your committee special task force meetings, were there any discussions on potential safety concerns regarding other alternative restorative materials, like estrogenic effect of composite resins.

DR. PHILIPSON: Your first question was -- can you just repeat part of it?

DR. LI: Yes. Was there a discussion for the specific measures to address the environmental concerns for these specially permitted uses?

DR. PHILIPSON: Right, right, in hospital care.

DR. LI: Right.

DR. PHILIPSON: I don't know the regulation of the use of medical devices in general. It's done by the National Board of Health and Welfare, and I'm not sure how they are going to express what are the special patients and the reasons for the use of dental amalgams in hospital care. I haven't seen those recommendations yet.

But they say for very special cases. What I heard, you would like to avoid longer periods of anaesthesia, for example, and you might need a longer period of anaesthesia if you used an alternative material to amalgam if you do many fillings at once. So that could be one reason.

But I haven't seen the recommendations. I'm not sure they exist yet.

DR. LI: Can you comment on the second question? My question was were there any discussions during your committee meetings on potential safety concerns with other alternative restorative materials, for example, the potential purported estrogenic effect of composite resins? Were there any discussions on that?

DR. PHILIPSON: I have not been in discussions like that. I'm sure this is being discussed among experts, but the regulatory system is the same for the new dental filling materials as it is for the older ones. It is up to the manufacturer to show and prove that the new dental filling material is safe and fit for the intended purpose. It's up to the manufacturer to show that.

DR. LI: Thank you.

CO-CHAIRMAN BURTON: Yes. In the corner and then Dr. Sacco, please.

DR. TAYLOR: Dr. Philipson, in designing the registry, it sounds like the principal focus is on outcomes, events and conditions that might occur. Were there any considerations for registering the exposures and what the dental profession might

contribute?

DR. PHILIPSON: I think I said already I don't know what the register or how it is going to be built. They are still designing it., and so I'm afraid I cannot answer that question.

CO-CHAIRMAN BURTON: Dr. Sacco.

DR. SACCO: This is a question again maybe regarding a little bit more of the European framework. This Swedish government rule regarding prohibition, is this only in Sweden?

And then the larger question is are other European nations part of or not part of the European Union considering anything else like this?

DR. PHILIPSON: This is a national decision, and of course, we're going to communicate this to the European Commission and other countries might follow and might not follow.

What could happen is that the European Commission is critical to this national decision, if they find that our local decision stops the free movement of goods across the European Union, but we hope not, but it's a theoretical possibility that they will not love our national decision in Brussels.

CO-CHAIRMAN BURTON: We're running a little bit behind our agenda. So I'm going to make a

couple of modifications. We're going to take our break at this time, and it will be limited to ten minutes.

I did want to make one comment before we adjourn for our break. I'd just like to remind everyone about the comments by Mr. Adjodha earlier about disrupting the meeting and safety concerns and code issues, not allowing signs or signs with sticks in the meeting room. The hotel has provided a display area for that.

It is currently 10:35. We will return at 10:45 and pick up with our agenda at that time.

Thank you very much.

(Whereupon, the foregoing matter went off the record at 10:38 a.m. and went back on the record at 10:51 a.m.)

CO-CHAIRMAN BURTON: Again, in kindness to our next speaker, could we please take our seats so that we can get started with our next presentation?

Our next presentation is Dr. Richard Canady who is a senior health science in the Office of the Commissioner of the Food and Drug Administration. His presentation will be on the U.S. Public Health Agencies' evaluations relevant to dental amalgam prior to 1997.

Dr. Canady.

DR. CANADY: Thanks.

While we're bringing it up on the screen, I'll just introduce myself. I'm Richard Canady. I'm a 20 year veteran as a toxicologist. I work in the Office of Science of the Office of the Commissioner of the Food and Drug Administration.

It's my simple task today to try to run through some of the U.S. Public Health Agencies' evaluations prior to 1997 relevant to amalgam, and this is in the way of presaging the white paper that you're going to see this afternoon.

I'm going to focus on three groupings, three agencies or actually two agencies and then one grouping of U.S. Public Health Service Agencies: the Environmental Protection Agency, which as you all know is primarily concerned with environmental issues; Safety Values, they develop with respect to environmental decisions; the Agency for Toxic Substances and Disease Registry, which you may be a little less familiar with, ATSDR, down in Atlanta. They do, again, reviews related to environmental issues, particularly hazardous waste sites. They also develop safety values for environmental decisions to support decisions of further analysis, for example, at

hazardous waste sites.

The U.S. Public Health Service=s combined agencies, which comprise, for example, the Food and Drug Administration, Environmental Protection Agency, other parts of the Department of Health and Human Services.

The U.S. Public Health Service evaluations that I'm going to talk about include input from experts across the agencies, but then also from academia. They evaluated safety of amalgam back in 1993 and 1997, and the 1997 data, again, is the precursor for what you're going to see in the evaluation this afternoon, in the white paper this afternoon or -- I'm sorry -- tomorrow afternoon.

The Environmental Protection Agency's mission I just put up here quickly is to protect human health and the environment. It has been around since 1970. We probably don't need to spend a lot of time on that.

Within the Environmental Protection Agency's activities or processes, they develop what are called reference concentrations or reference doses, and these are evaluations of the toxicity of individual chemicals. The reference dose and reference concentration generally is defined as a dose

or an air level likely to be without an appreciable risk of deleterious effects during a lifetime.

For mercury, particularly two forms of relevance. There's inorganic mercury, which is predominantly the salts of mercury. They developed an RFD for that, a reference dose, an oral dose back in the late 1980s.

For mercury vapor or the elemental form of mercury, they developed a reference concentration, an air concentration, an air back in about the same time, in the late '80s.

So these evaluations provide an understanding of the toxicology, and as defined in the top of this slide, a dose or an air level that is likely to be without appreciable risk of deleterious effects, and so, therefore, it's useful information in understanding the amount of risk associated with exposures to dental amalgam or the mercury within dental amalgam.

Also, in the mid-'90s, but then culminating with a report in 1997, EPA did a report to Congress. This was associated with Clean Air Act requirements. This report to Congress was primarily related, obviously to environmental evaluations, and I give the Web address here in this slide.

Within this analysis though they did a detailed compendium and evaluation of mercury toxicity studies. There's approximately 650 pages of analysis within the full report, which is about double that length in its entirety, in which they looked at exposure to mercury of all kinds and health effects of all kinds or, rather, for all forms of mercury.

Within that report they confirmed the late 1980s values reference dose and reference concentrations for inorganic and vapor mercury.

They briefly reviewed amalgam exposure within that report, but they did not do a risk assessment of it. They simply spent I think it was approximately a page of two within that looking through the reports about exposures to mercury that derive from amalgam use in dental restorations.

Moving on to ATSDR, the Agency for Toxic Substances and Disease Registry, ATSDR was created by Congress in the '80s to assess the presence and nature of health hazards specific to different sites, prevent or reduce further exposure and illnesses that might result from such exposures and expand the knowledge base, particularly, about health effects from exposure to hazardous substances.

Again, this is useful information,

corollary information that helps us understand the effects of mercury exposure and is a place where a compendia of information are available to try to understand those effects and to, again, ensure that we've looked through all of the available sources for information.

ATSDR, as part of its mandate, is charged with preparing what are called toxicological profiles on environmental contaminants. Mercury, again, all forms of mercury, was profiled at ATSDR in the late 1980s in the first sets of profiles that ATSDR actually prepared.

It was then updated in 1990, 1994, and again for the last time in 1999. The 1999 profile -- and, again, this is just as a way of giving you an indication of how detailed or how extensive the analysis is -- is about 670 pages long. It has an 85 page reference list.

Each of these profiles that ATSDR does, as a matter of practice, goes through a peer review process. They go through an external public comment draft, which is sent out to the public. All public comments are received, reviewed, and then addressed within the subsequent final draft that goes out.

So these profiles go through two separate

peer reviews and a public comment round. So the rather careful ATSDR is in trying to figure out where the data sources are and to address them and incorporate them appropriately.

Within the ATSDR profiles they derive values which are analogous to the reference doses and reference concentrations that EPA develops. The minimal risk levels are what ATSDR calls them. They've developed them for mercury vapor and inorganic mercury, the two relevant forms of mercury for this committee's evaluation.

The MRLs go through an independent interagency review and then are released with the ATSDR profiles, again, through their public comment process and go through the peer reviews that the normal profile goes through.

And the definition of the MRL is given at the bottom, or actually an excerpt from the definition of MRL is given at the bottom of that slide, and you'll note that it's quite similar to what EPA's definition of an RFD or an RFC is, and that is that it's an estimate of a daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects, and they specify that it's non-carcinogenic, but the RFD and RFC from EPA are

also in reference to non-carcinogenic effects.

So the ATSDR MRLs are based on the same studies, and I'm going to provide a graphic in a minute that lays all of this out and shows you where the various values lay out and their derivation. They're based on the same studies that EPA based their RFC and RFDs on.

And like EPA, the values that are in place today for ATSDR are the same ones that were derived in the late 1980s and early '90s. And this is despite ongoing literature searches, yearly lit searches as we'll hear tomorrow afternoon in the white paper, and despite updates of the profiles. So they have looked pretty exhaustively and retained the same values they had back in the 1980s.

I want to spend a little bit of time going through how those values, the reference dose, the reference concentration, and the MRL are derived, actually just the reference concentration for EPA and the MRL for ATSDR are derived for the vapor form of mercury.

Both the EPA and ATSDR values are based on a 1983 study of occupational exposure, Fawer, et al., 1983, and this is referenced in the white paper, by the way. So you have the full citation for this.

Within that paper, the Fawer, et al., study, they identify a dose, the lowest dose that caused adverse effect, and in this case it was increased at velocity of an intention tremor that they measured as the effect on which they based their dose response analysis.

So that air concentration was 26 micrograms in a cubic meter of air. Now, both WPA and ATSDR use that value, which was an occupational exposure so that it was a 40 hour work week, to get to what would be an equivalent 24 hour a day, seven days a week exposure.

EPA came to nine micrograms per meter cubed. ATSDR came to 6.2 micrograms per meter cubed. The difference is largely because or is because, rather, EPA actually used the difference in inhalation in an eight hour work day versus a 24 hour day. So they divided ten hours or the ten cubic meters that you would get while you were in a job by the 20 cubic meters that you would get if you were, you know, having a 24 hour exposure. So that explains the difference.

There is no policy difference between these two values. There is just a different way of accounting for the exposures and trying to estimate

the 24 hour exposures.

And actually, you know, there's experts on this panel who know probably a little more about this than I do. So if there's further questions, we might go into detail with discussions amongst yourselves.

Both EPA and ATSDR then derived that their values, their respective values -- and, again, it's nine and 6.2 -- by uncertainty factors to protectively account for the uncertainty and whether the database was sufficient and whether they have accounted for sensitive populations and so on.

The resulting values were that the EPA reference concentration in the air is .3 micrograms per meter cubed, and the ATSDR MRL for vapor in the air is .2. Within our world, these are pretty much exactly the same number, I mean, between ATSDR and EPA. So the difference is really not material.

Now, if you lay these values out on a graph, and I'm going to provide a non-log graph in just a minute for those of you who don't like log axes, you have the Fawer value at 26, the two derivations that lead to a 24 hour exposure below that, and then the ATSDR and EPA reference values, health based reference values, below showing, again, the 30-fold uncertainty factor.

If you provide that on a non-log graph, it looks a little different, and that's it, and this is just by way of laying out the information that was presented in those two analyses.

And, again, I'm going through the EPA and the ATSDR values or, rather, the EPA and ATSDR evaluations, including the values, as a way of showing independent evaluations of the information that were available at the time in 1997 and that helped substantiate the understanding of risk at that time.

The U.S. public health service, as I laid out earlier in the presentation, did two or actually one analysis and then an update. The U.S. Public Health Service agencies included in those evaluations participants from the Centers for Disease Control, Environmental Protection Agency, National Institute for Environmental Health Sciences within the National Institutes of Health, National Institute of Dental Research, which is now dental and craniofacial research. NIOSH is National Institute of Occupational Safety and Health; Food and Drug Administration, and also ATSDR, which is not on this list, but it was included.

But that also included consultation from academia. The expertise ranged across a wide range of

toxicology issues and included in addition to that exposure expertise.

The findings were published in a 1993 U.S. PHS report, and I'm going to show you the major conclusion or, rather, an excerpt of the conclusions from that in just a second, and then an update was published in 1997.

The 1993 U.S. Public Health Service report conclusion excerpted here reads, "The current scientific evidence does not show that exposure to mercury from amalgam restorations poses a serious health risk in humans, except for an exceedingly small number of allergic reactions."

Now, this 1993 report is a rather detailed evaluation of a lot of studies. It shows 119 studies reviewed here. There were actually a fair number of studies that were researched within the literature searches and that were considered for evaluation and detail within the report.

There were a number of independent working groups that looked at independent issues, such as exposure which I'll go into in a few slides, but then also independent toxicology evaluations. So there's a fair amount of work that went into this report.

One of the findings within the report had

to do with the exposure that we would estimate people received from dental amalgams in their mouths. There's a fair amount of variation in estimates that have been derived for this based on different methodologies, different estimation techniques, different instruments used, and so on. And there is within the 1993 report a fair amount of evaluation of those various publications and analyses, with an effort to understand what you might most reasonably assume or most reasonably estimate is the exposure from amalgam.

That report, and again, I'm just reporting the information, came to the conclusion as you can read on the slide up on the screen that values in the range of one to five micrograms per day per person would represent exposures from amalgam. They provide it as a range. It's not described in percentiles or distributions, and this is the range of values that we have from that report.

You can take this, and I'm going to go through this calculation just quickly in order to get us back to the graphic I showed a minute ago just as a way of providing a rough comparison between the ATSDR and EPA values and the intake from amalgam that was estimated in the '93 report.

Within this calculation I assumed a 15 meter cubed per day inhalation rate, which is out of the current EPA exposure factors handbook, which is a fairly detailed, again, compendium of information about exposure factors such as this.

And so if you do this analysis, and this is just a very rough evaluation, you get to a range of air concentrations that would lead to a five microgram per day dose of .33 micrograms per meter cubed and an air concentration of the result in a one microgram per day intake of about .066 micrograms per meter cubed.

If you put that in comparison to the ATSDR and EPA reference concentrations or reference values, rather, health based reference values, it gives you the following comparison, and again, I'm doing this just as a way of trying to connect the dots between the various evaluations and show you what information was out there in 1997, presaging, again, the analysis that will come tomorrow afternoon from NCTR.

The 1993 U.S. PHS report also identified research needs or research priorities, rather, and I'll let you read through them on this slide. I think the overall message is that there were indications of additional research needed through that evaluation that could help us understand the doses and potential

for effects from amalgam exposures, from mercury in amalgam exposures.

Within the 1997 update, the following conclusion was reached. And, again, this 1997 update evaluation by the U.S. Public Health Service included evaluations or, rather, participation from a wide range of agencies, Centers for Disease Control, Food and Drug Administration, Environmental Protection Agency, and so on.

Their conclusion was that the analysis of the cited studies, and in this case they reviewed an additional 65 studies, indicated that the current body of data does not support claims that individuals with dental amalgam restorations will experience adverse effects, including neurological, renal or developmental effects. And, again, they have the code except for rare, allergic or hypersensitivity reactions.

At the time of the '97 report, they also identified -- and this is my last slide. So we're almost done -- research that was currently in progress that was indicated in the 1993 report, at least in part in the 1993 report as potentially informative to decisions about dental amalgam. One is the ranch hands study, which is a rather large cohort of

individuals who served in the Vietnam War for which there's a fair amount of existing information regarding their dental history or regarding their medical history and a lot of follow-up. That study was ongoing in 1997.

There are also two studies in children, two epidemiologic studies that were at the planning states at that time. There were also studies about immune function in progress, studies of changes in antibiotic resistance related to amalgam use, and then also discussions about the relative burden of amalgam to body burdens.

They also had research about alternative materials that was in progress at the time, and again, I'm giving this as a way of presaging the white paper that you'll hear about this afternoon.

And with that I'd like to close and, again, I just hoped to give you a brief whirlwind tour of what had happened prior to 1997 that was informative to lead you up to evaluating the white paper.

Thanks very much.

CO-CHAIRMAN BURTON: Thank you, Dr. Canady.

Do any of the committee members have any

questions for Dr. Canady? Yes, over on the right, please.

DR. DOURSON: Mike Dourson.

Thank you very much, Dr. Canady, for your talk.

The question I had to you regarding the range of distribution of mercury intake, you say it's between one and five micrograms per day, and the question regards since 1997, has anybody done studies to better characterize that range, perhaps the full distribution or at least give us some probabilistic understanding of those numbers, please?

DR. CANADY: I would love to be able to answer that question, but that's actually the subject of the white paper, is the review of information since 1997. My job this morning is simply to provide information up to 1997 as a way of saying here's where we were. The white paper takes us from there.

So I think that question is better addressed to discussion tomorrow.

CO-CHAIRMAN BURTON: Yes, that's correct. That will be covered. The portion since 1997 will be covered in the white paper.

DR. DOURSON: Thank you.

CO-CHAIRMAN BURTON: Yes, Dr. Goldman.

DR. GOLDMAN: Dr. Canady, two questions, one having to do with the risk assessments that were performed by both the EPA and the ATSDR. These uncertainty factors that they applied are not always transparent. It's not clear to me at all kind of the basis of the 30, why 30, and if you have any insight as to why they did that.

And the second thing that I also find a bit mysterious is why it is that they were focused on the fillings in children and the levels and the effects on children and not on the fetus, or were they studying the effects on the fetus at that time or trying to support that kind of work?

DR. CANADY: The first question about the uncertainty factors, the dose in the Fawer, et al., or rather the air concentration of the Fawer, et al., was associated with the lowest. It was associated with an adverse effect. So it was not a no adverse effect level.

So in both cases they divided by a factor of ten, and this is a pretty standard approach for that. The additional factor of three differed between the agencies, and I am not entirely sure how it was attributed between the two agencies, but I think in one case it was attributed to database insufficiency,

but I'm not sure. I'd have to look that up and get back to you if I could on that.

With regard to sensitive populations, and in particular, fetal exposures, both agencies would have used the information, and again, I'm just reporting information that was previously derived, and I can help us find that information if you'd like in more detail, but both agencies have the assumption that the tenfold uncertainty factor or, rather, the uncertainty factors are intended to deal with sensitive populations, and so their assumption is that if we identify a dose within a population that shows adverse effect, we can then use standard assumptions to get to a dose that's below effects that would occur in sensitive populations, such as field exposures.

And the validity of that sort of an assumption is something that we need to discuss in quite a lot more detail, and I'm not sure I have the time to do that.

CO-CHAIRMAN BURTON: Okay. I would like to go ahead and move on. I'd like to thank all five of our speakers, particularly Canady, at this time for providing the background information that you have to the committee.

I have a few comments. We will be moving

on to the next portion of the agenda, which is the first of our two sessions of open public hearings. I have some remarks to make prior to our first speaker.

The second open public session will be held tomorrow morning. Of course, this afternoon it will be the continuation of the first session, which we are starting at this time.

At these times public attendees are given the opportunity to address the committee, to present data or views relevant to the committee's activities.

The FDA values your input, and members of the public have the opportunity to speak to the committee at the public meeting, but there are practical considerations which limit the amount of time that we can allocate to public speakers as a group and, therefore, any individual speaker within the overall group.

For this reason, the FDA established a docket, FDA Docket No. 2006N0352, for all interested members of the public to submit written comments of any length to the FDA. Those will be reviewed in addition to oral testimony to see what light they shed on the questions and issues raised at this meeting. Those have been provided to the committee members both in printed form and electronically.

We are especially welcoming public comments about peer reviewed scientific literature on dental amalgam and its potential mercury toxicity specifically as it relates to neurotoxic effects. Based on the number of requests received to this point and to allow adequate time for committee deliberations, tomorrow we have allotted each speaker seven minutes for his or her presentation.

Those who have registered to speak have been given a number which corresponds to your order of appearance. When it is your time to speak, please come to the podium area in advance so that the transition time between speakers can be minimized. The FDA staff will direct you to the appropriate podium.

Please remain within your time constraints. As there are many speakers, time limits will be strictly enforced. Between the two podiums there is a light box. We'll be using a timer for this meeting. The yellow light on the timer will signal you to finish your presentation. The red light means that your time is up, and at that point in time the microphone and video will be turned off.

PARTICIPANT: When you get the yellow light, how much time?

CO-CHAIRMAN BURTON: One minute.

Both the FDA and the public believe in a transparent process for information gathering and decision making. To insure such transparency at the open public hearing session of the advisory committee meeting, the FDA believes it is important to understand the context of an individual's presentation. For this reason, the FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with a company or organization that may be affected by the topic of this meeting.

For example, this financial information may include a company's or organization's payment for your travel, lodging or other expenses in connection with your attendance at the meeting.

Likewise, the FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose, however, not to address this issue of financial relationships at the beginning of your statement, it does not preclude you from speaking.

I would like to remind the public observers at this meeting that while this portion of

the meeting is open to public observation public attendees may not participate except at the specific request of the Chair.

Also, the Chair and other members of the committee may question a person about his or her presentation. No other person may question the presenter or interrupt the presentation of another participant.

Those who did not register prior to the meeting to speak may be given time if that is permitted. If you wish to address the committee, please give your name to Ms. Ann Marie Williams during the breaks. We will try to accommodate tomorrow's presentation from this list if time permits.

I ask that speakers bring only their written comments or presentation materials with them to the podium. Also, please state your name for the record and begin with the financial disclosure.

To clarify one other issue, the hotel will not permit people holding signs to be on their property because of concerns about security and disruption. We know that some of our audience have brought signs. We have asked the hotel to set up an easel near the podium so that a public speaker who wants to include a sign as part of his or her

presentation may do so.

After your presentation, please take the sign outside to the area where they are being stored. We are unable to provide a display on the Holiday Inn property.

Okay. As we move now to our first speaker, I'd like our first speaker to come forward to the microphone to address the committee. I believe it is Ms. Linda Brocato.

If you have a copy of your talk available, please provide it to the FDA staff for the transcriptionist to help provide an accurate record.

MS. BROCATO: Thank you for giving me the opportunity to speak. My name is Linda Brocato. I am from Chicago, and I don't have any kind of financial that would impair anything with this committee.

I'm a victim of mercury poisoning. As of 2007, it will be 30 years that I have been suffering from mercury poisoning. I originally had my amalgam fillings placed in my mouth at seven or eight years old.

Symptoms of mercury poisoning started about 1977 when I was about 27 years old. I used to have pounding and throbbing migraine headaches leading to light sensitivity and also temporary dizziness,

uncoordinated movements, numbness, and tingling of the legs and the hands and the feet, weakness of one leg and then the other.

I also had loss of balance. My legs felt like they had lead in them, where I just couldn't move them. Very, very difficult.

In 1980, I was diagnosed as having a demyelinating disease and optic neuritis. In 1981, I was diagnosed as having multiple sclerosis, commonly known as MS. Between 1987 and 1990, I had three hospitalizations. The first hospitalization lasted for about two to three weeks, the second hospitalization, one week; the third hospitalization, a month and a half.

I had eight different kinds of medications, including chemotherapy of cytotoxin and immuran, and also the controversial treatment of plasma phoresis.

Nothing helped, absolutely nothing. I might have had a temporary relief of my exacerbations, but then they continued and it=s continued for a very, very long period of time.

My medications included ACTH prednisone, Attatrophen, Immuran cytotoxin, and also plasma phoresis.

When I got out of my third hospitalization, when I was released, I was unable to take care of myself. I required 24 hour care seven days a week. I required a Hoyer lift, a hospital bed. I required ramps, all different kinds of paraphernalia needed for helping me get around the house, and it was a very, very difficult period of time.

And then one day I heard about the amalgam fillings, and I thought, "Do you know what? If I'm going to die, this is my last chance." And I had my 16 amalgam fillings taken out. It took a long time. It took about three months, and when I had my last filling removed my slurred speech started to disappear because I had slurred speech for a while, and I was bedridden for ten years.

After the ten years of being bedridden, I also had to have live-in help 24 hours a day for seven days a week, and all of this dissipated after the ten years.

So in the year 2000, as of September 10th of 2000, I have been on my own. The important thing here is some of the tests that I've had. I've had the mercury vapor test, which revealed a very high concentration of mercury, and the dentist told me he

didn't know what this was going to do for me, but he suggested that I did have it removed.

The other thing is that I had a neurometric brain mapping EEG and EP report. The summary of that report was as a result, there is evidence which supports both a degenerative disease and toxicity.

I also had another test which was regarding the amalgams that were in my mouth, and this is from Clifford Research Foundation, and it said the fillings may not be suitable or may require concurrent body burden reduction and risk management.

Well, after I had the filings removed, I have not had another symptom of MS for 17 years. I have not seen a neurologist for MS or had any other kind of MS medication for 16 years.

I am by myself. I am able to do my own grocery shopping, my own cooking, somewhat my own cleaning, and I take a bus wherever I go, but the unfortunate part is I'm still in this wheelchair, and I will probably have to be here for the rest of my life.

And my dentist never told me there was mercury in the silver fillings, never, and had he told me that there was mercury in the silver fillings I

would have prevented myself from having the amalgams and had them removed a lot earlier than when I did, and I do not believe that I would be in a wheelchair right now.

It's a very, very difficult thing every single day not knowing what's going to happen. I still fall because I don't have the balance that I should, but the important thing is I don't have the exacerbations, and I was having exacerbations, two or three a day, for ten years requiring all different kinds of medication.

So it was a very difficult thing for me, and I do believe that mercury was a very big part of that.

I don't know what else to say. I really don't, and at what point did I develop a hypersensitivity to mercury? I don't know. The only thing I know is that I had them in at a very young age, and what I know now is I don't have any of the exacerbations anymore, and I have known MS patients who have had their amalgams removed and are still having exacerbations. I can't account for that. I really can't.

But thank you for your time.

CO-CHAIRMAN BURTON: Thank you for your

input.

Are there any questions from the committee? Okay. Yes. I'm sorry. Dr. Aschner.

DR. ASCHNER: Thank you very much.

How long after the removal of the amalgams did you start feeling better?

MS. BROCATO: Two weeks.

DR. ASCHNER: Thank you.

CO-CHAIRMAN BURTON: Ms. Cowley.

MS. COWLEY: Would you attribute the condition you're in at this time to having had the mercury fillings?

Is this as good as you're going to get, according to your doctors?

MS. BROCATO: I believe that I will get better. I believe that I do need more physical therapy. I do need a person to take the time with me because I was at the point back in 1993 where I was going for physical therapy, and I was able to get up on the parallel bars myself and be able to move through the hips, and I didn't -- I wasn't able to complete that because the physical therapist had moved out of state.

CO-CHAIRMAN BURTON: Okay. Thank you very much.

MS. BROCATO: You're welcome.

CO-CHAIRMAN BURTON: We're going to move on to our next speaker, which is Mr. Charles Brown.

MR. BROWN: Thank you very much.

Good morning. I'm Charlie Brown. I'm National Council of Consumers for Dental Choice.

Our major goal is to abolish mercury dental fillings, and I want to make that clear.

I appreciate the question on the fetal health. Everyone has the same first name here. It's very helpful, Doctor. Anyway, and your question, yesterday three organizations, the Consumers for Dental Choice, the Mercury Policy Project, and the International Academy of Oral Medicine and Toxicology -- that's a mercury free dental society. The ADA is pro mercury, but dentistry is very divided on this, and the IOAMT is anti-mercury, mercury free.

We filed a petition with the Commissioner to ban mercury fillings immediately for pregnant women, and that needs to happen, and we urge you tomorrow to make that recommendation to the Commissioner.

Now, what do you need to know? Amalgam is 50 percent mercury. We know that. Amalgam is an exposure to mercury. We know that. In fact, even Dr.

Mackert concedes -- and, by the way, he's the ADA's point man around the country. I mean, I think everyone should put their conflict on the table as we do.

Anyway, amalgam is an especially acute jolt at the moment they're put in. Now, for a pregnant woman, that's more mercury going through her body. So amalgam is 50 percent mercury, and mercury is a neurotoxin. it is an exposure to mercury.

Now, the Centers for Disease Control calls it a major exposure. The staff at FDA wants to ignore the Centers for Disease Control. The U.S. Public Health Service says it's one of the two major exposures to humans, along with diet. The Canadian Health Canada says it's the major exposure.

So although the FDA staff wants to pretend it's not a problem, it is an exposure, probably a major exposure, but let's just say it is an exposure. So the pregnant woman is getting an exposure to mercury that affects the unborn child.

Well, then is there any benefit to this? And the answer is no. I mean, FDA had to wrangle the fish issue, and I'm not saying they got a good or bad result, but they had to balance the fact that some people feel, a lot of people feel fish is a good thing

for the diet. They had to balance that against the mercury for pregnant women.

There is no balancing here. Do you understand? Mercury fillings aren't needed, not for a single cavity. All through this room are men and women who have been mercury free dentists year after year after year, decade after decade. Some of the pro mercury dentists maybe even on this panel are going to say, "Say we need to use it." The only advantage for the mercury fillings today is dentist economics. The drill, fill, and bill system for the dentists who are the assembly line dentists and the old fashioned dentists.

Modern dentists don't use mercury fillings. Every dental school graduate of every dental school represented here knows how to do the non-mercury filling for any cavity. So again, no benefit for mercury fillings. Every cavity can be filled in every child and every adult by alternatives to mercury fillings.

So you have the pregnant woman exposed. The unborn child is exposed to mercury. There are no countervailing benefits. That should be a slam dunk, and that should be your decision. We very much hope you will move forward on that.

Now, why is this continuing? And to do this, and I know we've got a lot of physicians, a lot of dentists here, and a lot of scientists. The contrast between organized medicine and organized dentistry is huge, and you may not know that as a physician.

The ADA endorses products for money, their seal of acceptance system. It's pay to play contracts. The AMA says that's unethical.

The ADA has a gag rule on mercury. They tell dentists, "Don't talk about the mercury unless it's suggested."

I mean, how else do you account for the fact that a Zogby poll this year said 76 percent of the people could not name the main component of amalgam. Certainly most people go to a dentist. They aren't learning it.

What are they learning? They're learning the deception of the ADA, of silver fillings. They're learning the ADA has a brochure -- I thought I had it in my package -- a brochure that calls this "silver fillings." The ADA in its brochure says, well, you can have an allergy to mercury, something like you could have to pollen or dust.

I mean, the ADA endorses products for

money. The ADA has a gag rule. The ADA has patents on amalgam, but again, the AMA doesn't do any of that. I'm not shilling for any other group, but I mean, I know the ADA wants to fight for its interest. A big part of its interest are these pay to play contracts.

So they have a gag rule. They have patents. They have pay to play contracts, and they still endorse mercury. When did the AMA stop endorsing mercury? About 1900. I know medicine used it in the 19th Century and every physician knows that was an historical mistake. It's an historical mistake for dentists today.

In fact, if you talk to dentists and you talk to the ADA, the ADA proposed rule -- and it's rule is dead; I'm going to explain that. That rule is dead, legally dead -- but the ADA rule, proposed rule, had said that, hey, this is good. The most compelling reason is that it has been used for over 100 years. Like cigarettes? I mean, what are we talking about? It has been used a long time, and that makes it safe?

That's unbelievable. Imagine a medical school professor saying, "Class, this is the procedure we've used since before the Civil War. Stand by it."

You know, we quit cutting off legs. And, by the way, there's an economic justice issue, and

that's huge. I think Congresswoman Watson may address it here. A lot of the pro mercury dentists say, "Well, but that's all we can afford for poor people."

You know, pre-Civil War we sawed off legs. It's a lot cheaper, a lot faster, quicker. The surgery is over and they're out, but we don't say today to the Medicaid patient, "We're going to saw off your leg because it's cheaper." We do the full Nelson on the broken leg.

Now, the dentists says but for the poor person, the minority, they get mercury. Medicaid allows choices. Most people don't know that. Most people don't even know it's mercury. So basically this silver deception has got in.

I mean, think of a pregnant woman walking in a dentist office, and if the dentist says, "Ma'am, here come your mercury fillings," she would have her posterior out of that chair immediately and out of that office. But the dentist says, "Here come your silver fillings," a massive deception, an outrageous deception, and it should not continue.

We'll hear the next speaker. I'm sorry. Okay. I have to sum up. I didn't realize I had moved that fast.

Okay. Now, you know, I really think of

this as needing a push, just needing a push. The pro mercury dentists are the only ones supporting this. Even manufacturers aren't supporting it.

I think a Mississippi friend of mine, white friend of mine that said, "You know, we just needed a push to get rid of segregation. We didn't really want it. We needed to push them out."

Please don't let professional courtesy make your decision for you, Doctors, please. These dentists -- and some of them are on the panel; some of them are ideologically pro mercury -- are going to say, "Let us decide."

Let dentists decide if it injures the unborn child or the child's developing brain, the live child's developing brain? The kidney of an adult? Come on. You're the neurologist. You're the scientist. You've got to step up to the plate.

FDA is regulating this by the dentists.

CO-CHAIRMAN BURTON: Thank you very much, Mr. Brown.

MR. BROWN: They don't know.

Okay. Well, please --

CO-CHAIRMAN BURTON: Thank you.

MR. BROWN: How do I get this in front of the panel?

CO-CHAIRMAN BURTON: It can be given to one of the staff over on the side, to Ann Marie, and she can provide that to that.

Thank you very much for your input, Mr. Brown.

Our next speaker is Dr. Amid Ismail.

Dr. Ismail.

DR. ISMAIL: Thank you.

This doesn't come on. Now it's time.

Thank you for allowing me to speak before you about this issue of amalgams and mercury.

I am in the gag order. So I cannot give my presentation because I represent the American Dental Association. I only received travel expenses to come here. I received no fees.

My name is Amid Ismail. I am a Professor of Epidemiology and Health Services Research at the School of Dentistry and the School of Public Health, University of Michigan, Ann Arbor. For the past four years I have served as a volunteer member of the American Dental Association Council on Scientific Affairs, and this year I am the council chair, and that's why I'm here.

I want to focus my comments on two important issues: how the ADA develops its policy and

position, contrary to what the previous speaker has said, on scientific matter and how the choice of safe and effective restorative materials impact access to dental care.

The Council on Scientific Affairs is charged by the ADA with responsibility for advising on safety and effectiveness of dental materials, among its other duties. The council fulfills this responsibility by keeping abreast of publications in the scientific literature, listening to the opinions of others in the scientific community and conducting its own periodic assessment of the scientific evidence.

For example, the council published a comprehensive review of the literature on amalgam safety in the April 1998 issue of the American Dental Association. Since then the council has updated its assessment whenever new information has appeared, most recently with the publication of the withdrawal of the American Medical Association of the long anticipated studies known as the children amalgam trials.

The council is a body of independent, just like this panel, scientific experts and has no interest in the outcome of scientific debate other than provide dentists with the best available

scientific information on which to base their treatment decisions.

Individuals who serve on the 17 member panel are chosen at large among the ADA membership for their expertise, scientific expertise in a wide variety of fields affecting our health. Like me, most members of the council hold academic appointments at dental schools and are involved in active research. this gives us the experience and expertise to read and assess the scientific evidence according to the accepted standards of scientific rigor.

The counsel is served by a professional staff that includes toxicologists, microbiologists, material scientists and other research personnel, in addition to dentists. We have access to a panel of over 200 scientific consultants covering all the clinical dental specialist, as well as pharmacology, material sciences, biostatistics, and many other disciplines.

One fourth of the council memberships change every year, insuring that we have the benefit of fresh perspective in our deliberations. Although we are a committee of the ADA, our scientific decisions and opinions are our own. They are not dictated to us by anyone. Council statements and

positions are submitted for publication in the Journal of the American Dental Association subject only to constraints of the regular peer review process.

In the opinion of the counsel, dental amalgam is a safe and effective restorative material. The current scientific evidence does not support an association between dental amalgam and any adverse health effects, except for the small number of documented cases involving individuals who are allergic to one of its components.

Dental amalgam is a valuable restorative option for dentists and their patients. All dental patients deserve the right to choose the most appropriate course of treatment. Eliminating dental amalgam as a restorative option precludes a dentist from offering his or her patients what may be the best choice for a clinical perspective.

Dental amalgams are generally the preferred material for large fillings in back teeth and very deep fillings or fillings that end at the gum line. Alternatives are often less effective in these situations.

Amalgam is also the only restorative material that can successfully be placed in a wet environment in the oral cavity. This is especially

critical when a dentist cannot create a dry field that is necessary for successful placement of a composite resin. Without the ease of use offered by dental amalgam, the dentist might be required to use other more expensive methods to manage the patient or the patient might choose tooth extraction over restoration of a tooth that could be made perfectly serviceable.

Loss of natural dentition and their circumstances would rarely be necessary with dental amalgam.

The ADA's position is that all dental patients should be provided with the full range of appropriate treatment options that are supported by the scientific and experiential evidence available. Decisions on the most appropriate course of oral health treatment are best made by the dentist in consultation with the patient prior to treatment.

Dental caries or tooth decay is the single most common chronic disease in humans. The Surgeon General reports that dental cavities in children is five times more common than asthma and seven times more common than hay fever.

Epidemiological evidence demonstrates that the prevalence and severity of dental caries and restorative treatment needs are highest in low income

and special needs populations. Those who qualify for Medicaid and state children's health insurance program, or SCHIP.

Access to quality dental care for all children, but especially poor children is a vital element for all health care and development. The ADA is concerned that efforts to eliminate the use of dental amalgam would create unwanted public anxiety, increased disparities, eliminate viable treatment options.

We strongly believe that all Americans are entitled to quality dental care. Those populations that have always received this care deserve to have all dental care options available to them.

In conclusion, based on its review of the current scientific evidence, the ADA Council on Scientific Affairs supports the continued usefulness of dental amalgam as a safe and effective dental material. The overwhelming body of scientific evidence supports the safety of dental amalgam. It remains an important restorative option for all Americans.

And thank you for listening to me.

CO-CHAIRMAN BURTON: Thank you, Dr. Ismail.

Our next public speaker is Dr. Ronald Zentz.

DR. ZENTZ: Thank you.

Members of the panel, thank you on behalf of the American Dental Association for allowing us to provide these comments today. I'm Dr. Ronald Zentz, a dentist and a pharmacist by training and Senior Director of the ADA Council on Scientific Affairs.

For almost 150 years the ADA has been committed to the oral health of the public. It's a science based organization, and as such we rely on the Council on Scientific Affairs to provide guidance on key issues. This includes policy on the safety and effectiveness of dental materials used in restorative practice.

The council actively promotes research to insure that the public and the profession have the most current, scientifically valid information on which to make choices about dental treatment. The ADA does not advocate for the use of one specific dental restorative material over another. Instead we champion the principle that the dentists and their patients should be able to select from a range of materials that are supported by scientific evidence and shown to be safe.

The best and latest scientific evidence indicates a dental amalgam is safe. Findings of two highly anticipated clinical trials widely known as the children's amalgam trial were published in the April Journal Of the American Medical Association. The two randomized clinical trials funded by the National Institutes of Health were designed to examine the effect of mercury released from amalgam on central and peripheral nervous system and kidney function in children.

The investigators found no adverse health effects related to the neuropsychological function, memory, attention, visiomotor function, nerve conduction velocities, or function arising from the placement of amalgam restorations in children.

While the safety of dental amalgam has been the subject of a number of previous publications, panel meetings, conferences, two new clinical trials are the first to compare overall health effects in children treated with amalgam restorations and resin composite restorations.

Dental amalgam is accepted by the scientific community as safe and effective restorative material based on the weight of the scientific evidence. As one example, I cite an article from 2003

in the prestigious New England Journal of Medicine. "Current concern arises from claims that long-term exposure to low concentrations of mercury vapor from amalgam either causes or exacerbates degenerative diseases, such as ametropic lateral sclerosis, Alzheimer's disease, multiple sclerosis, and Parkinson's disease. However, several epidemiological investigations failed to provide evidence of the role of amalgam in these degenerative diseases. Patients who have questions about the potential relation between mercury and degenerative diseases can be assured that the available evidence shows no connection."

Many other organizations from across the world have found dental amalgam to be safe and effective in treating dental decay. In addition to the ADA those bodies include the World Health Organization, U.S. Food and Drug Administration, Centers for Disease Control and Prevention, and the National Institutes of Health, as well as others.

In 1998, the ad hoc working group of experts from countries in the European Union issued a report on dental amalgam that concluded there is no scientific evidence of systemic health problems or toxic effects from dental amalgam, and the working

group did not recommend any special reservations on its use. A few countries have made recommendations limiting amalgam use in certain populations. These same countries admit that the body of scientific evidence does not substantiate or support the limitations.

While amalgam is still a valued option in treating dental decay, its use is declining. Those cavities that previously would have been treated with amalgam are now primarily filled with resin composite materials. This trend is primarily driven by ongoing improvements in resin materials, better education for dentists in placing the composite restorations, as well as changes in dental disease patterns, and the patient's desire especially in the United States for aesthetic and tooth colored restorations.

Dental amalgam is a solid material composed of mercury, silver, tin, and copper. It's a hard, stable, and safe intermetallic compound. exposure to dental amalgam cannot be correctly compared to exposure to an equivalent amount of mercury, whether in the human body or in the environment, nor is mercury contained in dental amalgam present as methyl mercury or readily converted to that material.

Methyl mercury is a form which is of most concern for human health. At present there's no direct restorative material that works as well as amalgam for large fillings in the back teeth or in very deep fillings below the gum line. Alternatives are often less effective in these situations, especially in the wet environment.

The ultimate decision for dentists and patients on filling materials is best made between the dentist and the patient at the time of treatment. To aid in that decision, the ADA has developed a chart that compares restorative dental options. It has been widely circulated through ADA publications. I have a copy of that here with me today, and I can provide copies to the panel if you would like to have that.

We have also developed a patient brochure that's available in brochure form as well as ADA.org for explaining the various options available to patients, the advantages, disadvantages.

In conclusion, the public deserves health care policy and FDA regulation based on sound science, not on political agendas. As a leader of the science based profession, the ADA is open to new scientific information and welcomes the opportunity to discuss it according to the standards that prevail in the

scientific community.

Clearly, the overwhelming evidence of scientific evidence supports the safety and efficacy of dental amalgam and shall continue to be made available as a restorative option for patients.

Thank you for the opportunity to discuss this. I look forward to answering any questions if you have any.

CO-CHAIRMAN BURTON: Yes?

DR. DOURSON: Yes. Mike Dourson.

Thank you for your presentation. One quick question.

Has the ADA ever characterized the exposure to its patients from dental amalgams in a probabilistic sense?

DR. ZENTZ: From a probabilistic sense, meaning they're --

DR. DOURSON: In other words, characterize the exposure to mercury from dental amalgams.

DR. ZENTZ: Regarding the overall exposure?

DR. DOURSON: Right. Means, averages, standard deviations.

DR. ZENTZ: My understanding of the literature that I'm familiar with is that the

component from dental amalgam is a lower component of the overall mercury exposure. Also elemental mercury versus methyl mercury, which is the major concern.

DR. DOURSON: Thank you.

CO-CHAIRMAN BURTON: Dr. Goldman.

DR. GOLDMAN: Yes. I have one comment first, and that is that I'd love to see a copy of the chart and the fact sheet, and a question, and that is whether the ADA surveys its members about the use of different kinds of fillings and whether you have data that you gather on that, and if that's the kind of data that's available.

DR. ZENTZ: Yes, I believe there is some data available. The most recent that I'm familiar with is in 2003, which is an estimate of about 30 percent of restorations were amalgam restorations, but there may be some more recent data.

DR. GOLDMAN: And also, do you have data about adverse effects? Does the ADA gather data on adverse reactions?

DR. ZENTZ: The ADA does take calls from members, the profession as well as patients related to adverse events. We do refer them to the FDA from the standpoint of their surveillance activities. We don't have a full registry by product related to adverse

events though.

CO-CHAIRMAN BURTON: Okay. Thank you. We need to move on. I'm sorry. Thank you very much, Dr. Zentz.

Our next speaker is Ms. Kathleen Nelson.

Ms. Nelson.

MS. NELSON: Yes, thank you very much.

My name is Kathleen Nelson. I have no financial affiliations here.

I am from Austin, Texas. I'm a 54 year old mother of two sons and a grandmother of four beautiful grandsons and a federal civil servant.

I'm the survivor of mercury amalgam poisoning, but before I share my personal experience I would like to sincerely thank the FDA for having the courage to hold these hearings, but I must say I am terribly saddened that these hearings are even a reality.

This question to use mercury or not use mercury in dental products is simply absurd to me. The question defies common sense. It does not take a doctorate in chemistry or toxicology to understand that mercury is a known neurotoxin and degrades our health.

it does not take a panel of experts to

argue with doing biased medical studies to determine whether or not mercury should be placed in our bodies. The scientific evidence about the hazards of mercury is not new. History has documented that fact for us over and over.

The basic understanding of mercury toxicity is indisputable. This notion to prove this or that nuance only serves to cloud this issue, thus distorting the truth.

The truth is we cannot see the forest through the trees unless we are willing to attack this problem from a different angle, a paradigm shift of thinking, thus a dramatic change of heart. There is no doubt that every single one of us here today acknowledges that mercury itself is a neurotoxin and harmful to our health. This ultimate truth is our common ground.

Where we disagree is why we keep using mercury. So I ask this question: why are mercury fillings still being used in America knowing full well the hazards? There is no denying that no one single scientific or medical case can be made to ethically, ethically support the intention use of toxic materials.

I applaud the FDA; I sincerely do. I

applaud the FDA for warning pregnant women and young children of the harmful effects of eating fish tainted with mercury. But yet the FDA stays silent when asked to warn the same pregnant women and young children of the toxic effects of mercury amalgam fillings.

On one hand, the FDA warns mercury is not health. Be careful, but on the other hand, the FDA continues to support the use of mercury amalgams by not warning the Americans.

It's bad for your health to eat fish, but somehow it's okay to directly put it in your head. FDA, you can't have it both ways. Mercury is either toxic or it isn't, no matter how it is delivered, be it in fish, vaccinations, co-plane emissions or amalgam fillings.

The answer is scientifically indisputable. The truth is that simple. The truth is mercury is a neurotoxin and causes harm to our lives, to our immune systems, to our embryos, to our babies, to our mothers and fathers. The more frequent the exposure one has to mercury, the more mercury burden the body carries.

My own personal diagnosis and experience with mercury amalgam poisoning came to a head a couple of years ago. For years I suffered with chronic sinus

and ear problems, hypothyroidism, allergy symptoms, dry, itchy skin, burning skin, severe headaches, dizziness, extreme fatigue and flu-like symptoms.

After years of symptoms that became increasingly worse with time, I became very ill. The doctors checked for brain tumors, aneurysms, MS, West Nile, Lyme, lupus, and other disorders and diseases. Per the doctors, the cause of my illness was most likely an unknown virus.

I waited for over a year for this mysterious virus to pass, and I barely functioned from day to day. A year later and much sicker, information by the grace of God came to me through my manager at work who had gone to church with a lady who had experienced similar health problems. She encouraged me to see Dr. Kendall Stewart in Austin, Texas.

I thank God every day I was able to see this man. The truth is my mercury poisoning by silver mercury amalgam fillings has been scientifically and medically documented. The truth is Blue Cross and Blue Shield of Texas paid for my medical expenses caused by mercury amalgam poisoning.

My peak illness symptoms were vertigo, vomiting, nausea, dizziness, peripheral and nervous system disorders, burning and itchy skin, burning

brain sensations, imbalance, severe fatigue, severe muscle aches, et cetera.

Through scientific testing, Dr. Stewart confirmed I had levels of mercury in my body that were very, very high. Dr. Stewart recommended immediate removal of all seven of my 36 year old mercury fillings. After ten months of chelation and the removal of my fillings, I am a new woman. I am here today being able to talk to you to try to convince you to do the right thing.

The truth is simple. I have no allergies or fatigue. My thyroid medication has been reduced by 33 percent since the removal of my amalgam fillings and chelation therapy. My prescription has twice been reduced within a year of treatment.

So I ask this question once again. Why in God's name do we still use mercury in amalgam fillings? There's only one deriver for this unethical behavior. No one here can dispute that if minimal profits were involved with mercury dental products, we would not be having this hearing today. The truth is that simple.

Finally, this question to use or not use mercury in dental products mocks our intelligence to argue at what point mercury becomes more harmful than

harmful is nonproductive. The fact is we don't have to poison our children. The fact is we do not have to poison our earth. And the fact is we do not have to poison our future.

The ugly, ugly truth is we simply choose to.

(Applause.)

CO-CHAIRMAN BURTON: Thank you very much, Ms. Nelson for your input.

Our next speaker is Dr. Joel Berg.

DR. BERG: Thank you.

I am Joel Berg. I'm Professor and chair of the Department of Pediatric Dentistry at the University of Washington in Seattle, Washington.

Today I thank you for the opportunity to present the comments on behalf of the American Academy of Pediatric Dentistry, the AAPD.

As pediatric dentists, we are the front line providers of oral health care to America's children and educators of dentists and other health professionals about children's oral health. The AAPD is the recognized authority on pediatric oral health care. Among its many activities is the development of pediatric dentistry oral health policies and clinical practice guidelines based on the best

available scientific evidence.

It is on this basis that the AAPD is testifying today as to the safety of dental amalgam as a restorative material.

Today I want to highlight a few key items from our written submission. In 2002, the AAPD sponsored a pediatric restorative dentistry consensus conference, and the individual research papers prepared for that conference were subsequently published in the peer reviewed, scholarly journal Pediatric Dentistry.

The consensus statement related to amalgam reads as follows: "The dental literature supports the safety and efficacy of dental amalgam in all segments of the population. Furthermore, dental literature supports the use of dental amalgam in the following situations: Class 1 restorations in primary and permanent teeth; two surface Class 2 restorations in primary molars where the preparation does not extend beyond the proximal line angles; Class 2 restorations in permanent molars and pre-molars; and Class 5 restorations in primary and permanent posterior teeth."

Our written submission included the two research papers related to dental amalgam from this

consensus conference by Osborne and Fuchs. Because the AAPD's clinical guidelines are based on the best available scientific evidence, the recommendation I just read is included in the current AAPD Guidelines on Pediatric Restorative Dentistry, which was also submitted with our written statement.

Quoting from that statement, dental amalgam has been used for restoring teeth since 1880. Amalgam's properties, such as ease of manipulation, durability, relatively low cost, and reduced technique sensitivity compared to other restorative materials have contributed to its popularity.

Aesthetics and improved tooth color restorative materials, however, have led to a decrease in its use. Dental amalgam has been one of the restorative options used in daily clinical care for children in both dental schools where I have served as a faculty member for a combined period of over 20 years. Prior to my current position I worked for nine years in the dental industry. There if there were evidence in peer-reviewed scholarly literature as to the negative effects of amalgam, I can guarantee you there would be many companies rushing to the market touting this claim to advertise and sell vast quantities of alternative restorative materials, such

as glassonomers or resin composites.

But because of adherence to scientific standards, it would be unethical for any organization to claim that dental amalgam is unsafe as a restorative material.

Further, it would be unethical of dentists to inform a patient's family that dental amalgam should not be used in any situation because, due to the current higher cost of other restorative materials and techniques, it could increase the treatment cost for a child's care.

Even more recently, studies published in the Journal of the American Medical Association by Bellinger and DeRouen provide even stronger evidence related to dental amalgam safety. According to the results, children with amalgam fillings experience no difference in neurological and renal function compared to the control group of children with composite fillings.

These studies support the existing scientific understanding that the infinitesimally small amount of mercury released by amalgam fillings during common activities, such as eating and drinking, does not adversely affect health.

Based on all of the available research,

the AAPD supports the continued use of dental amalgam as an important treatment option.

I thank you for the opportunity to present these comments, and I would be pleased to answer any questions.

CO-CHAIRMAN BURTON: Yes, Dr. Dourson.

DR. DOURSON: Yes, Mike Dourson.

Thank you very much. I do have one question in regards to a previous presenter's statement that there might be a jolt -- I'm not quite sure of the word used -- of mercury when the amalgam is put in.

Has your society or this one symposium that you had where you had lots of scholarly papers, have they characterized the exposure to mercury from not only subsequent to putting the amalgam in, but also during the amalgam's placement?

DR. BERG: Yes, I heard your question earlier and now as well. No, we have not. We based it on the available scientific literature that was presented as part of that symposium that was presented, as part of the written comments, but it did not characterize the different amounts at different time periods.

DR. DOURSON: Okay. Thank you.

CO-CHAIRMAN BURTON: Yes, Dr. Fleming.

DR. FLEMING: Dr. Fleming.

What I want to ask you is this. What is your group's opinion on informed consent with respect to use of any restorative material, whether it's amalgam or composite? Should these discussions take place prior to installation?

You mentioned it as unethical. The second part of the question is do you consider it unethical to have a discussion with a parent or guardian of a child prior to any dental work being performed?

DR. BERG: Well, I think there should be informed consent before any dental procedure and the patient should be aware of the alternatives, of the risk of the procedure itself and the alternatives.

In the case of pediatric dentistry that applies to the longevity of the restoration in many cases. So in different situations we have two to three different options, but one is the preferred based on the age of the child and the size of the restoration.

DR. FLEMING: So my follow-up to that is who makes the final decision on what is installed?

DR. BERG: It's ultimately the parents' choice, but it's based on information from the doctor-

provider to that parent.

DR. FLEMING: And do you think that is occurring on a regular basis in offices now or is this something we need to address more deeply?

DR. BERG: I believe it is occurring. I think it should constantly be reinforced.

CO-CHAIRMAN BURTON: We're going to break at this point for lunch. I'd like to thank all of the committee members for their attention this morning and to those attending our presenters and to those in the public session.

It is now five after 12. I'd like you back at 12:55. We will start promptly at one o'clock. So please return to the room and take your seats at 12:55.

And Dr. Kieburtz will be assuming the chair at that time.

Thank you very much.

(Whereupon, at 12:07 p.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

AFTERNOON SESSION

(1:07 p.m.)

CO-CHAIRMAN KIEBURTZ: We won't repeat into the record from this morning everything we said about the interest in hearing from the public and the material about conflicts of interest, but those still stand for this open hearing.

We will continue with speakers in the list we have. There will be some movement around as we are waiting for Representative Watson, but we will just carry on.

I will just reiterate to the members of the committee in anticipation of management of our interests tomorrow I would like to keep the speakers to seven minutes. If there is any time left in their seven minutes, then we can have some questions. I'd like those questions to be about the material the speaker presented, not to introduce new topics beyond which they already spoke about.

So if you have questions about what the speaker presented, please keep your questions to that.

If there is no time left, we will have time for questioning that particular speaker, but if at the end of the day and before the breaks if you have written down to yourself someone you really want

to question, most of the speakers will still be in the audience. If we have time, we may be able to come back to them and ask them questions. If not, we'll have to forego those questions.

If you do have a question, I ask you to do the following. Just hit your light on your mic so that it goes on or catch the eye of myself or Darrell Lyons, and once we see, you can turn your light back off. That way we will keep a list of who has questions. We'll follow the same procedure tomorrow afternoon when we get into the discussion because there's a lot of us here, and we want to make sure everybody has the chance to speak.

Does everybody understand the procedures? Any questions for me from the committee members this afternoon?

(No response.)

CO-CHAIRMAN KIEBURTZ: If not, then we'll proceed with the first speaker who will be Dr. Paul Gilbert. Is Dr. Gilbert here?

DR. GILBERT: Thank you, everyone.

As far as financial interests are concerned, unfortunately I don't have any. I had to pay my way down myself.

My name is Dr. Paul Gilbert, and the title

of my little talk is "Amalgam, It no Longer has Benefits that are Worth the Risks."

I have been practicing dentistry for more than 40 years. I've been a member of the American Dental Association since I started practicing in 1962 and have remained a member in spite of the ADA support of the use of mercury in dentistry. I am now a lifetime member of the ADA, a distinction that I suspect the ADA will regret having conferred on me.

Using mercury never made any sense to me because mercury is a heavy metal, and heavy metals, which also include lead, cadmium and arsenic, are all highly toxic to living organisms, including humans.

In the late 1970s, I found out that a few very progressive dentists were measuring significant amounts of mercury vapor coming off patients' fillings using a sophisticated measuring device called the Jerome analyzer. This contradicted the ADA's long-held position that amalgam mercury fillings are stable and do not emit mercury vapor.

The Jerome analyzer was created specifically for OSHA to measure the mercury in the air of a manufacturing facility that stored or used mercury for some product or products. It measures the mercury in the air of a person's mouth with mercury

fillings just as accurately and readily as it does in the air of a factory. It could even be used to measure the mercury levels in a dental school, but I am not aware that OSHA has ever done this.

I really didn't fully understand then the simplicity of the concept that mercury is a deadly poison or the complexity of symptoms that mercury creates as a poison, but I did have the common sense to realize that if patients were actually being exposed to mercury from their fillings, then it was time to stop using this dental filling material. This was more than 25 years ago.

So I discarded all of my dental equipment for placing amalgam mercury fillings and totally stopped implanting it in patients' teeth. I was now a mercury-free dentist, although I didn't see it that way back then, especially since I made this decision based only at that time on common sense and intuition.

Fortunately, there were other open minded dentists then, including a very astute dentist in Canada, Dr. Murray Vinnie. Dr. Vinnie realized that exposing patients to mercury didn't necessarily mean that they were absorbing it into their bodies. If they weren't, then it couldn't be a poison at least from amalgam fillings.

So we decided to scientifically find the answer to this question. At a research facility of the medical school at the University of Calgary in Canada, he, along with other researchers created a seminal piece of animal research which proved beyond a shadow of a doubt that mercury in dental fillings is absorbed into the bodies of mammals.

First, he placed amalgam fillings in sheep and then in monkeys with both studies clearly demonstrating the spread of the mercury from the fillings into the various organs and tissues. The results, which were published in the most distinguished scientific journal in the world were astonishing and irrefutable because he cleverly used the radioactive isotope of mercury to track the mercury from the fillings.

Using a manmade radioactive isotope of mercury which doesn't exist in nature made it impossible for the mercury he tracked to come from any source other than the fillings. I couldn't come from fish or water or the atmosphere or food.

Dr. Vinnie actually had the audacity to assume that the ADA, American Dental Association, an organization that claims to make its professional decisions based on science, would have an open mind

and would at least start a dialogue with him about this research.

Instead, his extremely credible sheep research was severely attacked and criticized by the ADA, presumably because it discredited the ADA's long-held position that amalgam is safe and stable. It was a sign of things to come.

Ironically, when the study was repeated in monkeys to lie to rest any concerns that sheet are just too different to draw any valid conclusions that could be applied to humans, the ADA ignored the monkey research even though the results were very similar to the sheep research.

Since then a growing and still growing worldwide collection of research articles collectively condemning mercury in all of its forms and in all its uses, including amalgam fillings, has been published mostly by non-dental researchers in non-dental peer reviewed publications for anyone, including the ADA and the FDA to study.

Another particular area of interest to me and I assume should be of interest to both the ADA an the FDA is the scientific validity of the concept that mercury has no known level below which it can be shown to be a non-poison. Mercury is the most harmful

poison of all the heavy metals, and its toxicity does not decrease with smaller exposures.

With smaller exposures all that happens is that the poison effect becomes more and more subclinical. It never goes away. This is known in scientific circles as a NOEL, or no observable effect level.

The NOEL for mercury is zero because mercury can be scientifically shown to be a poison in any amount no matter how minuscule, as the ADA likes to say, the amount is. The centuries old and outdated concept that the dose make the poison has no scientific validity with mercury. This is likely true for all the heavy metals.

Meanwhile, I continued to learn how to practice general restorative dentistry using mainly the new composite filling materials. They weren't very good then, and the dental schools whose curricula are directly imposed by the ADA's Committee on Accreditation pretty much refused for many years to teach students how to use white fillings.

Instead, the driving force came from manufacturers of dental materials who didn't give a hoot about mercury, but they did recognize the huge aesthetic improvement with white filling materials,

and the marketing potential that these composite filling materials offered.

They kept on developing this filling material of the future until composites became durable, functional, strong, essentially nonpoisons, and economically in the same ballpark as amalgam mercury fillings. I know that from my own personal experience with composites for more than 25 years of general clinical private practice dentistry.

Yes, they are harder to place in patients, which just makes any dentist who learns how to use composites, well, a better dentist.

I also noticed that I was attracting relatively young patients, many in their 30s, who were afflicted by all sorts of neurological diseases and disorders, such as fibromyalgia, Parkinson's, MS, lupus.

CO-CHAIRMAN KIEBURTZ: Dr. Gilbert, I'm sorry to interrupt you. Thank you for your testimony.

Dr. Kennedy.

(Applause.)

DR. KENNEDY: Good afternoon. I'm Dr. David Kennedy, and I have no financial interest in mercury amalgam and this issue. It would probably save me quite a bit of money because I came here at my

own expense and actually helped some other people come.

I have before you given you a nice printout because we have so limited time. We can't possibly cover what 20 years of research has accomplished, but I will briefly summarize for you what the International Academy of Oral Medicine and Toxicology has focused on for the last 20 years.

Back in the 1980s, the question was is there exposure and intake and body burden. This has been demonstrated for over 70 years. Albert Stock first demonstrated mercury vapor was coming off in 1926. It took another 28 years for the NIDR and the ADA to acknowledge mercury is coming off.

Germany reviewed this in detail. You have a copy of the German peer reviewed -- oh, I guess not. I guess not. Anyway, James Mazi, a metallurgist, talked at the meeting in Achtenhauzen in 1994. He took an electron micrograph of a 25 year old set dental of amalgam that he touched in four places with an ozitron that pushed one pound per square inch. That's a lot less than you hit with your teeth.

Do you see the droplets of mercury on the surface of a 25 year old filling? You heard this morning it was a stable alloy. Then there's no free

mercury. Well, that's not true, and that hasn't been true for 150 years.

Rodney Mackert talked to the World Health Organization in 1990 and they determined that his estimate of dose was too low and it did not fit the empirical data. They estimated the daily dose at 17 micrograms.

You heard Richard Canady. That exceeds Richard Canady's minimum risk level. So pay attention. We've got lots of numbers here.

Intake with mercury fillings in sheep. You just heard about that. You put them in monkeys. You heard about that.

Then you probably didn't hear about the autopsies of humans and they measured mercury in humans and they showed that the amount of mercury in humans is proportional to the number of fillings in their teeth. No other factor, and they had good controls, and they said overall the results were better than neutron activation analysis by a fourfold, and the amount of mercury in their brains was proportional to the number of fillings in their teeth, not the fish they eat.

So we have accomplished one, two, three: exposure, intake, body burden. Let's go on.

How about pathophysiology? Maternal fetal transfer into the vulnerable subsets. Okay, fine. Mercury from dental fillings impairs sheep kidneys. In 30 days, we had a 60 percent drop in the kidney's ability to clear inulin. We did not find the same thing in monkeys, and we did not know until they published the terribly unethical Casa Pia mercury exposure study that it happens in children.

Here is a study of children where they put two fillings in to start with and you can see they doubled the amount of mercury coming out of the child's urine, and about one filling more a year. What happened, at two years the mercury peaked and then began to decline.

So at the end of seven years there's no statistically significant difference in the urinary mercury levels. This group is relying entirely upon urinary mercury levels to discredit the science showing mercury from fillings is harmful. This study alone shows that you have damaged that child's kidney exactly like we damaged the sheep's kidney.

Pathophysiology, Ann Summers couldn't afford to come here on her own, but she has shown in repeated studies, including her Ph.D. thesis, and now she is a professor, in multiple studies that when you

put mercury fillings in the teeth, you select for antibiotic resistant organisms. You have that paper before you.

Dr. Frickholm you heard this morning couldn't find any mercury in the animals that he put mercury fillings in, and here's a guy putting mercury fillings in rats and finds it in the fetuses. I think there might be a flaw in having a dental student do an experiment.

Dr. Drash found it in the human fetuses. We showed in animals that it happens. It goes from the animal into the fetus, and when you put them in, every conceivable tissue in that fetus goes up, but just like humans, the fetal blood is almost twice as high as the maternal blood.

So when you do a risk assessment, you can't use the mother's blood level. You've got to use cord blood. One out of eight children in the United States are born today with a blood level of mercury that will cause neurological impairment. Where do you think it's coming from?

They look to the ocean. Oh, maybe it's the fish. They look to the sky. It might be the air. We've counted the fillings. It's the fillings.

Get over it, and it also comes out in the

milk. The fetuses, the sheep, continue to be exposed to the maternal transfer of mercury from her teeth into the milk.

There are vulnerable subsets. Nobody has talked about that. There's a genetic subset. They are nonexcreters, and they have extremely low levels of mercury in their urine, their fingernails, and their hair. That's one of the studies that was supposedly discredited by the FDA white paper that we showed in children that were autistic. They have almost no mercury in their hair regardless of the number of fillings in the mother's teeth.

In the controls, the amount of mercury in the baby's hair was proportional to the number of fillings in the mother's teeth. That should be of concern to everyone that wants to have healthy children.

There's another subset, which is a porphyrin formation. So now we've got two subsets and a gene that represents probably less than five percent of the population. What epidemiologist in this room thinks you can find a subset of the population in which you have two genetic subsets with an epidemiologist study? You're not going to find it.

So they were confused today. You've asked

over and over what's going on, what's the dose. Nobody seems to be able to answer your questions. Maybe you have the wrong people talking to you.

Is there pathophysiology? Yes. Maternal-fetal transfer? Yes. Multiple subsets? Yes. And the sad news is there's no evidence of benefit. You hear over and over the risks outweigh the benefit or the benefits outweigh the risk, blah, blah, blah.

In order to put the filling in the tooth, you have got to drill away 75 percent of the strength of that tooth. Do you know what happens then? It breaks and then you need a crown or a root canal and it has to be extracted. Factor that cost in. Don't tell me the cost of a piece of filling material. Tell me the cost of the damage.

Amalgam is also linked to gum disease. When you put a mercury filling in the tooth, you lose a millimeter of bone around your tooth. Do you want to do that? That's what you're doing.

Sixty-six percent of tooth extraction is because of gum disease. You haven't even addressed that. That's a proven consequence of mercury in your teeth.

And then there's what they say is an allergic reaction. It's also called the pre-cancerous

lesion. Sixty-six percent of them resolve if you remove the fillings.

And then the cost of neurological impairment. These people misunderstood the source of the mercury. They called it methyl mercury, that Nielander and Eggelston and I had to go too fast.

CO-CHAIRMAN KIEBURTZ: Sorry to interrupt you. Thanks for your testimony.

DR. KENNEDY: Well, thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Dr. Higgins, Huggins. My apologies.

DR. HUGGINS: I'm having a hard time getting into the 20th Century. I will try to play the buttons here.

All right. This is an explanation basically of the graph that I like to use in determining the changes that have occurred in we have got about 200,000 chemistries over a period of 38 years. Most of the changes that are shown here occurred within six to ten days. What we are trying to do is show that there's a stability point.

Normal range as shown on the bottom of this covers by definition 95.56 percent of the population, but over a period of time the high has

come down. The lows come up upon dental intervention, and there appears a stability point.

The stability point is an area which doesn't move a whole lot, and it is the area in which you find most people who do not have disease.

Ten years ago, the Adolph Coors Foundation sponsored a study on 30 patients with at least three amalgams and no more than 11. These people had no other dental restorative materials in their mouths, no nutrition or any other intervention was performed. Chemistries were run, amalgams removed, composites placed; duplicate chemistries were placed. A lot of changes were noted.

The most unexpected change was in cholesterol. Here you can see that the higher cholesterol levels dropped, some over 40 to 50 milligrams percent.

Expanding this into the non-Coors study, we found in a study with people with excess of 250 milligrams that the drops were 80 to 100 milligrams percent in six days after amalgam removal without any drug intervention.

Hemoglobin has four binding sites into which oxygen can attach. Mercury has a high affinity for these sites. Should two sites be saturated with

mercury the total carrying capacity for oxygen drops 50 percent.

As curious as that, the sequential removal of amalgam frequently produced a drop in the red cell count, hemoglobin, and hematocrit. This was accompanied by a simultaneous increase in urinary excretion of mercury. We expected red cell values to be reflected in an increase in fatigue. However, the patients reported a dramatic increase in energy. Now, where did this come from?

A study of the venous oxyhemoglobin or the actual oxygen carrying saturation showed the answer where huffing and puffing might increase oxyhemoglobin one percent. Dental intervention produced an average increase in oxygen of 22.5 percent with some values reaching as much as 40 percent increase in oxygen.

Where does hemoglobin come from? From porphyrins in the blood stream. Porphyrins develop into heme, from there into hemoglobin, and by another pathway into ATP. If there is a toxic blockage somewhere, porphyrins are excreted in the urine.

The presence of toxicity is sometimes assessed by measuring the amount of porphyrins in the urine. This is a slide of a male that has never had amalgam in his mouth. The test shows only one

porphyrin, the four carboxy, and the total was 12 micrograms.

This porphyrin test is on a wheelchair bound multiple sclerosis patient showing the presence of four, five, six, seven and eight carboxy porphyrins with a total of 2,400 micrograms in the urine. Ten days after dental intervention -- that means getting rid of the amalgam and other things -- the level had dropped to 200 micrograms. This means that far more energy was available for normal biochemical reactions and less energy was literally going down the toilet.

Is there any wonder that the patient was able to get out of the wheelchair and take a few steps unaided?

Looking further into multiple sclerosis, these spinal tap results show multiple unusual proteins in the spinal fluid. Albumen which is present at about 55 kilodaltons is the only protein that should be there.

The next slide looks very similar because on the right side of the test, the same patient, you find only albumen. Four days after dental intervention all four patients physically improved and all four demonstrated a total disappearance of the unusual proteins. Only albumen remained. Were these

the illegal clonal globulins that disappeared?

Is there a mechanism that could link mercury to an autoimmune response similar to that in MS? The meter histocompatibility complex, MHC, on the cell's surface signals to the immune system whether a cell is self or non-self. Non-self or abnormal cells are flagged for destruction. Should an atom of mercury bind to a sulfur binding site on the cell surface, the MHC is altered such that the normal self cell will be seen as non-self or abnormal and be scheduled for destruction. Thus the origin of autoimmune disease.

Now, I'll cut this one briefly. Those of you who have experience in immunology would recognize lymphocyte viability, and you notice after four days' exposure to the amount of mercury that you would have in six fillings. The lymphocyte viability dropped from 100 percent, to 92 percent, to 21 percent. This suggests that the differential slide of the CBC is not always indicative of immune competence.

This slide demonstrates normal DNA, contains a single spike of chromosome numbers and more than one by definition is malignant. This patient showed abnormal physiological changes immediately after the placement of dental materials. Serious

immune deficit was found, but surprisingly a malignant DNA was also found.

Within two months after dental intervention, the malignancy was changed to nonmalignant. The conclusion is objective laboratory evidence confirms that adverse effects of mercury on biochemistry are amenable to dental interventions. Clear our DNA. Ban amalgam.

Thank you, ladies and gentlemen.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you, Dr. Huggins for your testimony.

Our next speaker will be Representative Watson.

(Applause.)

CO-CHAIRMAN KIEBURTZ: And there are no time limits on your presentation. Thank you for speaking to us.

If you could turn your mic on please, which would just be -- thank you.

MS. WATSON: I certainly want to thank the Chairman and the members of the two-part panel assembled here today plus the Associate Commissioner Lutter and the FDA staff for allowing me a chance to present testimony to the FDA on the issue of dental

amalgam.

I am Congresswoman Diane Watson, representing the 33rd Congressional District in Los Angeles, Culver City, and that includes Hollywood as well.

Prior to my current tenure in the House of Representatives, I served for 20 years in the California State Senate, and I chaired the Health and Human Services Committee for 17 years, and I have for many, many decades been an advocate for banning the use of dental amalgam in the field of dentistry, and in my capacity as the chairperson of the Health and Human Services Committee, I had to educate my colleagues.

And so I wrote legislation into law that requires dentists in the State of California to provide their patients with a fact sheet --sheet -- was that Freudian? Anyway --

(Laughter.)

MS. WATSON: -- with a fact sheet listing the risk of mercury amalgam fillings, better known as silver fillings.

It was called the Watson law, and it passed the legislature in 1992. However, it took another 12 years for the dental board of California to

finally be convinced of the wisdom of complying with the law. I had to go through two governors, and finally when I got the right governor in, the first thing he did was to disband the Board at the time, recompose it, and it wasn't until about two years ago that we finally got a brochure that would inform the patients what was in their fillings.

I am also the co-author of HR-4011, and that is the Mercury and Dental Fillings Disclosure and Prevention Act, which prohibits after 2008 the introduction into interstate commerce of mercury intended to be used in dental fillings.

In October of 2003, Washington, D.C.'s fire department and HAZMAT unit responded to a mercury spill at Ballou High School. A student had obtained 250 milliliters, approximately eight ounces, of liquid elemental mercury from the high school's science laboratory and sold some of it to students. Don't know what that was all about, but the HAZMAT team did not respond in time to contain the spill.

So Ballou High School closed its door for 35 days, and EPA and HAZMAT teams eventually tested over 200 homes for mercury contamination. Total cost of the clean-up was estimated to have been in the range of $1.5 million.

And last year a student at Cardozo High School, also located in Washington, D.C., removed a vial of mercury from the chemistry lab and disposed of it improperly. Consequently, school officials closed the school for over a month in order to contain and clean up the contamination.

The clean-up cost ran into the multiples of tens of thousands, which did not include the sizable additional cost of relocating a whole student body to another site.

Now, the two mercury contaminations of D.C. Public Schools dramatically illustrate that mercury is one of the most toxic substances known to man. Even a small amount of mercury exposure and contamination can have catastrophic consequences and require massive and expensive clean-up efforts.

To date the FDA has banned mercury in disinfectants and thermometers, warned against mercury in certain foods, and prohibited the use of mercury in all veterinary products.

The U.K. prohibits -- United Kingdom -- prohibits the use of mercury silver fillings for pregnant woman, and the Scandinavian countries are phasing out its use altogether. Canada is also limiting the use of mercury fillings, and despite the

growing awareness among school administrators, among medical experts, scientists, government officials around the world, and the general public, in spite of the awareness of the dangers of human exposure to a very small amount of mercury, the U.S. federal government continues to allow the unregulated use of mercury silver fillings in dentistry.

The FDA, the agency in charge of regulating mercury fillings, is permitting the sale of a product that has not been proven safe and has not been classified as the law requires. It continues to allow the sale and the use of a mercury filling without disclosing to the patients or the American people that mercury vapor is released during the entire life of the dental filling, and that amalgam fillings contain 50 percent mercury, one of the most dangerous neurotoxins known.

And concerns about the FDA's failure to address properly a mercury based product implanted just inches from a person's and in many cases a child's brain have been raised by Senator Enzi and Senator Kennedy in letters that have been sent to Acting Commissioner Von Eschenbach, by Senator Hatch in a letter to former Commissioner Crawford and by Senator Lautenberg in a letter to NIH Director

Zerhouni.

Congressman Burton, the former Chairman of the Government Reform Committee, and myself, we teamed up to hold three hearings addressing mercury amalgam. Congressional concern clearly reaches across party lines, but Congressional legislation is not only what is needed. It's time for the FDA to treat mercury amalgam as it has treated many other mercury containing products, and it has already banned the use of mercury, as I said, in disinfectants, also in veterinary medicines, and warns pregnant women and parents of young children to stay away from fish with mercury.

Why would we want to embed anything that had any amount of mercury in a child's mouth? It is now time for the FDA to take the next logical step with respect to mercury amalgams. Let's take away the risk. If we know that mercury is a neurotoxin, why allow it to be imbedded in someone's mouth? At least give them a choice and give them the knowledge to make a rational and reasonable choice.

So the FDA's silence of mercury amalgam stands in contrast to other federal agencies. The Centers for Disease Control in 2005 called amalgam a source of major exposure to mercury and the U.S.

Public Health Services warned in 1999 that mercury amalgam is one of the two largest sources of mercury exposure.

It should there come as no surprise that dental offices are one of the prime sources of mercury pollution in our environment. In my discussions with doctors of dentistry, it is estimated that nearly or roughly five dental offices in higher traffic, urban areas use the equivalent of 250 milliliters of mercury each year, the same amount illicitly taken from Ballou High School, in the processing of dental amalgam material.

In each urban community there are hundreds of dentists who use mercury fillings and in my own area, I border on the close line, Santa Monica and Venice in California, and we're finding that the fish are coming up with a high level of mercury, and we're warning not to eat fish along the western coast, at least that segment, and we find our plants that take care and process our waste are dumping the waste from dental offices in the ocean waters along the coast.

It is also my understanding that due to the toxicity of mercury, dentists are instructed not to touch the amalgam before putting it into the patient's mouth. They're also instructed to change

their clothes before leaving the office and not to place carpet on the floors of the actual part of the office where they're doing the fillings.

Clearly, the amount of mercury used in dental offices around the nation dwarfs the mercury spill that happened at Ballou High School. The potential for accidental spills and contamination in dental offices is enormous.

So the term "dental filling" used by the profession is misleading and inaccurate since dental amalgam contains 50 percent mercury.

A 2006 Zogby poll found that 24 percent of Americans could identify the major component of amalgam. When informed that mercury is used in dental amalgam, over 90 percent of the respondents said that consumers should be entitled to know that nontoxic alternatives are available.

And a subgroup of those polled were asked if they believe amalgam should be legal or illegal, and by a ratio of seven to one they said it should be banned.

So with fewer than one in four Americans knowing that amalgam contains significant amounts of mercury and with over three in four Americans seeing a dentist, it is clear that the dental profession is

failing to disclose a fact that would be of extreme importance to most consumers if they were only made aware of it.

When the private sector fails to disclose a salient fact, then it is the duty of the FDA to act and to inform the American public.

Two ironic tragedies exist with the ongoing use of mercury. First, mercury amalgams are completely unnecessary. Most dentists will tell you that any cavity in a child or an adult can be filled with non-mercury alternatives.

Second, the demographics of those who receive mercury fillings are changing. Today a growing number of middle class adults do not receive mercury fillings. Increasingly, mercury fillings are used on children because it's easier, it's quicker, and it's cheaper to use them, and lower income groups.

That children and low income pregnant women are more often exposed to mercury amalgams than any other group should be a cause of alarm for FDA. So I must also note that the issue of dental amalgam is of growing importance in my own African American health community. Both the NAACP and the National Black Caucus of state legislators have endorsed legislation to protect children and pregnant women

from mercury fillings.

And sadly, the National Dental Association is in opposition to my bill, and they have come to my office and they have said to me, "Look. Our people don't like to go to the dentist." Well, who likes to go to the dentist. "But they don't like to come. So we give them these fillings because they're cheaper and they're quicker."

That is no excuse for allowing toxics. I don't care how well embedded they are in the compound into someone's mouth. And so we're working on them. As I said, it's all a matter of educating.

The privilege sanctuary for mercury amalgam must end, and the fact of the matter is that it is, I hope, dying of natural causes, and if I can use an imperfect metaphor because many dentists are beginning to use alternatives, they understand. But we cannot afford the luxury of allowing dental amalgam to succumb to a slow death. Its toxicity to humans and the environment requires us to act now.

The FDA must, therefore, move ahead in the five following areas.

Number one, public awareness. The FDA must immediately take the simple step of insisting that the public be told in advance of placement that

amalgam is 50 percent mercury; that it constitutes an exposure to a neurotoxin; and that alternative fillings are available and they can be less expensive than most would imagine.

I have always believed that the most important factor in improving public health is greater public awareness and education. That is simple, but I believe very important messages of California's Watson's law must get out.

The second thing, environmental impact. The FDA has a legal duty to conduct an environmental impact study of dental amalgam, which it has not done yet, before it classifies the material. So let's look even at the laboratories that manufacture mercury and how they transport it to their sources. So the second issue is the environmental impact.

The third issue, proof of safety. Makers of amalgam like any advice or device containing a dangerous substance should have the burden of proving it is safe. The burden should be on them.

In the case of the encapsulated dental amalgam, however, amalgam manufacturers have neither sought nor been provided premarket approval of their product. There is no excuse for a product that contains one of the most potent neurotoxins known to

man to be distributed to the public without prior approval from the Federal Drug Administration.

Number four, children and pregnant women. Ten years ago Canada directed its dentists to cease placing mercury fillings in the teeth of children, pregnant women, and persons with kidney disease, those who have mercury hypersensitivity or who have braces, and it is well past the time for the FDA to take this sensible and important step to ensure the health and welfare of the people in our nation.

So in closing, I do want to commend the FDA for holding what I consider this essential and important hearing, but hearings alone are not the answer. It is now time for the FDA to address thoroughly and completely the environmental impact of mercury fillings require proof of safety, and level, be honest with the American people about the fact that silver fillings contain a significant amount of mercury that can be dangerous to the health of everyone.

And remember regardless of how well contained that mercury is, it still gives off vapors. The vapors are working on the system, particularly in the teeth zone, constantly. When you have a cracked tooth, and you know children are always falling,

cracking their tooth. They will take a hard ball candy, bite on it, a cracked tooth. That vapor escapes, and so we should test all of our children to see if the fumes are there, and they will be if there is mercury in the fillings.

So there are so many things that need to be done, and I task our federal bureau, the FDA, with doing what's in its authority to do, to prove that it is safe, and depending on these other studies, unless we get out and do our own study, it is just second hand information.

So in closing now, I thank all of you for listening and I would hope that you would join with me in getting the FDA to move on mercury amalgams.

Thank you so very much.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you, Congresswoman Watson.

The committee appreciates you giving your testimony. We'll move on to the next, Ms. Sara Moore-Hines.

MS. MOORE-HINES: Thank you.

Good afternoon. I'm a psychotherapist in Pennsylvania and nationally certified counselor. I have worked for over 25 years with a wide variety of

adults, children, couples, and families. I've served on two mental health boards advocating for professional standards of licensure, for professional counselors and managing family therapists.

Ten years ago my life was good. Both personally and professionally, I was happy. I worked full time in a private practice and was in excellent health. I was frequently engaged in long walks, bike rides, and dance classes. My family life was positive, and the future looked promising.

Who would have suspected that a few well intended visits to the dentist would have resulted in ten years of unexpected devastating damage to my health?

In the summer of 1996, a local dentist repaired three to four silver mercury amalgam fillings, and I felt good that I had caught up on some long needed dental work. Within one to two months, my energy began to deteriorate for no apparent reason. Additionally, I began to experience frequent viral-like symptoms mimicking early stages of the flu.

A top notch Harvard M.D. did an extensive battery of blood tests that indicated a good bill of health. I have since learned that blood tests do not effectively test mercury levels.

He stated that he had no idea what was happening to me. Over the next four years my energy worsened in exhaustive chronic fatigue, and after eight hours of sleep even I had great difficulty getting out of bed in the morning and getting through my work day.

Eventually I could no longer walk around the block. I often felt like I had a low grade fever and a systemic infection. Increasingly I came down with frequent colds and illnesses and began to cancel personal engagements, as well as professional appointments, including my own counseling clients, with little advance notice.

When I did get the flu, I was so sick I wondered if I would survive. I noticed that I didn't have my usual emotional resistance and then started experiencing bouts of mild and occasionally moderate depression. I sometimes became very anxious or frustrated. Both feelings felt hard to contain, quite unlike my usual calm and understanding personality style.

It became difficult to control worrying and clearly something was having a powerful and increasing effect on my body and nervous system. Eventually it became a challenge to focus and

concentrate. I became the most worried and my memory began to decline, and I was no longer able to easily do checkbook calculations.

For an extended period of time my sexual libido declined and my hair fell out. Other problems emerged, including thyroid and adrenal damage, tachycardia, chest pains, chronic urinary tract infections, et cetera.

In 2000, a holistic M.D. who was trained in heavy metal testing performed a DMPS urine challenge test that indicated that I had an extremely high level of mercury in my body. Because my immune system had been so damaged from the mercury, it took almost a year for a holistic dentist to safely remove each amalgam one by one separately.

I also discovered that the mercury from two to three amalgam fillings had migrated into my jaw bone, requiring specialized cavitation surgery. I had trusted that amalgams were safe.

By 2001, all of the amalgams had been replaced with white composite fillings and over the next five years, I engaged in a comprehensive and challenging medical protocol of mercury detoxification, consulting with several M.D.s who were knowledgeable in this area. In order to function and

effectively heal, I needed to take intermittent injections as well as numerous daily supplements for the purpose of mercury detox, nutritional and endocrine support.

Healing has occurred, but slowly with disappointing setbacks and financial burden. The real cost was the cost to my health. Two additional DMPS tests in '04 and '05 indicated the good news of a gradual decrease of the mercury level in my body. I have fought hard to restore my health, and in the last year my health has significantly improved. Most of the mercury toxicity symptoms have finally disappeared or gradually decreased in intensity.

My energy is better. I can work consistently again and recently I have been able to walk considerable distances and occasionally bike. This has been a joy.

I continue daily healing efforts in the hope that some day I will feel completely normal and whole again, including not needing thyroid medication or multiple supplements to get through my day.

The truth is that these years of devastation to my health were not necessary and should not have happened. So I ask: how can other people be protected from the internal assault of this powerfully