Best Management Practices
Waste Water Discharge Permit Application
C. City Approved Amalgam Separator Equipment List
Amalgam Separator Information Form
Amalgam Separator Installation Report Form
D. Quarterly Monitoring Report Form
Wastewater Sampling and Analysis Method
E. EPA Grant work plan
F. Rebate Application Form
Rebates for Community Service
G. Invitation to Amalgam Waste Management Vendor Expo
Completed Vendor Expo Survey Form

Website: http://www.sfwater.org/main.cfm/MC_ID/4/MSC_ID/85
OR
(http://sfwater.org > ENVIRONMENT > Dental Mercury Reduction Program)

1.0 Text of oral testimony by Parin Shah

Mercury is one of the most toxic elements known to man, yet it persists at dangerously high levels in San Francisco Bay, not to mention many of our mouths. The most prevalent, and preventable, commercial source of mercury contamination remains unregulated – and that's the dentist's office.

The most common type of dental filling is made from something called "silver amalgam," in reality these fillings are a mixture of metals and contain fifty percent mercury and should rightly be know as "mercury fillings". Each one contains about one half gram of mercury, enough to contaminate up to 5 million gallons of water, or 20 Olympic-sized swimming pools. A person with four fillings has enough mercury to make a 20-acre lake unfit for fishing.

Mercury from dental offices extracts a huge burden on the taxpayers. The cost to extract a pound of mercury of mercury from the water is $21,000,000, according to the U.S. House Subcommittee on Wellness and Human Rights. The U.S. dental industry, admits the California Dental Association, used a colossal 48 tons – i.e., almost 100,000 pounds -- of mercury in 2001. If only 10% of that mercury is getting into the waterways, the clean-up costs exceed two hundred billion dollars. Dental offices could save taxpayers most of this projected astronomical clean-up bill by installing equipment to catch the mercury, equipment that costs a mere $2000 per dental office.

Mercury used to be part of a variety of health medicines and devices, such as Mercurochrome (now banned), childhood vaccines (pulled recently), and contact lens solution (voluntarily withdrawn). Last year, the FDA even pulled a horse medicine off the market because it contained mercury. The American Dental Association stands alone as the only health group who advocates putting mercury into children and adults – based on the preposterous rationale that it's OK because they have done it for 150 years.

This year, the City came to an agreement with San Francisco dentists and the California Dental Association to reduce the amount of mercury leaving dental offices. Individual dental offices will choose to comply with a new permit by installing an approved amalgam separator device that takes the mercury out of the system before it can make its way to the Bay. The mercury is then collected and sent for proper disposal.

We hope our efforts will inspire similar programs across the nation, but the next major step for San Francisco is for dentists to phase out of mercury entirely. It's certainly doable: an estimated 27 percent of dentists nationwide have already taken this important step. Indeed, most middle-class adults no longer get "mercury amalgams". Sadly, children and low-income adults still do, which is something only the state legislature can change.

Mercury fillings are toxic before going into the mouth, and are considered hazardous waste the moment they are removed. It's time for dentists everywhere to recognize the inevitable: mercury has no place in the human body or in the environment.

2.0 History (see Attachment A)

- Results of a study during the 1990 of San Francisco's dental practice wastewater discharge showed that **dentists are the largest source of mercury in Publicly Owned Treatment Works** (POTW) influents.
- As a result of these findings, San Francisco Water Pollution Prevention Program (located at SF Public Utilities Commission) worked with the **dental community** over the last several years to **address mercury loadings into wastewater through voluntary programs**. Dental practices were urged to implement recommended Best Management Practices (BMP's) and install amalgam separator equipment (ARE).
- A survey that was done in **1999** to gauge effectiveness of the program found that only **1.5 % of SF dentists had installed amalgam separators**.
- After working with the dental community for 10 years, it was found that the **voluntary measures alone were not enough to produce sufficient reduction in mercury** and more aggressive measures were required to achieve significant changes.
- Under the **Federal Clean Water Act** the Southeast wastewater treatment plant, which handles approximately 80% of SF's wastewater was issued a National Pollutant Discharge Elimination System (NPDES) permit. The **limit for mercury set in the permit issued in 2002 was lowered from 210 ng/l to 87 ng/**l.
- The permit required that San Francisco implement a mercury source reduction program. **The current program using voluntary compliance was found to be inadequate**.
- Historical data from the Southeast treatment plant shows that from 1998 to 2003, discharges would have **exceeded** the current **allowable discharge limit** (87 ng/l) for mercury by at least **500%.**
- SF Commission on the Environment and the SF Department of the Environment (henceforth "SFE") expressed interest in assisting in the mercury reduction efforts.
- Commission Meetings and **public hearings** took place to discuss this issue, where dentists, advocates city staff and industry presented public testimony.
- The Commission and SFE established a program whereby a **mandatory mercury reduction permit** requirement was introduced to the SF dental community.

3.0 Permit Process – Nuts & Bolts (see Attachment B)

- By December 31, 2003, all dental offices that discharge wastewater to the City's sewer system must file an application for a wastewater discharge permit with the SFPUC, Bureau of Environmental Regulation and Management (BERM).
- **The permit requires that dental offices reduce their mercury discharges to the lowest practicable level.** The lowest practicable level or the highest concentration of mercury allowed in a dental office waste stream, set at 0.05 mg/L. This can be archived in two ways:

OPTION 1 – Install ARE (amalgam separators) & Implement BMPs.
(see Attachment C)
AREs employ filtration, settlement, ion exchange and/or centrifugation to remove amalgam and its metal constituents from the office vacuum system. Chair-side traps and screens capture the largest particles, therefore, AREs focus on much smaller particles. **SFE maintains an approved separator database** that dental practitioners can choose from. In order for an ARE **to be approved**, the **unit must attain at least 95 % amalgam removal efficiency** when tested in accordance with the ISO 11143 by an ISO-certified testing laboratory. Different AREs are suitable for different offices depending on size, location (chair side vs. central vacuum), type of vacuum (wet or dry) and other factors.

- OPTION 2 – Implement BMPs and sample & test wastewater discharges to show mercury concentration lower than 0.05 mg/L. (see Attachment D)
  Option 2 requires that dentists obtain a **contractor to install special sampling equipment and hire an approved laboratory to conduct the sampling & analysis of their wastewater discharge**. The sampling device called a Berglund device, must be configured, used & maintained in accordance with City specifications. The frequency of sampling and inspection could range from once a year to 12 times a year, depending on the results of the initial testing. Each sample collection & testing session lasts an entire week.

- OPTION 1 vs. OPTION 2
  The offices that choose to install an ARE **(Option 1) are presumed to be compliance with the City's mercury discharge limit** if the unit is installed correctly and the BMPs are implemented properly. Whereas, **Option 2 dental offices must continuously monitor and test wastewater discharge** in order to demonstrate compliance with the discharge limit.

  The annual costs incurred by dental offices for the two options are below:
  OPTION 1:
  Purchase - $600 average cost ($150-$2000 range)
  Installation – $200 average cost ($50-$500 range)
  Maintenance -$350 average cost/yr ($250-$600 range/yr)
  OPTION 2:
  Costs range from $1000 (once a year testing) to $12,000 (12 times/yr testing)
- EXEMPTIONS There are some exemptions from obtaining the discharge permit, available to certain types of dental practices that are not expected to release mercury into the wastewater system, like endodontics, oral & maxillofacial pathology, oral & maxillofacial radiology, oral & maxillofacial surgery, orthodontics & dentofacial orthopedics, pediatric dentistry, periodontics and prosthodontics. Exemptions are also available to practices that place or remove amalgam fillings less than 3 times/year.

4.0 Success of Mandatory Program

Below are the figures as of 1/22/04:

Total # of active dental offices that should be permitted: 644
# of exemptions granted: 78 (~12 %)
# of offices that chose Option 1: 461 (~71.6 %)
# of offices that chose Option 2: 4 (~0.6 %)
# of offices not yet responded (have not submitted application yet): 101 (~15.7%)

Note: The number of dental offices that "voluntarily" installed separators i.e. 1.5% of the total number of SF dentists, with the number of offices that installed separators when mandated, roughly 72% (and rising) for very little additional cost.

5.0 Key Program Elements

5.1 EPA Grant for Dental Mercury Reduction (see Attachment E)
SFE applied for grant funding from EPA's Source Reduction division to help achieve significant reductions in dental mercury. The main tasks under this grant work plan include:

1. Permit Application System set-up (not scope of EPA-grant)
2. ARE Subsidy or Rebate Program
3. Training & Outreach (workshops, vendor fairs, educational material, office visits)
4. Mercury Monitoring (measuring mercury in wastewater & comparing with baseline)
5. Effectiveness Measurement (mercury monitoring, surveys, tracking ARE installations)

5.2 ARE Rebate Program (see Attachment F)

In order to promote the installation of ARE, SFE issued cash rebates for the first 100 dentists that installed AREs. The cash rebates covered partial cost of purchase. This program was found to be very popular and widely successful. The first 100 rebates were issued within 2 months of the rebate announcement (with more applications still coming in).

The vendors, local distributors and installing technicians were working round the clock to meet the huge demand and race for the rebates!

SFE is now offering "rebates for community service" to dental practices primarily serving the underserved populations/communities within the City and County of San Francisco and/or practicing on a low-profit or non-profit basis.

5.3 Amalgam Separator Vendor Expo 2003 (see Attachment G)

SFE hosted a vendor expo, in collaboration with BERM & (San Francisco Dental Society (SFDS), in order to help SF dentists make informed choices. Invitations were sent out to dentists, inviting them to attend for free. Neighboring City and County officials were also invited to learn more about the mercury reduction process; and expressed great interest in the program. There were many dental practitioners from neighboring jurisdictions/dental associations at the event.

Vendors were charged a fee of $200.00 a booth to display their ARE unit(s); booth costs were used for supplying snacks/drinks at the event. Hazardous waste haulers were also invited to set up booths and advertise their hazardous waste hauling/collection services. They were not charged any fees.

The event was very successful, with a minimum of 300 attendees. All, but two, vendors manufacturing AREs approved by the City displayed their units. Many units (over 15) were sold during the event itself.

5.4 Mercury Monitoring

Current mercury handling practices by dentists will be assessed by surveying dentists regarding their practices and monitoring dental wastewater discharges. In order to gauge the effectiveness of the program, wastewater monitoring will be conducted on three levels: in the collection system, at selected side sewers, and at volunteer dental clinics.

Collection system monitoring will be done in selected trunk lines in the City to provide background data on ambient mercury concentration and temporal variations in the sewage collection system.

Selected side sewers will be monitored at medical-dental buildings where the concentration of dental practices is high. The sampling apparatus and test protocol will closely match the procedure adopted by Hampton Roads (VA) Sanitary District in their national, 5 POTW "AMSA" dental mercury study.

Volunteer dental practices will also be monitored to measure the effectiveness of amalgam removal equipment actually used in clinics. The sampling apparatus will closely match the "Berglund device" developed by the Metropolitan Council Environmental Services division (St. Paul, MN).

Prior studies of dental wastewater in San Francisco showed that approximately 20% of samples collected exceeded the City's Local Limit for mercury, 0.05 mg/l Hg (as total). It is hoped that by monitoring at three levels, fast, unambiguous improvements will be demonstrated, and that long-term reductions in dental mercury introduction will be readily discerned against other sources of mercury entering the sewer system.

6.0 Future Goals

For SFE, the focus will be on training the dental hygienists and other staff to implement the BMPs correctly. SFE is planning to organize workshops for dental staff and site-visits to train them in their own offices. There will also be a Regional Workshop aimed at passing on San Francisco's experience to the other counties of the Bay Area.

BERM will focus mainly on the permit issuance, compliance check and wastewater monitoring issues.

7.0 Highlights

- The implementation of the program in San Francisco was very simple. In that, the program was introduced to the community in September 03 and within the first 3 months, roughly 72% have installed separators and are assumed to be in compliance.

- The vendors/manufacturers of the ARE units played a very important role in the program implementation, with their aggressive marketing to the dental community, as soon as the program was announced. This helped in "spreading the word" to dentists that had not been targeted through the mailing.

- Between 2000-2001, consultant Tom Barron did a study to estimate the amount of mercury captured by a dental office through the implementation of BMPs only vs. the amount of mercury captured through installation of a separator and implementation of BMPs. The results are as follows (personal communication with Tom Barron):

  Without implementation of BMPs & no separator, the loss to sewer = **90%**
  (Remaining 10% is swallowed by the patient initially, lands up in sewer later)
  With the implementation of BMPs & no separator, the loss to sewer* = **20%-30%**
  With the implementation of BMPs & a separator, the loss to sewer* = **2%**

  *(It is assumed that the implementation of BMPs is done properly & separator installation & maintenance is correct)

  Maximum capture of amalgam particles can be achieved through the installation of separators.

* * *

EPA – Environmental Protection Agency
ARE – Amalgam Removal Equipment OR amalgam separators
SFE – S F Environment
SFDS – San Francisco Dental Society
BERM – Bureau of Environmental Regulation & Management
POTW – Publicly Owned Treatment Works
NPDES – National Pollutant Discharge Elimination System
ISO – International Organization for Standardization
BMP – Best Management Practices
ng/l – nanograms/liter
mg/l – milligrams/liter

Mr. BURTON. Thank you.

Let me start with you, Mr. Shah. You know we had, I think from Newport News, VA the Naval base down there, the waste water treatment system stopped the Naval base from flushing things from its dentistry lab there where they took care of the Naval, the personnel of dentistry. They stopped them from flushing that into the waste water treatment plants down there and they had them put it into barrels because they were contaminating the water supply down there so severely. So the problems that you are talking about that were very real in San Francisco are not just a problem for San Francisco, you are absolutely correct. And I would just like to say if we did not have mercury amalgams, how much would that reduce the amount of mercury in the water that goes into the fish that gets into the food chain if there was no mercury amalgam.

Mr. SHAH. Absolutely.

Mr. BURTON. How much?

Mr. SHAH. How much would it reduce?

Mr. BURTON. Yes, 100 percent?

Mr. SHAH. 100 percent.

Mr. BURTON. 100 percent. OK. That is the first thing.

So we know that we reduced or removed mercury from people's teeth, then dentists would not be flushing it down the drains, it would not be going into the waste water treatment plants, it would not be getting into the water and it would not be getting into the fish, and it would not be getting into our bodies when we eat the fish. So there is something that we have not talked too much about, but it is pretty relevant.

Mr. SHAH. Yes.

Mr. BURTON. Because it is not just the teeth we are talking about.

Mr. SHAH. And may I say——

Mr. BURTON. Go ahead, sure.

Mr. SHAH. That we did try. Actually that was one of the first things that we tried to do was basically ban amalgam fillings in San Francisco. And we leave that to your wisdom——

Mr. BURTON. That is what we are working on, yes, right now.

What is the cost difference, Dr. Slavkin between a composite filling and a mercury filling? Cost?

Mr. SLAVKIN. Maybe three fold difference.

Mr. BURTON. Three fold difference? If it was done on a massive basis if the vessel was used to replace amalgams, would the cost go down?

Mr. SLAVKIN. I do not know the benefit of volume. It is a very technique sensitive procedure so that the time it takes to do—a composite done poorly is poor.

Mr. BURTON. Sure.

Mr. SLAVKIN. So the time involved and the technique sensitive nature, I do not know if there is an economy of scale by volume.

Mr. BURTON. You know, the thing that interests me about scientific research, we went into the space program and spinoffs from the space program turned out to include microwaves. I remember when I had my first microwave. How in the world can they cook a baked potato like that, when it takes me an hour when I put it in the oven. It is just not possible. But it happened.

Do you believe that if we made it mandatory that mercury be taken out of amalgams, that we might find an alternative source of composites that maybe would make it less expensive? I mean if the——

Mr. SLAVKIN. Well, people are today engaged in developing biocompatible better materials for all kinds of applications, hip replacements, bone replacement and all of the——

Mr. BURTON. You are the dean of dentistry here. Have you done any research or are you into——

Mr. SLAVKIN. I have personally done research and my colleagues have done research trying to develop a replacement for enamel, a biological enamel. That is a research project and we hope that will succeed.

Mr. BURTON. Have you tried to find a substitute for the amalgams?

Mr. SLAVKIN. I personally have not, but——

Mr. BURTON. Has anybody that you know of?

Mr. SLAVKIN. But in Gaithersburg, sort of down the road from the NIH in Gaithersburg, MD there is a facility called Paffenbarger Institute.

Mr. BURTON. Yes.

Mr. SLAVKIN. And they have a team of people working on a number of restorative materials that do not contain mercury or nickel or cadmium or beryllium which are some of the other components in an inorganic solution.

Mr. BURTON. Well, in any event, I think that science being what it is could come up with an alternative. I certainly do not know what it would.

Mr. SLAVKIN. Sure.

Mr. BURTON. But it must be better than having 50 percent mercury being put into a person's tooth. And if for no other reason than stopping the environment from being polluted because of amalgams being flushed into the waste water treatment systems and into the rivers and everything, that alone seems to me to be a reason to work toward getting rid of amalgam.

But let me ask you a question, Mr. Khorrami. You are a lawyer. When people go on a bank board or a savings and loan board when we had the savings and loan scandal, those people on those boards are subject to liability if they do make decisions that are not in the best interests of the people that they represent, is that correct?

Mr. KHORRAMI. That is my understanding.

Mr. BURTON. What about this board here in California? If it is proven, and I will be and it already has been, but I believe at some point it is going to be so conclusively proven that there will be no doubt.

Would you say that the dental board here in California might be subject to a substantial lawsuit because they did not carry out the will of the people in Proposition 65?

Mr. KHORRAMI. Well, it is funny you should mention that. I think it is under a duty to answer just such a lawsuit. We filed one about a month ago. And we will go through the process of deposing each and every board member if we have to and getting all the documents we need to in order to prove whatever we need to to make

sure that those Prop 65 warnings are getting out and if they are not, yes, we will hold them liable.

Mr. BURTON. Let me ask you one more question, because I think that is a real risk those people are facing. I think they are really facing, and they probably do not have that kind of coverage because a lot of people do not even provide that kind of professional liability coverage anymore. That was my business before I went into Congress. And a lot of people do not want to get on boards anymore because of the liability exposure. And I do not know if anybody is here from the State dental board, but I hope you will get that message back to them that I believe they are exposing themselves to a real liability if they do not comply with the law.

Now let me ask you a——

PARTICIPANT. [Off microphone.]

Mr. BURTON. Good. Do that.

Let me ask you this, the tobacco settlement that we had, and I know that it has been said here today that the manufacturers are the doctors or dentists themselves, but the dental association which is after that putting severe pressure on dentists not to publicize that they are amalgam free or mercury free dentists, would you say that there might be some exposure to them down the road like the exposure that was released by the tobacco industry when it was proven beyond a reasonable doubt that tobacco caused cancer and emphysema and all those other things?

Mr. KHORRAMI. Well, we feel there is. They do try to keep themselves about one step removed by saying well we do not manufacture this stuff, we do not have anything to do with it. We just sort of speak out in the public. It is amusing that they do raise up the issue that they have a person and their right to say all this stuff, and yet the other side does not have any person and a right. But that would be the only different. Past that, we feel that——

Mr. BURTON. The fact of the matter is, though, I do not know if you agree or not, that there is a possible exposure there and the dentists themselves have an exposure if they continue to knowingly put a toxic substance in people's mouths and they do not warn them about it and ultimately it is proven that it results in neurological damage.

Mr. KHORRAMI. Absolutely. And one thing that I want to not, actually the dental association were all too happy in Maryland when we were arguing some motion against them to hang their members out to dry by actually suggesting that we have sued their members rather than them for the amalgam issue. And I thought it was amusing that the members have been paying all these dues to have the dental association walk into court and say you should have sued our members.

Mr. BURTON. Yes. You know, I have not been a big fan of trial lawyers in the past and if you watch my record in my Congress, you have probably seen that. But I have to tell you, when something as obviously wrong is going on, it seems to me that the public has a right to be able to sue the pants off these people until they get this thing right.

You know, Dr. Slavkin, you saw the film that we had on this a few minutes ago. You talked about the risk benefit issue. It is obvi-

ous that the mercury smoke does come off of a dental amalgam. There is no question about that in your mind, is that?

Mr. SLAVKIN. May I respond?

Mr. BURTON. Yes. Yes. I mean, do you or do you not agree with what was on that screen?

Mr. SLAVKIN. I saw what was on the screen. I do not agree with the interpretation of what was on the screen.

Mr. BURTON. What do you think it was?

Mr. SLAVKIN. Well, in doing science——

Mr. BURTON. Yes.

Mr. SLAVKIN [continuing]. You raise an idea that you want to test and you make measurements, and you convert and you develop tests to determine the biological significance, whether it is toxicity or not toxicity. So in the case of seeing a vapor and then interpreting what that vapor to be bad without knowing the biological burden, the amount of material, the responding I believe is one of those arguments a little while ago Mr. Shah inferred that the source of mercury in San Francisco Bay was from dental amalgam. And all of us in this room, I believe, would acknowledge that the source of mercury in Santa Monica Bay or in San Francisco Bay or in Boston Bay is accumulation of hundreds of different sources and the dental amalgam source is minuscule.

Mr. BURTON. Well, let me interrupt you. Yes. In Newport News, VA we had the commander from that Naval base there. We had the people from the sewage water treat plant there. And they said that there was no question that the mercury amalgams were causing a huge problem for the water supply in that area. As a matter of fact, they said they would no longer accept any refuse coming out of that facility and they had to put it in drums and take it away to a storage facility so they could figure out a way to dispose of it. So, you know, sometimes I think that scientists do not want to look at things as they really are.

I am not a scientist. But the fact of the matter is, we have scientists appear before our committee from the University of Kentucky and elsewhere who attest to the fact that the things that you saw on the screen was coming from the mercury amalgams and it could cause neurological damage.

I have talked too long. Ms. Watson.

Ms. WATSON. Thank you so much, Mr. Chairman.

Dr. Slavkin, give me your title again?

Mr. SLAVKIN. I'm a dentist. I am the dean of the School of Dentistry at USC.

Ms. WATSON. You are the dean of the School of Dentistry at USC?

Mr. SLAVKIN. Yes.

Ms. WATSON. All right. As you train your dentists, your students who are dentists, what do you tell them about the various fillings, particularly amalgams? I want to focus in on amalgams. What do you train your potential dentists to do with the amalgam before they put them into the filling, before they themselves mix them and once they remove them? Remove a tooth that might have the amalgams, what do you tell them?

Mr. SLAVKIN. Well, I am very impressed with our faculty. We have 100——

Ms. WATSON. No, no, no. I want to keep you on track. Because this hearing is about——

Mr. SLAVKIN. Right.

Ms. WATSON [continuing]. This particular leaflet. Now, what do you train——

Mr. SLAVKIN. If you would like me to respond, I would be more than happy to.

Ms. WATSON. Yes. I want you to respond to my question.

Mr. SLAVKIN. I think the——

Ms. WATSON. Your only response has to address what you teach the potential dentists about the handling of mercury amalgams.

Mr. SLAVKIN. Right. All of the dental students are exposed to the guideline that I gave you a few moments ago, which has all of the restorative materials and filling materials that are used by their name, by the application, by the ingredients. So they have that.

All of the students have the current EPA guidelines for the handling of dental amalgam. It is basic—and all other restorative materials as part of their education. All of the students. The same goes with local anesthetics or sedation anesthetics.

Ms. WATSON. Let me give you a direct question. Let me see if you can answer it.

Does your faculty ever mention mercury amalgams?

Mr. SLAVKIN. Of course.

Ms. WATSON. OK. Good. Direct answer.

What do you teach your students about the handling of mercury amalgams?

Mr. SLAVKIN. They are taught how to handle it, how to dispose of it, how to look after it in the most professional prudent fashion. They are also taught that it has risks because dentists are people also. And this dentist in front of you is a member of the ADA and is a member of the CDA and is not gagged by anybody and is speaking directly to you and is speaking on behalf of the USC School of Dentistry where we pride ourselves on making sure that all students understand the risks and the benefits of all procedures that they are involved with either as patients or as providers.

Ms. WATSON. Thank you so much for that answer.

Now, have you seen this brochure?

Mr. SLAVKIN. Yes.

Ms. WATSON. Is there anything in here that does not do what you do for your students? Is there anything in here you would like to contradict?

Mr. SLAVKIN. In front of you is the——

Ms. WATSON. No. No. This is the subject of this hearing. Is there anything in here——

Mr. SLAVKIN. I cannot.

Ms. WATSON. Take it down.

Mr. SLAVKIN. The October 2001 version, which I gave you, we have read carefully and distribute that throughout the school. I am not sure——

Ms. WATSON. Is that the October 2001 version?

Mr. BURTON. No, he is referring to the one that he handed you.

Ms. WATSON. No. No. Sir, my reference is to that pamphlet. That is the one that was approved by the dental board.

Mr. SLAVKIN. I have not been given this pamphlet before.

Ms. WATSON. OK. What I would like you to do is read it thoroughly. Address a letter to me and the Chair, if you choose, as to what you find inaccurate in there.

Mr. SLAVKIN. Inaccurate?

Ms. WATSON. Inaccurate.

Mr. SLAVKIN. Yes.

Ms. WATSON. OK. And whether you feel that complies with my legislation of 1992.

I want to really make it clear for everyone within the sound of my voice, the purpose of the hearing today is to investigate why the California Dental Board has not released a mandated pamphlet.

Now, I must commend you for putting this out. I do not think it is circulated wide enough, because if I heard you clearly, it goes to the students who are dentists and those dentists——

Mr. SLAVKIN. No. It is posted. It is for all patients. All patients.

Ms. WATSON. But all patients where?

Mr. SLAVKIN. Wherever we are located. We are located——

Ms. WATSON. Where are you located?

Mr. SLAVKIN. We have a mobile clinic that goes as far north as Bakersfield. We have 14 of them.

Ms. WATSON. Does it go to Eureka?

Mr. SLAVKIN. We are not in Eureka.

Ms. WATSON. OK. You just answered my question. It is not generally circulated——

Mr. SLAVKIN. Why would you ask if we were in Eureka?

Ms. WATSON. Eureka is part of California.

Mr. SLAVKIN. But, I mean, we are——

Ms. WATSON. OK. Listen. Let me——

Mr. SLAVKIN. But the Dental School——

Ms. WATSON. Let me zero in. You cannot snow me with the scientific talk and methodology, OK.

Now, I am the author of a mandated bill that has been completely ignored by the board of professional, supposedly dentists and maybe there might be a non-dentist. I am terribly upset because we have been working with Dr. Yokoyama. And this was, the one that you were just handed, a leaflet that was approved by the majority of the board.

Then they come back in and they give us something that has never been seen by the Chair of the committee. It all gobbledygook as far as I am concerned when professionals come and try to argue scientific methodology to me. Because that is not what my bill was all about. I directed the California Dental Board to come up with a brochure that would be user friendly, elementary language, not four pages of a scientific debate. That is not what I wanted to do.

Mr. YOKOYAMA. Ms. Watson.

Ms. WATSON. Yes.

Mr. YOKOYAMA. If I could just respond quickly. I understand Dr. Slavkin's situation here. He has really been asked to come and talk about this, but he is not responsible for the disruption, so to speak, of the fact sheet as it has gone through the process. So, I do not think he in particular has a particular responsibility.

I understand that you would like him to read the pending brochure, and I think that would be important. But I do not think that

it is his responsibility here today, particularly, concerning that, what I called an extremely disappointing turn of events.

Ms. WATSON. That is not where I am going with this.

Mr. YOKOYAMA. Fine. I just wanted to let you know.

Ms. WATSON. I just wanted everyone to be clear. Am I not speaking English?

Mr. YOKOYAMA. Yes.

Ms. WATSON. OK. My main concern for having this hearing is to find out why these California Dental Board has not complied with the law. OK?

Now, do not give me the scientific gobbledegook about research. That is not why we are here. That is another debate at another time.

I commend you, Dr. Slavkin, for putting this in every office where your program goes. Eureka is part of California. You do not go that far, so they do not have this. They do not see this. What I want is for anyone who goes to a dental office to be aware of what you are putting into their system. I do not know why that is so difficult to do.

Can you explain that to me, Dr. Yokoyama. I see the hand in the back.

Mr. YOKOYAMA. Well, no.

Ms. WATSON. Can you explain why that is difficult.

Mr. YOKOYAMA. I tried to explain in my testimony that it was done. It was in the hands. I mean, you see the result. The brochure ready. It was made ready by the California Department of Consumer Affairs. They went over it very carefully, the language was——

Ms. WATSON. By the way, excuse me for a minute. The bill was written in the Consumer Affairs Code section intentionally because my intent as Chair of California Senate Health and Human Services Committee for 17 years was to protect the consumer. So that is why we wrote it in that code. Some people do not get that. It is about protecting the consumer.

Mr. YOKOYAMA. Right.

Ms. WATSON. And I simply ask. Excuse me. I simply ask that the board of professionals come up with a leaflet that would show the benefits and the deficits, the risk as well as the benefits.

Mr. YOKOYAMA. And I believe that I have come up with that. I believe that was produced. It is in the hands of the board ready to go. It was somehow derailed.

Ms. WATSON. Thank you very much.

Mr. KHORRAMI. Congresswoman.

Ms. WATSON. Yes.

Mr. KHORRAMI. If I may speak just a moment. Perhaps a better question for Dr. Slavkin would be is if he is putting out this warning which you held up that he has in his clinics is I believe the Prop 65 warning that we were talking about, then what would be the opposition to having this same information handled to the patient in the form of a leaflet? Because that warning, unfortunately because of the shortcomings of the law, only has to be passed out by entities that have more than 10 employees which leaves out a big portion of the dentists in this State.

So this pamphlet following your law, pursuant to your law, would take out a huge gap in the law that we have. And perhaps a better that Dr. Slavkin could answer is what would be the opposition of doing just that?

Ms. WATSON. Yes, that is why I said do you a go to Eureka. I mean, do you cover the State? Obviously not. And I am just wondering, that is why I referred to Dr. Yokoyama. Why is it that we cannot get compliance from the dental board.

Mr. BURTON. Ms. Watson, do you have any more questions right now? I have a couple more if you——

Ms. WATSON. OK. If somebody would like to respond to me, someone who has read the brochure, can you tell me what it is in that brochure that Dr. Yokoyama wrote that is so offensive that we have had people blocking us from getting it completed? If anybody would like to respond. If there is some inaccuracy in there, if there is something that you question? Is there anyone in the audience that has seen it who would like to come forward and point it out? If so, would you write me a letter specifying.

The National Dental Association, I gave them the same challenge. I said take my law and take the brochure and then rewrite it and send it back to me. Well, all I got was the letter stating their position in opposition. So I'm missing something and I would like you to help educate me as to what it is I am missing. Will anyone like to respond?

OK. Well, thank you so much, Mr. Chairman.

Mr. BURTON. Thank you. I just have a couple of more questions.

And before we finish, I want to thank our staffs, your staff and my staff, who worked so hard to put this together today. They had to fly all the way out here from Washington, and I really appreciate your hard work. You picking me up today, thank you very much. All the things you guy have done, thank you very much.

Let me just ask a couple more questions here. You are not a doctor of chemistry, are you, Dr. Slavkin?

Mr. SLAVKIN. No.

Mr. BURTON. All right. Well, in May 2003 there was a hearing held by my subcommittee, a Dr. Maths Berlin who is a Ph.D. and professor emeritus in environmental medicine at the University of London presented the finding of his report, which was entitled "Mercury in Dental-Filling Materials—An Updated Risk Analysis in Environmental Medical Terms." Are you familiar with his study at all?

Mr. SLAVKIN. No.

Mr. BURTON. Well, here is what he said. This was the conclusion of his report. "With reference to the fact that mercury is a multipotent toxin with effects on several levels of the biochemical dynamics of the cell, amalgam must be considered to be an unsuitable material for dental restoration. This is especially true since fully adequate and less toxic alternatives are available."

That was his statement, and he has done extensive studies on this.

And then the chairman of the Department of Chemistry at the University of Kentucky Dr. Boyd E. Haley testified before our committee that were absolutely no doubt whatsoever that what we saw on the screen today was accurate; that those emissions were com-

ing from the mercury in those amalgams and they did cause toxicity to the brain.

These are people whose life's work is in that area. And so I hope, and I understand what you said and I admire the work you do here, but I hope you will take a hard look since you are one of the leaders in this area here in California, take a hard look at some of these studies. Because some of these people who have really worked at this as far as from a chemical standpoint, heads of chemistry departments throughout the world, are absolutely convinced that the amalgams are a major part of the problem.

And with that, are there any more questions?

Ms. WATSON. I just wanted to ask Dr. Slavkin, since you are here at USC, would you agree to work with myself and my staff to give us information? Because I really need to get the input from your professionals as to why there is a feeling among the organized dental community that we need to continue to use mercury in amalgams?

Mr. SLAVKIN. Yes. Whatever we can do to, I mean USC and the School of Dentistry. We are interested in facilitating anything that will improve the quality of oral health in the Nation and in California. And if we can be helpful, we would like to——

Ms. WATSON. You know, since I am very, very proud of this institution and you happen to be located in my District, I would like to say that based on the scientific information I received from the University of Southern California and the Dental Department that we have been able to come to this conclusion. I would be very proud to quote the scientific data. And this is for all the panelists. What I am not going to do is tolerate more delays in complying with the law. And what I am going to do, and everyone hear this, is support the lawsuits against the board. And I hope we can look at them individually. Because how dare them violate a mandate. In some way they are not getting that. And I intend to pursue this to its final conclusion.

I would love to have the support of any of you that are willing to work with us, but in particular, Dr. Slavkin, I could use your input.

So let me know.

And thank you so much for putting this out. I wish you would go all the way to Eureka. And with that, I want to say thank you for your participation and your input.

Mr. BURTON. OK. Well, thank you very much.

I think Representative Watson and I put out a press release. I do not know if it is printed or will be printed, but in that press release one of the things that we did was we commented that there was a school where a very minute amount, I believe in a chemistry lab, was spilled. The children had to be taken out of school. Their clothes had to be confiscated. The school had to be evacuated while they cleaned it up because it is such a toxic substance. So I think the point you made is well taken.

I would just like to end up by saying thank you all for your patience.

Thank you, Ms. Watson, for being here today.

And I would like to make one more comment to the board out here on behalf of Ms. Watson. I think if they continue to ignore the

law, they certainly are doing it at their own peril. I think that they are opening themselves up to all kinds of legal exposures if they do not get on with following the law very, very quickly. And if I can help you in anyway, you may rest assured I will.

Thank you very much. We stand adjourned.

Ms. WATSON. Thank you.

[Whereupon, the subcommittee adjourned.]

[Additional information submitted for the hearing record follows:]

CALIFORNIA DENTAL ASSOCIATION®

January 23, 2004

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

CDA®

Dear Chairman Burton:

Thank you for inviting me to testify at the "Subcommittee on Human Rights and Wellness," at the University of Southern California in Los Angeles on January 29. I regret that I am unable to attend due to a business conflict.

We have attempted to find a representative for the California Dental Association (CDA) who would be available to attend your hearing, but we have been unable to do so. Your concerns are very important to CDA and we respectfully request that you accept the attached as our statement to be entered into the Congressional record.

CDA believes that dental amalgam is a valuable and safe choice for dental patients and encourages and supports continued research and constructive dialogue with organizations and individuals to further public health and environmental quality goals.

Thank you for the opportunity to respond on this important subject.

Sincerely,

Cathy Mudge
Assistant Director, Public Policy

c: The Honorable Diane Watson

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CALIFORNIA DENTAL ASSOCIATION
STATEMENT FOR THE CONGRESSIONAL RECORD
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS OF THE COMMITTEE ON GOVERNMENT REFORM
The Honorable Dan Burton, Chairman
"California's Compliance with Dental Amalgam Disclosure Policies"
January 29, 2004
University of Southern California
Los Angeles, California

Position Statement on Dental Amalgam

The California Dental Association (CDA) supports the continued use of dental amalgam as a safe, long-lasting, and versatile dental restorative material.

Dental amalgam has been used to restore the teeth of more than 100 million Americans and many more worldwide. It contains a mixture of metals including mercury, silver, copper, and tin, which chemically binds together into a hard, stable and safe substance. Concern about adverse health affects from amalgam's mercury content is unfounded. Dental amalgam has been studied and reviewed extensively, and has established a long record of safety and effectiveness.

CDA looks to the federal and international public health agencies to determine the safety of all products used in the practice of dentistry. The U.S. Food and Drug Administration, U.S. Public Health Service, World Health Organization, Centers for Disease Control and Prevention, National Institutes of Health, and U.S. Department of Health and Human Services all have found dental amalgam to be a safe and effective dental restorative material and have recommended no limitations on its use except for patients that are allergic to any of the metal components contained in amalgam.

Continued Research on Dental Amalgam

To ensure public safety, these public health organizations continue to review and monitor the literature and research. The U.S. Public Health Service reviewed the body of science regarding the safety of dental amalgam and published reports in 1993 and 1997, not recommending any restrictions be placed on its use. FDA, NIH, and NIDCR are currently sponsoring another independent review of the scientific literature since 1997 and a report will be published later this year.

History of the Dental Materials Fact Sheet

Beginning in 1993, dentists received the Dental Materials Fact Sheet, referred to as the DMFS, from the Board of Dental Examiners of California. The legislation requiring the creation of this fact sheet was passed in 1992 (Chapter 801, 1992 Statutes) and specifically required:

> "...the Board of Dental Examiners of California to develop, distribute, and update as necessary, a fact sheet describing and comparing the risks and efficacy of *the various types of dental restorative materials* that may be used to repair a dental patient's oral condition or defect..."

This law did not single out dental amalgam; it specifically required information for all restorative materials. This fact sheet was intended as a resource to dentists when speaking with the patients about the restorative material choices available to them.

During the dental board's review by the California's Joint Legislative Sunset Review Committee in 1999, public citizens expressed concern that the DMFS had not been updated recently. The following year, a revision to the fact sheet was pursued by the board. The process spanned almost 2 years, beginning with the dental board establishing a process to identify an objective and independent expert to assist them in developing a revised fact sheet -- a process that could withstand scrutiny. The new fact sheet was approved by the Dental Board in November 2001, following months of public hearings held by the board throughout the State of California to ensure that the public had the opportunity to hear and comment on the proposed fact sheet. That document was published and sent to dentists before the end of 2001.

At the same time, legislation also passed (SB 134, Chapter 532, Statutes of 2001) amending the original law regarding the fact sheet, now requiring that the DMFS, effective January 1, 2002:

> "...shall be provided by a dentist to every new patient and to patients of record prior to the performance of dental restoration work."

The legislation also requires that the patient must acknowledge receipt of the DMFS in writing.

To comply with the law, dentists began providing the DMFS to their patients in January 2002.

Since the new law required the dentist to provide the patient with a copy of the DMFS, and although not specifically required by the legislation, the dental board proposed creating a consumer-friendly version of the DMFS, simplifying the language to meet the recommended reading level standard used by the Department of Consumer Affairs for information distributed to the public.

The board established a two-person subcommittee to develop this consumer-friendly fact sheet, and that process is ongoing. In 2003, one member of the subcommittee proposed a new fact sheet containing significantly different information from that contained in the current fact sheet, information that is not supported by the body of scientific literature. Support was not provided for this version of the fact sheet by the other subcommittee member. The board has asked the subcommittee to bring forth a document that the board can vote on. Currently two versions are scheduled to be discussed at the dental board meeting scheduled for January 29-30 in Sacramento.

Related Legislation

Recently CDA supported legislation giving state dental Medicaid (Denti-Cal) providers the flexibility to place non-amalgam posterior fillings, while allowing them to bill for the covered benefit of amalgam, supporting CDA's position that dental treatment should be decided by the dentist and the patient.

The impact of dental amalgam on the environment continues to be studied as well. Although dental amalgam can be found in dental office wastewater, its exact impact on the environment is undetermined. Dentistry, as a health profession, is the steward of the public's dental health and includes being a responsible member of the community with regard to our impact on the environment. Where it is deemed prudent for dentistry to take meaningful steps to reduce amalgam waste, dentistry is prepared to do so. Currently CDA is proposing legislation to create uniform, comprehensive statewide best management practices which will significantly reduce the presence of dental amalgam in wastewater.

Conclusion

We believe that California dentists and the licensing board are complying with dental amalgam disclosure policies. We are not only complying but we continue to support and encourage dentists to inform their patients of all the dental treatment options recommended and available to them, not only restorative materials.

In addition, we continue to work successfully with every wastewater treatment organization that has asked for our assistance in reducing the amount of dental amalgam in wastewater leaving our office.

CDA believes that dental amalgam is a valuable and safe choice for dental patients and encourages and supports continued research and constructive dialogue with organizations and individuals that further public health and environmental quality goals.

CDA believes that dental amalgam is a valuable and safe choice for dental patients and encourages and supports continued research and constructive dialogue with organizations and individuals that further public health and environmental quality goals.

The following document is the Dental Board of California's Dental Materials Fact Sheet. The Department of Consumer Affairs has no position with respect to the language of this Dental Materials Fact Sheet; and its linkage to the DCA Web site does not constitute an endorsement of the content of this document.

The Dental Board of California
DENTAL MATERIALS FACT SHEET

Adopted by the Board on October 17, 2001

As required by Chapter 801, Statutes of 1992, the Dental Board of California has prepared this fact sheet to summarize information on the most frequently used restorative dental materials. Information on this fact sheet is intended to encourage discussion between the patient and dentist regarding the selection of dental materials best suited for the patient's dental needs. It is not intended to be a complete guide to dental materials science.

The most frequently used materials in restorative dentistry are amalgam, composite resin, glass ionomer cement, resin-ionomer cement, porcelain (ceramic), porcelain (fused-to-metal), gold alloys (noble) and nickel or cobalt-chrome (base-metal) alloys. Each material has its own advantages and disadvantages, benefits and risks. These and other relevant factors are compared in the attached matrix titled "Comparisons of Restorative Dental Materials." "A Glossary of Terms" is also attached to assist the reader in understanding the terms used.

The statements made are supported by relevant, credible dental research published mainly between 1993 - 2001. In some cases, where contemporary research is sparse, we have indicated our best perceptions based upon information that predates 1993.

The reader should be aware that the outcome of dental treatment or durability of a restoration is not solely a function of the material from which the restoration was made.

The durability of any restoration is influenced by the dentist's technique when placing the restoration, the ancillary materials used in the procedure, and the patient's cooperation during the procedure. Following restoration of the teeth, the longevity of the restoration will be strongly influenced by the patient's compliance with dental hygiene and home care, their diet and chewing habits.

Both the public and the dental profession are concerned about the safety of dental treatment and any potential health risks that might be associated with the materials used to restore the teeth. All materials commonly used (and listed in this fact sheet) have been shown – through laboratory and clinical research, as well as through extensive clinical use – to be safe and effective for the general population. The presence of these materials in the teeth does not cause adverse health problems for the majority of the population. There exist a diversity of various scientific opinions regarding the safety of mercury dental amalgams. The research literature in peer-reviewed scientific journals suggests that otherwise healthy women, children and diabetics are not at increased risk for exposure to mercury from dental amalgams. Although there are various opinions with regard to mercury risk in pregnancy, diabetes, and children, these opinions are not scientifically conclusive and therefore the dentist may want to discuss these opinions with their patients. There is no research evidence that suggests pregnant women, diabetics and children are at increased health risk from dental amalgam fillings in their mouth. A recent study reported in the JADA factors in a reduced tolerance (1/50th of the WHO safe limit) for exposure in calculating the amount of mercury that might be taken in from dental fillings. This level falls below the established safe limits for exposure to a low concentration of mercury or any other released component from a dental restorative material. Thus, while these sub-populations may be perceived to be at increased health risk from exposure to dental restorative materials, the scientific evidence does not support that claim. However, there are individuals who may be susceptible to sensitivity, allergic or adverse reactions to selected materials. As with all dental materials, the risks and benefits should be discussed with the patient, especially with those in susceptible populations.

There are differences between dental materials and the individual elements or components that compose these materials. For example, dental amalgam filling material is composed mainly of mercury (43-54%) and varying percentages of silver, tin, and copper (46-57%). It should be noted that elemental mercury is listed on the Proposition 65 list of known toxins and carcinogens. Like all materials in our environment, each of these elements by themselves is toxic at some level of concentration if they are taken into the body. When they are mixed together, they react chemically to form a crystalline metal alloy. Small amounts of free mercury may be released from amalgam fillings

over time and can be detected in bodily fluids and expired air. The important question is whether any free mercury is present in sufficient levels to pose a health risk. Toxicity of any substance is related to dose, and doses of mercury or any other element that may be released from dental amalgam fillings falls far below the established safe levels as stated in the 1999 US Health and Human Service Toxicological Profile for Mercury Update.

All dental restorative materials (as well as all materials that we come in contact with in our daily life) have the potential to elicit allergic reactions in hypersensitive individuals.[1] These must be assessed on a case-by-case basis, and susceptible individuals should avoid contact with allergenic materials. Documented reports of allergic reactions to dental amalgam exist (usually manifested by transient skin rashes in individuals who have come into contact with the material), but they are atypical. Documented reports of toxicity to dental amalgam exist, but they are rare. There have been anecdotal reports of toxicity to dental amalgam and as with all dental material risks and benefits of dental amalgam should be discussed with the patient, especially with those in susceptible populations.

Composite resins are the preferred alternative to amalgam in many cases. They have a long history of biocompatibility and safety. Composite resins are composed of a variety of complex inorganic and organic compounds, any of which might provoke allergic response in susceptible individuals. Reports of such sensitivity are atypical. However, there are individuals who may be susceptible to sensitivity, allergic or adverse reactions to composite resin restorations. The risks and benefits of all dental materials should be discussed with the patient, especially with those in susceptible populations.

Other dental materials that have elicited significant concern among dentists are nickel-chromium-beryllium alloys used predominantly for crowns and bridges. Approximately 10% of the female population are alleged to be allergic to nickel.[2] The incidence of allergic response to dental restorations made from nickel alloys is surprisingly rare. However, when a patient has a positive history of confirmed nickel allergy, or when such hypersensitivity to dental restorations is suspected, alternative metal alloys may be used. Discussion with the patient of the risks and benefits of these materials is indicated.

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[1] *Dental Amalgam: A scientific review and recommended public health service strategy for research, education and regulation, Dept. of Health and Human Services, Public Health Service, January 1993.*

[2] *Merck Index 1983. Tenth Edition, M Narsha Windhol z, (ed).*

GLOSSARY OF TERMS

General description – Brief statement of the composition and behavior of the dental material

Principal uses – The types of dental restorations that are made from this material.

Resistance to further decay – The general ability of the material to prevent decay around it.

Longevity/durability – The probable average length of time before the material will have to be replaced. (This will depend upon many factors unrelated to the material such as biting habits of the patient, their diet, the strength of their bite, oral hygiene, etc.)

Conservation of tooth structure – A general measure of how much tooth needs to be removed in order to place and retain the material.

Surface wear/fracture resistance – A general measure of how well the material holds up over time under the forces of biting, grinding, clenching, etc.

Marginal integrity (leakage) – An indication of the ability of the material to seal the interface between the restoration and the tooth, thereby helping to prevent sensitivity and new decay.

Resistance to occlusal stress – The ability of the material to survive heavy biting forces over time.

Biocompatibility – The effect, if any, of the material on the general overall health of the patient.

Allergic or adverse reactions – Possible systemic or localized reactions of the skin, gums and other tissues to the material.

Toxicity – An indication of the ability of the material to interfere with normal physiologic processes beyond the mouth.

Susceptibility to sensitivity – An indication of the probability that the restored teeth may be sensitive to stimuli (heat, cold, sweet, pressure) after the material is placed in them.

Esthetics – An indication of the degree to which the material resembles natural teeth.

Frequency of repair or replacement – An indication of the expected longevity of the restoration made from this material.

Relative cost – A qualitative indication of what one would pay for a restoration made from this material compared to all the rest.

Number of visits required – How many times a patient would usually have to go to the dentist's office in order to get a restoration made from this material.

Dental amalgam – Filling material which is composed mainly of mercury (43-54%) and varying percentages of silver, tin, and copper (46-57%).

COMPARISONS OF DIRECT RESTORATIVE DENTAL MATERIALS

COMPARATIVE FACTORS	AMALGAM	COMPOSITE RESIN (DIRECT & INDIRECT RESTORATIONS)	GLASS IONOMER CEMENT	RESIN-IONOMER CEMENT
GENERAL DESCRIPTION	Self-hardening mixture in varying percentages of a liquid mercury and silver-tin alloy powder.	Mixture of powdered glass and plastic resin; self-hardening or hardened by exposure to blue light.	Self-hardening mixture of glass and organic acid.	Mixture of glass and resin polymer and organic acid; self hardening by exposure to blue light.
PRINCIPAL USES	Fillings, sometimes for replacing portions of broken teeth.	Fillings, inlays, veneers, partial and complete crowns; sometimes for replacing portions of broken teeth.	Small fillings; cementing metal & porcelain/metal crowns, liners, temporary restorations.	Small fillings; cementing metal & porcelain/metal crowns, and liners.
RESISTANCE TO FURTHER DECAY	High; self-sealing characteristic helps resist recurrent decay; but recurrent decay around amalgam is difficult to detect in its early stages.	Moderate; recurrent decay is easily detected in early stages.	Low-Moderate; some resistance to decay may be imparted through fluoride release.	Low-Moderate; some resistance to decay may be imparted through fluoride release.
ESTIMATED DURABILITY (Permanent teeth)	Durable	Strong, durable.	Non-stress bearing crown cement.	Non-stress bearing crown cement.
RELATIVE AMOUNT OF TOOTH PRESERVED	Fair; requires removal of healthy tooth to be mechanically retained. No adhesive bond of amalgam to the tooth.	Excellent; bonds adhesively to healthy enamel and dentin.	Excellent; bonds adhesively to healthy enamel and dentin.	Excellent; bonds adhesively to healthy enamel and dentin.
RESISTANCE TO SURFACE WEAR	Low; similar to dental enamel; brittle metal.	May wear slightly faster than dental enamel.	Poor in stress-bearing applications. Fair in non- stress bearing applications.	Poor in stress-bearing applications. Good in non-stress bearing applications.
RESISTANCE TO FRACTURE	Amalgam may fracture under stress; tooth around filling may fracture before the amalgam does.	Good resistance to fracture.	Brittle; low resistance to fracture but not recommended for stress-bearing restorations.	Tougher than glass ionomer; recommended for stress-bearing restorations in adults.
RESISTANCE TO LEAKAGE	Good; self-sealing by surface corrosion; margins may chip over time.	Good if bonded to enamel; may show leakage over time when bonded to dentin. Does not corrode.	Moderate; tends to crack over time.	Good, adhesively bonds to resin, enamel, dentine/ post-insertion expansion may help seal the margins.
RESISTANCE TO OCCLUSAL STRESS	High; but lack of adhesion may weaken the remaining tooth.	Good to Excellent depending upon product used.	Poor; not recommended for stress-bearing restorations.	Moderate; not recommended to restore biting surfaces of adults; suitable for short-term primary teeth restorations.
TOXICITY	Generally safe; occasional allergic reactions to metal components. However amalgams contain mercury. Mercury in its elemental form is toxic and as such is listed on Prop 65.	Concerns about trace chemical release are not supported by research studies. Safe; no known toxicity documented. Contains some compounds listed on Prop 65.	No known incompatibilities. Safe; no known toxicity documented.	No known incompatibilities. Safe; no known toxicity documented
ALLERGIC OR ADVERSE REACTIONS	Rare; recommend that dentist evaluate patient to rule out metal allergies.	No documentation for allergic reactions was found.	No documentation for allergic reactions was found. Progressive roughening of the surface may predispose to plaque accumulation and periodontal disease.	No known documented allergic reactions; Surface may roughen slightly over time; predisposing to plaque accumulation and periodontal disease if material contacts the gingival tissue.
SUSCEPTIBILITY TO POST-OPERATIVE SENSITIVITY	Minimal; high thermal conductivity may promote temporary sensitivity to hot and cold. Contact with other metals may cause occasional and transient galvanic response.	Moderate; Material is sensitive to dentist's technique; Material shrinks slightly when hardened, and a poor seal may lead to bacterial leakage, recurrent decay and tooth hypersensitivity.	Low; material seals well and does not irritate pulp.	Low; material seals well and does not irritate pulp.
ESTHETICS (Appearance)	Very poor. Not tooth colored; initially silver-gray, gets darker, becoming black as it corrodes. May stain teeth dark brown or black over time.	Excellent; often indistinguishable from natural tooth.	Good; tooth colored, varies in translucency.	Very good; more translucency than glass ionomer.
FREQUENCY OF REPAIR OR REPLACEMENT	Low; replacement is usually due to fracture of the filling or the surrounding tooth.	Low-Moderate; durable material hardens rapidly; some composite materials show more rapid wear than amalgam. Replacement is usually due to marginal leakage.	Moderate; slowly dissolves in mouth; easily dislodged.	Moderate; more resistant to dissolving than glass ionomer, but less than composite resin.
RELATIVE COSTS TO PATIENT	Low; relatively inexpensive; actual cost of fillings depends upon their size.	Moderate; higher than amalgam fillings; actual cost of fillings depends upon their size; veneers & crowns cost more.	Moderate; similar to composite resin (not used for veneers and crowns)	Moderate; similar to composite resin (not used for veneers and crowns).
NUMBER OF VISITS REQUIRED	Single visit (polishing may require a second visit)	Single visit for fillings; 2+ visits for indirect inlays, veneers and crowns.	Single visit.	Single visit.

COMPARISONS OF INDIRECT RESTORATIVE DENTAL MATERIALS

COMPARATIVE FACTORS	PORCELAIN (CERAMIC)	PORCELAIN (FUSED TO METAL)	GOLD ALLOYS (NOBLE)	NICKEL OR COBALT-CHROME (BASE METAL) ALLOYS
GENERAL DESCRIPTION	Glass-like material formed into fillings and crowns using models of the prepared teeth.	Glass-like material that is "enameled" onto metal shells. Used for crowns and fixed-bridges.	Mixtures of gold, copper and other metals used mainly for crowns and fixed bridges.	Mixtures of nickel, chromium.
PRINCIPAL USES	Inlays, veneers, crowns and fixed-bridges.	Crowns and fixed-bridges.	Cast crowns and fixed bridges; some partial denture frame-works.	Crowns and fixed bridges; most partial denture frameworks.
RESISTANCE TO FURTHER DECAY	Good, if the restoration fits well.	Good, if the restoration fits well.	Good, if the restoration fits well.	Good, if the restoration fits well.
ESTIMATED DURABILITY (Permanent teeth)	Moderate; Brittle material that may fracture under high biting forces. Not recommended for posterior (molar) teeth.	Very good. Less susceptible to fracture due to the metal substructure.	Excellent. Does not fracture under stress; does not corrode in the mouth.	Excellent. Does not fracture under stress; does not corrode in the mouth.
RELATIVE AMOUNT OF TOOTH PRESERVED	Good - Moderate. Little removal of natural tooth is necessary for veneers; more for crowns since strength is related to its bulk.	Moderate-High. More tooth must be removed to permit the metal to accompany the porcelain.	Good. A strong material that requires removal of a thin outside layer of the tooth.	Good. A strong material that requires removal of a thin outside layer of the tooth.
RESISTANCE TO SURFACE WEAR	Resistant to surface wear; but abrasive to opposing teeth.	Resistant to surface wear; permits either metal or porcelain on the biting surface of crowns and bridges.	Similar hardness to natural enamel; does not abrade opposing teeth.	Harder than natural enamel but minimally abrasive to opposing natural teeth. Does not fracture in bulk.
RESISTANCE TO FRACTURE	Poor resistance to fracture.	Porcelain may fracture.	Does not fracture in bulk.	Does not fracture in bulk.
RESISTANCE TO LEAKAGE	Very good. Can be fabricated for very accurate fit of the margins of the crowns.	Good – Very good depending upon design of the margins of the crowns.	Very good – Excellent. Can be formed with great precision and can be tightly adapted to the tooth.	Good-Very good – Stiffer than gold; less adaptable, but can be formed with great precision.
RESISTANCE TO OCCLUSAL STRESS	Moderate; brittle material susceptible to fracture under biting forces.	Very good. Metal substructure gives high resistance to fracture.	Excellent	Excellent
TOXICITY	Excellent. No known adverse effects.	Very Good to Excellent. Occasional/rare allergy to metal alloys used.	Excellent. Rare allergy to some alloys.	Good. Nickel allergies are common among woman, although rarely manifested in dental restorations.
ALLERGIC OR ADVERSE REACTIONS	None	Rare. Occasional allergy to metal substructure.	Rare. Occasional allergic reacations seen in susceptible individuals.	Occasional; infrequent reactions to nickel.
SUSCEPTI-BILITY TO POST-OPERATIVE SENSITIVITY	Not material dependent; does not conduct heat and cold well.	Not material dependent; does not conduct heat and cold well.	Conducts heat and cold; may irritate sensitive teeth.	Conducts heat and cold; may irritate sensitive teeth.
ESTHETICS (Appearance)	Excellent	Good to Excellent	Poor— yellow metal	Poor— dark silver metal
FREQUENCY OF REPAIR OR REPLACEMENT	Varies; depends upon biting forces; fractures of molar teeth are more likely than anterior teeth; porcelain fracture may often be repaired with composite resin.	Infrequent; porcelain fracture can often be repaired with composite resin.	Infrequent; replacement is usually due to recurrent decay around margins	Infrequent; replacement is usually due to recurrent decay around margins
RELATIVE COSTS TO PATIENT	High; requires at least two office visits and laboratory services.	High; requires at least two office visits and laboratory services.	High; requires at least two office visits and laboratory services.	High; requires at least two office visits and laboratory services.
NUMBER OF VISITS REQUIRED	Two – minimum; matching esthetics of teeth may require more visits.	Two – minimum; matching esthetics of teeth may require more visits.	Two - minimum	Two - minimum