toxic heavy metal amalgam that can damage the bodies and lives of any of us.

I'd like to suggest that there is no effective way of predicting who will get sick or who may be, quote, hypersensitive, unquote. It's a gamble.

I believe that the issue of mercury amalgam is a significant consumer protection and public safety issue. As a heartfelt request, I ask this FDA public hearing board and the rest of the panelists to please listen to and heed the truths of this amalgam matter; to take appropriate steps to protect consumers from being exposed to amalgam; to take steps regarding informed consent; to educate consumers, including requiring dentists to inform their patients about the potential health dangers so that patients have the opportunity to make informed choices for themselves and their families.

Change the phrase "silver fillings" that hides the fact that the primary component of amalgam is mercury. It would be more appropriate and in the interest of consumers to call them mercury fillings.

Classify amalgam so that consumers understand that it contains approximately 50 percent toxic mercury.

Set up an independent committee to review relevant and objective research on amalgam.

Abolish amalgam mercury fillings in the United States as soon as possible.

We have heard from Representative Watson. She has reminded us about the FDA having the wisdom to condemn the use of mercury in veterinary products. Certainly we as human beings, including our children should enjoy at least the same protection as afforded our pets.

There are safe, available alternatives to amalgam that truly serve our citizens well.

In conclusion, in every walk of life, in every profession I do believe there are certain crucial times when there was a need for leaders to emerge.

Regarding the issue of mercury amalgam, now is that time for those who can and will to take informed responsible action. Now is the time to resist the pressures of vested interests, to take the higher ground, to act wisely and courageously, and to do so will serve and deeply benefit tens of millions of Americans across our nation.

And I would just like to add that it's my understanding that according to the World Health

Organization, amalgam dental feelings are the primary source of mercury exposure, and my own dentist herself, who is a female dentist, experienced many of the symptoms similar to mine in terms of mercury amalgam, including depression. Many of her staff experienced similar symptoms including infertility, and her own son who had never had any amalgams put in his mouth experienced some similar symptoms.

Thank you. Any questions?

CO-CHAIRMAN KIEBURTZ: Thank you.

MS. MOORE-HINES: You're welcome.

CO-CHAIRMAN KIEBURTZ: Thank you.

Our next speaker is --

(Applause.)

CO-CHAIRMAN KIEBURTZ: -- Dr. Bruce Hutchinson.

DR. HUTCHINSON: Correct.

CO-CHAIRMAN KIEBURTZ: Thank you.

DR. HUTCHINSON: Yes, my name is Bruce Hutchinson. I'm a practicing dentist in Centerville, Virginia, about 50 minutes drive from here. So no one paid my way. I have no financial interest, and I'll be driving home when I'm done.

I am not a scientist. I'm a practicing dentist. I'm the guy you go to when you need a

filling. Okay? I'm here to represent many of my colleagues who go out there, do the work day after day, do the best we can with the materials we have and with the knowledge that we have, with the continuing education that we have available to us.

I think the vast majority of us do the very best we can and stay current with the facts and the topics as best we can.

When I began doing dentistry 26 years ago, amalgam was by far the choice of filling material to be used on any posterior or back tooth. In fact, it's really the only option we had 26 years ago other than going to a crown or a gold inlay or gold onlay, which, again, is quite a difference in cost as you can imagine.

Today I do very few amalgam restorations mostly because patients don't want them. They're ugly. They're black; they're silver. Patients don't like the way they look. They are aware of some controversy going on, although, quite frankly, they don't understand mercury or lead or molybdenum or anything else. The vast majority of patients think the fillings are made out of lead. They have no idea.

But I still believe that mercury based amalgam, amalgam fillings have a place in dentistry.

There are places where I find it to be invaluable and the only option that I think is doable in a certain situation.

Now, again, I have placed very few amalgams because the patients don't want them, but there are places where you cannot keep the tooth 100 percent dry. Any other filling material we have will fail. Amalgam will not.

So, again, we're at a point where is cost the only thing that matters, and I would say no, but my research, my reading, everything I hear from the FDA on down through other organizations says to me that amalgam is safe and effective and viable for patient usage. So why should I not use it?

If for any reason I thought, I actually believed that amalgam was causing harm to my patients, I would stop using it immediately, and I think most dentists feel that way. We have an obligation to our patients, to the public to do the best we can. Our patients trust us. They trust us to do what's right for them, and if I had a personal belief that it was bad for my patients, I frankly would not use it.

But, again, I think it's dying a slow death all on its own just because of the public cry that there are other materials out there that for the

most part can be used that look better, that work better, and are available. But if you take amalgam away from the practicing dentist's armamentarium, you really are doing a disservice to the public, I believe.

Many times I have patients walk in the door that have fillings that are 40 and even 50 years old that are dental amalgam, and you know what? A lot of them are still just fine. I have yet to see any other restoration other than possibly a gold one that lasts 40 or 50 years. They just don't happen.

I guess that's really all I had to say, but once again, I want to stress that if you take it away from the dentist, I think you are doing the patients a disservice because the only option in some of these cases is extremely more expensive because we are not talking about a different kind of filling material. If it is a place we cannot keep 100 percent dry, then we are going to have to go to something like a crown, which is instead of 100 or $200 for a filling, is going to be more like 1,000 or $1,200. So it's a huge, huge difference.

And I note Congresswoman Watson said it's not a big difference in cost. Well, it can be. It can be a huge difference in cost. And although we

shouldn't measure everything by what it costs and value and so on, I think cost is important. It's important to every one of you when you do your shopping, and maybe it is not important to you when you are valuing your health care, but I have patients that it is important to, that it is important that they could not have a filling if they could not have the cheaper alternative.

Thank you for your time. I think this is an issue that has been on the radar screen for years and years now, for decades, I would say, and the other thing I would add is that if this were a true danger to society after 150 years of using these things, I really think someone would have figured it out by now.

Thank you.

CO-CHAIRMAN KIEBURTZ: Thank you, Dr. Hutchinson.

Dr. Wilson.

DR. WILSON: Thank you.

Good afternoon. I'm Dr. Nairn Wilson. I represent the Academy of Operative Dentistry, which has paid my expenses to be here. I have no financial involvement in any respect in relation to dental amalgam.

The Academy of Operative Dentistry is

pleased to have the opportunity to participate in the present hearing. The purpose of the academy is to promote excellence in operative dentistry, including all matters pertaining to the conservation and, where necessary, restoration of teeth.

The academy, founded in 1972 is a worldwide organization with more than 1,200 members in 25 countries. The academy is a non-profit making organization of substantial international standing.

I'm representing the academy at this hearing as Chairman of the academy's Research Committee and as a member of the academy's Executive Council. I'm presently dean and head of the King's College, London Dental Institute, that guides King's College and St. Thomas' Hospital in London. My credentials are set out in a brief resume attached to the written submission.

While my interests, activities, and expertise have given me a great deal of involvement and understanding of the dental amalgam issue, I think it is of relevance to point out that I spent more than 30 years in research with a main focus on tooth colored filling materials, in particular, their clinical use, efficacy, and the teaching of these materials.

Regarding dental amalgam, the academy is of the view that this alloy is a safe, effective material for the restoration of teeth. Notwithstanding its long history, et cetera, which I understand and accept as not science justification itself, it is very clear that there are a small but significant number of people who do get adverse reaction typically of a localized allergic nature.

Available scientific information continues to reinforce the widely held, recognized safety and effectiveness of dental amalgam. The academy endorses the World Health Organization, WHO, and World Dental Federation, FDI, which sets the statement on dental amalgam of 1997, which amongst other matters considers dental amalgam restorations to be safe.

This statement has recently been reaffirmed by two scientific reviews confirming the safety of the dental amalgam. These reviews, one by Clarkson, Magos and Myer in the New England Journal of Medicine in 2003, and a second by Brownawell, Berent and Brent in Toxicology Reviews in 2005.

The conclusion of the Brownawell, Berent and Brent, et al., study is considered to be of particular relevance to the present hearing, and it concludes with the following statement: "despite

public controversy over the use of dental amalgams or restorative material, this systematic evaluation of current, peer reviewed, published studies did not reveal significant evidence to support a causal relationship between dental amalgam restorations and human health problems, with the exception of allergic reactions in some individuals."

In making this statement, the authors acknowledge notwithstanding existing knowledge and understanding that research grants still exist and well designed studies that were all sufficient numbers of subjects and control are required to ultimately resolve the dental amalgam controversy.

The Academy of Operative Dentistry also endorses the ADA, the American Dental Association's statement on dental amalgam in which the ADA's Council of Scientific Affairs' 1998 report on the scientific literature on dental amalgam is cited to have included. There currently appears to be no justification for discontinuing the use of dental amalgam.

This view is echoed in the recent 2006 Council of European Dentists resolution on dental amalgam which concludes by calling on European Union institutions to take full account of the scientific

evidence in relation to dental amalgam and the worldwide consensus of the dental profession that dental amalgam should remain part of the dentist's armamentarium to best meet the needs of patients.

In holding the view that dental amalgam is safe and effective, the academy acknowledges as stated in the WHO-FDI consensus statement there's a potential health risk to all health personnel from mercury exposure if working conditions are not properly organized and that mercury used in dentistry may contaminate the environment via disposal of waste products from dental clinics.

To these ends, the academy fully endorses the application of proper mercury hygiene in dental application and the use of equipment to collect metallic waste generated during dental amalgam placement and removal procedures.

Furthermore, the academy acknowledges that an adverse reaction to dental amalgam may occasionally occur, and despite the rarity of such reactions, oral health personnel should continuously be alert to such a possibility, in particular, in the managements of patients with a history of adverse reaction to any of the constituents of dental amalgam alloys.

In its pursuit of excellence in operative

dentistry, the academy also fully supports the importance of continued monitoring of the safety and effectiveness of all dental restorative materials. The academy is proud of its commitment to excellence in operative dentistry and in the interest of particular patients and will continue to encourage and promote an evidence based approach to clinical practice, including the rapidly expanding use of alternative restorative materials typically at the expense of the use of dental amalgam.

On the matter of dental amalgam, the academy would urge the hearing to be influenced in its deliberation by the most robust of scientific information available, let alone the conclusions of the various national, international and other organizations who have looked very carefully at the dental amalgam issue.

The overwhelming consensus is that with the exception of some rare patients with adverse reactions to dental amalgams and some of the constituents, the continued use of dental amalgam does serve a purpose and is of benefit to many patients and to them it is safe and effective.

Thank you.

CO-CHAIRMAN KIEBURTZ: Thank you for your

testimony.

Our next speaker will be Dr. Mayher.

I may just say that I'm just going to give speakers a little tap at one minute. Many of you have written comments and don't see the light go from green to yellow, just to give you a little heads up that you're heading into the last minute, if you don't mind.

DR. MAYHER: Just go easy on the tap. I startle easy.

Hi. Thanks for having me. I'm Dr. Vincent Mayher. I'm the President-elect of the Academy of General Dentistry, and I practiced general dentistry in Haddonfield, New Jersey for 25 years. The academy did pay for my transportation and room and board.

I am not anti-mercury. I am not pro-mercury. I am pro-choice. After all, in the end it comes down to two people, the practicing dentist and the patient who places his or her trust in their dentist.

Like the tens of thousands of my colleagues who place amalgams every day, I am not a research scientist. Instead I really on valid scientific articles presented in refereed journals

such as that of the American Dental Association and the Academy of General Dentistry to make clinical judgments based on sound science.

In addition, it is also important for the dental clinician to rely on credible entities, such as the National Institutes of Health, the U.S. Public Health Service, the Food and Drug Administration, the World Health Organization, and the Centers for Disease Control and Prevention.

These are home based. As a clinician, I have no choice but to look to these bodies for guidance. To deviate from the determinations made by these credible entities would be to turn my back on sound science and, therefore, place my patients in the vulnerable position of being the recipients of dental care that is being supported only by supposition.

All of these credible institutions have validated the safety of dental amalgam time and time again over years of research. That is not to say that there should not be options. There's a retail clothing store in my area whose slogan goes, "An educated consumer is our best customer."

Nothing could be more apropos when it comes to the relationship of a clinician and a patient in choosing a restorative material because while the

scientific aspects of the safety of amalgam is the major consideration in my world, it is also a consumer issue. Patients should have the right to make an educated decision as to the nature of any dental restorative material that is being placed into their bodies.

I have placed amalgams in my immediate family members' mouths in the past and I would not hesitate to do so in the future. If I had even the slightest concern that this material might place their health in jeopardy, I would simply choose another material.

Understand there is always an alternative to amalgam. The problem is the alternative may not be as strong, maybe require more frequent replacement or could cost much more.

A case in point. Many of my patients are senior citizens who have had crown and bridge restorations placed in the past. Often due to decreasing dexterity and dry mouth conditions, these people are more prone to recurrent dental decay around this crown and bridge work. Most of the time, due to the nature of these restorations, the recurrent decay is subgingival, that is, below the gum line where visibility and moisture control can be very

challenging.

Amalgam is ideally suited in repairing this type of recurrent decay. It performs better than any other direct restorative material when placed in a moist environment, and it can be contoured and finished with hand instruments.

One could argue why not replace the crown and bridge work, and that would be a valid clinical argument. Only with amalgam, we can do this for under $200. Replacing the crown and bridge work could potentially cost many thousands of dollars on these senior citizens, many of whom are on fixed incomes.

In other instances, individuals could have broken molar teeth requiring large restorations in the back of their mouths. Given the increase in stress in this area, amalgam is still considered stronger than directly placed composites.

As an alternative we could place a gold onlay. There is no better restoration in this clinical situation, but the cost would be four to five times more than an amalgam.

As a clinician I am obligated to educate my patients of these choices before I ever pick up a hand piece. In my office, we make every effort to explain the nature of amalgam as well as other

restorative materials that we use. We do this by educating the patient of their options both verbally and through informational brochures. The patient is informed that amalgam is comprised of approximately 50 percent mercury, that once this restoration is placed, the mercury is stable and bound to the other metals in this restoration, but then a minuscule amount of it will leak over time.

However, the patient is informed that despite this leakage all of the credible institutions and organizations that I referenced to earlier have repeatedly stood by its safety.

In addition, there is insufficient evidence to assure me or the public that components of alternative restorative materials have fewer potential health effects than dental amalgam. There's an old saying, "The dose is in the poison." And there are few, if any, materials which dentists use that are not toxic at some level.

For example, local anesthesia that dentists use are toxic if introduced at a high enough dose. Yet I assure you that my patients are very happy that I use local anesthesia, as I'm sure most of you are when you have dental work done.

The important thing here is to know what

the toxicity level is, to respect that level, and to adhere to limitations published.

Addressing the environmental impact in mercury and dental amalgam is a concern to all of us. To quote a phrase from the 2005 article in the Journal of the American Dental Association, dentists are obligated to be good environmental stewards and should follow practices that reduce environmental mercury release.

Amalgam that is used is encapsulated form. The capsule is sealed and not opened up until after the materials are thorough triturated. Handling and proper disposal of amalgam is addressed by the American Dental Association in what it calls its best management practices for amalgam waste.

Best management practices addresses all aspects of amalgam disposal from the collection and proper storage of amalgam particles themselves to proper disposal of used capsules to direct disposal of traps that capture amalgam scraps that are flushed out of the mouth. Introducing the use of quaternary ammonium compounds for disinfection which do not release mercury from amalgam into solution as oxidizing ones do is encouraged.

So in conclusion, I urge you to continue

to take the objective scientific approach to the use of dental amalgam that you had in the past. As health care providers and as concerned citizens, my colleagues and I rely on your continued diligent study into this matter. We rely on your guidance for the safety of our patients and for the environment, and we take these responsibilities very seriously.

But until such time as amalgam or any other restorative material previously approved for use in this country is determined by credible sources to have detrimental effects on a patient's health and on society, the decision whether or not to place this material should be made by an educated consumer under the guidance of his or her dentist, and I leave you with the words of Hippocrates, the Father of Medicine.

"There are, in fact, two things: science and opinion. The former begets knowledge, the latter ignorance."

Thank you.

CO-CHAIRMAN KIEBURTZ: Thank you, Dr. Mayher.

Dr. Marshall.

DR. MARSHALL: Thank you.

My name is Milton Marshall. I'm here at the request of the American Dental Association to

speak on the safety of dental amalgam. They are paying my travel reimbursement expenses, but I have received no other compensation from them.

I received a Ph.D. in biomedical sciences from the University of Texas Health Science Center in Houston, Graduate School of Biomedical Sciences. I'm also certified in toxicology from the American board of toxicology, and I've been certified in general toxicology since 1992. I hold adjunct appointments at the University of Texas Dental Branch in Houston, Texas, and the University of Texas Medical Branch in Galveston, Texas. I'm currently employed by Baylor College of Medicine in Houston, Texas.

My background includes regulatory and safety of product development, drugs, devices, biologics and combination products. I have experienced both preclinical and clinical safety testing. Key criteria to be considered and associated in effect with the exposure are the degree and length of exposure, and I would like to emphasize the fact that the form of mercury that's used in dental amalgam is elemental mercury, also referred to as HgO.

Because of the sensitivity of mercury detection instrumentation, volatile or elemental mercury can be measured in exhaled air, and the amount

of volatile mercury measured in the oral cavity is increased with chewing in persons with amalgam restorations.

The total inhaled dose of mercury is small though because of the small volume of the oral cavity and the amount of volatile mercury released depends on the number of amalgam restorations present.

After inhalation the majority of the mercury vapor diffuses across the alveolar membranes and is retained by the red blood cells in the pulmonary system. The catalase peroxidase system in the red blood cells oxidizes elemental mercury to divalent mercury species that is retained by the red blood cells.

Human red blood cells have a half life of 120 days, and the majority of the red blood cells in trapped mercury is excreted in the feces via the biliary system on removal of the red blood cells from the circulation by the liver. Thus, only a small amount of mercury that is not trapped in the red blood cells is available to interact with other tissues.

Chronic exposure to elemental mercury is best measured by monitoring urine mercury levels. Occupational exposure to elemental mercury provides the majority of information available on exposure

levels that are associated with adverse health effects.

Multiple studies have been conducted to correlate elemental mercury levels in air, urinary mercury, and adverse health effects associated with this exposure. From data obtained on the workers in the core alkali industry, a threshold level for subclinical effects was established in 50 micrograms of elemental mercury per gram of creatinine in Europe. Although exposure to elemental mercury can be documented by monitoring urinary mercury levels, toxicity occurs at levels far above those seen from persons with amalgam restorations which typically have two to four micrograms mercury per gram of creatinine.

Although it is good practice to correct mercury levels for creatinine content to account for hydration status, creatinine concentrations in urine is typically .5 to 3 grams per liter and an average value of one gram per liter has been reported, which enables a direct extrapolation with values in micrograms per gram creatinine and micrograms per liter.

Urinary mercury levels of dentists and dental assistants who are occupationally exposed to mercury from placing and/or removing amalgam fillings

have shown a stead decrease over time with the latest five-year average of urinary mercury levels at or below those in the general population of less than four micrograms per mL.

Further analysis of urinary mercury levels in dentists who participated in five different years of screenings at the annual American Dental Association health screening program indicate a downward trend in urinary mercury over time when the values are averaged from initial to final values.

Urinary mercury levels in dentists with both occupational exposure to dental amalgams and to some extent from amalgam restorations are much lower than those seen in persons with occupational exposure in the core alkali industry.

I would like to provide an overview of several recent reports on dental amalgam, including one published by the Life Science Research Organization, or LSRO, in 2004. This LSRO report is review and analysis of the literature on the health effects of dental amalgam.

For this report an expert panel was convened to identify and review the scientific literature that was available between January 1st, 1996 and December 2003, and health effects associated

with dental amalgam of more than 950 scientific articles reviewed by the expert panel.

The quality of literature reports within this time frame were assessed and reviewed to determine if it supported hypotheses relating to adverse health effects associated with dental amalgam. U.S. EPA general assessment factors were considered for determining scientific merit of the literature reviewed. The literature was reviewed for soundness, applicability and utility, clarity and completeness, and on certainty and variability in evaluation and review, independent verification, validation and peer review.

Evidence regarding adverse outcomes in human was evaluated from the perspective of the epidemiological studies, secular trend data, animal toxicity studies, dose dependent relationships, and biological plausibility. A summary of this report also appeared in Toxicology Reviews in 2005.

The LSRO report expert panel recognized the number of other expert panels had previously reviewed the safety of amalgam for dental use. Overall, with inclusion from these panels was that no adverse health effects were associated with amalgam use other than occasional allergic reactions.

In reviewing studies on exposure on the elemental mercury and urinary mercury levels, the LSRO panel drew the following conclusions from the literature review. Within the time frame of the review, 1996 to 2003, mean urinary mercury levels in the general population were less than two micrograms per liter in 95 percent of the individuals and the general population had urinary mercury levels at or below four to five micrograms per liter.

Long term use of nicotine gum, intense chewing, and more than 20 amalgam surfaces resulted in urinary mercury levels that approached occupational exposure.

Two consistent results were seen with occupational exposure: decreased tumor necrosis factor alpha in urine mercury levels greater than or equal to six micrograms per liter and elevated urinary inesto beta glucose aminodase in the mercury range of 25 micrograms per liter.

These observations were deemed to be indicators of elemental mercury exposure, not indication of adverse health effects.

Neither occupational exposure nor dental amalgam studies provided sufficient information to support the hypothesis that mercury exposure at levels

absorbed from amalgam restorations caused an adverse effect on renal function. There was insufficient evidence to support an association with dental amalgam and development of autoimmune diseases. Case reports and studies of immune function demonstrated a localized allergic response in some individuals.

Insufficient evidence was published in this time period to support or refute the hypothesis that elemental mercury contributed to adverse pregnancy outcomes.

There were some research gaps that were also identified and several other reports which I don't have time to go into also supported these conclusions.

So as a toxicologist, my opinion is that the overwhelming body of scientific evidence supports the safety of dental amalgam, and there are no adverse effects in children or in adults after long-term exposures.

CO-CHAIRMAN KIEBURTZ: Sorry. I'm going to have to interrupt you. Thank you, Dr. Marshall.

Ms. Ward.

MS. WARD: Can everybody hear me? Okay. I've learned to talk too soft.

My name is Carol Ward. I'm Vice President

of Dams International, and I'm a retired librarian, reference librarian, library supervisor, and I have 20 years of experience behind me as a coordinator and officer of Dams.

I've heard many scientific lectures on mercury and dental fillings and more importantly have spoken to countless individuals who have partly or fully recovered their health from having their amalgam fillings replaced.

I'm a survivor of mercury toxicity from my 16 mercury amalgam fillings. At age 45, I became catastrophically ill. For months no medical doctor could arrive at a diagnosis. I was too weak to walk, too weak to sit up in a chair. Over a period of months I became a semi-invalid, whereas prior to my breakdown I had been a jogger and a long distance hiker.

A biochemist-nutritionist finally was able to diagnose my condition. He said I was ill from my dental amalgam fillings and that my immune system had been virtually destroyed. When the several medical doctors assessed me and found no damage, I found it rather baffling, but a picture of my illness did fit with many other pictures of amalgam toxicity.

I am going to refer to my fillings as

mercury fillings because of their 50 percent mercury content. I was seven when the first one was place and 43 when the last two were placed, and my breakdown was at age 45.

I developed systemic yeast and am still on a special diet and will never be able to eat many foods that other people enjoy or have alcoholic beverages.

My symptoms included depression, equilibrium problems, repeated infections, dizziness, urinary and kidney infections, digestive disorders, memory loss, low thyroid, and visual field problems. My life was limited for a few months to one floor of home. I was unable to work, drive, or do anything but survive hour by hour, and I know there are many other toxicity victims who have been through this.

Following the systematic replacement of mercury fillings by composites by a mercury free dentist, I began to recovery, and I'd like to note that I had herculite composites put in, and they've been really pretty solidly lasting for 21 years.

Following the systematic replacement of these fillings I began to recover. I was still, however, unable to stand certainly or strongly at an intersection, to ballroom dance or play the piano the

way I used to, or even get proper rest at night. But the treatment that made all of the difference was BAL, British anti-Lewisite. It's in the Physician's Desk Reference, and I understand it's a precursor to DMPS from what I understand.

After 20 days of injections of this, I began to experience equilibrium improvement, intellectual functioning improvement. I could dance, play the piano, and sleep.

Since that time, I would say I've achieved about an 80 to 90 percent recovery. What I lived through from my amalgam fillings was hellish beyond description, and I really hope that there will be others who won't have to live through it because of what we're all doing here.

It is time to expose the real nature of these silver dental fillings as an unstable, toxic compound which vaporizes constantly in the human mouth. No one is safe from a potentially negative reaction to these fillings because if you don't get sick when you're younger, chances are it may get you when you're older. There is such a wide variety of possibilities.

And also a percentage of the public, one to 20 percent are unable to excrete mercury

efficiently. Speaking of genetics, it is significant that Congresswoman Diane Watson has reintroduced the bill this year, HR-4011, and I know you just heard her speak. So you don't need me to go over it again.

I'd like to talk a little bit if I have time about the children's amalgam studies. Dams has a position on that. They view that there are flaws in these studies. In particular, during the American children's study, despite the reported neurological illnesses, many children were kept in the study: 36 with sensory disorder; 24 had psychological disorders; 19 had asthma; and four had neurological disorders.

Dams is wondering why these children were not pulled out of the study to protect them from a known toxin when their health was already compromised.

Other weaknesses in the studies are that researchers DeRouen and Bellinger focused on statistical averaging so that the damage done to individual children may have been missed. The American children study was based on children, but they may not have been really representative of the general population as we imagine that children most susceptible to mercury injury from vaccines would have already been screened out.

A further question has already been

mentioned about the kidney damage to children with amalgam. So I won't go into that.

Our conclusion regarding the children's study is based on a vast body of scientific research, is that mercury amalgam fillings are inherently damaging and children were unwittingly exposed to this damage. Many of the effects may not show up until mid-life the way they did with me, and then they may appear as chronic diseases, rheumatoid arthritis, lupus, MS, ALS, Parkinson's, and many others.

I believe it is the FDA's responsibility to safeguard public health by properly classify -- Thank you.

CO-CHAIRMAN KIEBURTZ: You have another minute. I was just letting you know you had one more minute.

MS. WARD: Oh, okay. I'm very grateful to have been given the opportunity to speak today, and I think that it's wonderful that you're reviewing all of these questions and listening to people from the outside.

Thank you very much.

CO-CHAIRMAN KIEBURTZ: Thank you, Ms. Ward.

(Applause.)

CO-CHAIRMAN KIEBURTZ: We are actually going to take a break right now at our 2:30 time. We will reconvene in ten minutes. So please come back and we'll start promptly.

Thank you.

(Whereupon, the foregoing matter went off the record at 2:35 p.m. and went back on the record at 2:47 p.m.)

CO-CHAIRMAN KIEBURTZ: Okay. I think we will get started again and get back going with our public testimony.

I think our next speaker is Dr. Flynn. I'm sorry. Finn, Dr. Finn. Pardon me.

DR. FINN: Hi. Good afternoon, everyone. My name is Amanuel Finn, and I live here in the Washington, D.C. area.

I must tell you that my position here on this issue has no financial interest the present or the future. I simply am here to testify in support of amalgam restorations because I do believe that they work, and according to the body of evidence I saw here today has led me to think and act otherwise.

So I'm here to share my own personal and professional experience with this panel and with the audience, and also I'm here to represent the

Association of State and Territorial Dental Directors, ASTDD.

ASTDD is a national nonprofit organization representing the directors and staff of state public health agency programs for oral health in the U.S. It was organized in 1948 and is one of 17 affiliates of the Association of State Health Officials, ASTO. The membership of ASTDD is comprised of the chief dental public health officer, which I am here in Washington, D.C., state dental director of the State Health Department or the equivalent agency.

ASTDD has also established an associate membership which is open to the public.

And the organization which I represent today formulates and promotes the establishment of a national dental public health policy and also assists states' dental programs in the development and implementation of programs and policies for prevention of oral diseases.

I and also ASTDD strongly support the continued use of amalgam as a restorative material based on the significant body of peer reviewed, valid, scientific evidence which clearly supports amalgam safety and effectiveness, as well as its long history of over 150 years in the dental office.

Just as importantly, this issue impacts tremendously on the well documented access to oral health care issue for marginalized and vulnerable populations in our society. I can personally attest to that due to the fact as a former National Health Service Corps dentist and the dental director of a federal qualified health center in New York State for over seven years.

Now, I would like to just address a couple of issues some speakers have alluded to prior. First, the Honorable Watson, the gentle lady from California, she did state her position quite clearly, and one of the things that she said was that in urban settings the overabundant use of amalgam is documented.

What I would say to Honorable Watson if she was here is that according to the literature annually well over one million amalgam fillings are placed in teeth for the U.S. I can understand that the folks also who have testified on the effects of amalgam, the health effects on their personal lives, obviously I do sympathize with them.

However, according to the literature, and that's the only thing I could go by today at this moment leads me to think otherwise, again, without taking your personal issues into consideration.

I must also tell you though that this controversy, it seems to me, will not be solved today or tomorrow. It would seem this is going to take quite some time for a resolution if that will ever happen to come to pass.

But I'm encouraged by the fact that panels such as these, this one obviously is critically important in a democratic system to address critical health issue.

In closing I would just like to say to you that and to the panel that worldwide hundreds of millions of patients have amalgam feelings in their teeth, and I don't think this will be abated any time soon. So I think the discussion obviously will have to continue for some time in the future, and obviously by all indications it will continue.

But in the meantime unless the scientific literature says otherwise, I will be in full support of amalgam restoration as a material of choice, and also there is a cost issue for vulnerable populations, and I would like to underline that.

Thank you.

CO-CHAIRMAN KIEBURTZ: thank you, Dr. Finn.

The next speaker is Ms. Kilmartin.

MS. KILMARTIN: I'm Angela Kilmartin from London, England. I run the British patients group called Patients Against Mercury Amalgams, founded when I couldn't go through the courts and to get revenge.

I've been suffering from mercury poisoning since I was four and a half, when my teeth were filled up by a dentist who was paid by the filling. I immediately developed asthma, allergic rhinitis. I had ten days at school most terms, and by the time I was in my 50s my mouth was full of it, plus four gold caps.

This is about neurotoxicity. I should also say that I've paid my own way here and no one pays me to come. I believe very strongly in this cause.

I'd like to start with some science because that's what you want, and in a short stroll through my office full of this sort of thing I find the following: inhaling mercury will always be a hazard to human health. Neurobehavior effects in occupational chemical exposure; mercury in the rat hypothalamus after mercury vapor exposure; detection of mercury in the rat spinal cord and dorsal root ganglia after exposure to mercury vapor.

Mercury passes easily through the brain

barrier. Look at the dates as well: 1988, and you all have in front of you copies of this because I shall pass fairly swiftly.

Inhalation of mercury vapor associated with tremor, excitability. Chronic exposure has major effects on the central nervous system, and that is from a huge textbook called Toxicology published by Pergamon Press, and that's the 1991 edition.

The electrical charge is transferred to molecular species associated with nerve counts throughout the body. You can see where all of the science comes from.

Then there's an abnormal neuronal migration with deranged cerebral cortical organization and diffuse white matter astrocytosis of the human fetal brain. That is a major effect of methyl mercury poisoning.

Electromotor forces and electric currents caused by metallic fillings. Measurement of the electrical conductivity of dental cement which denies the fact that cement is supposed to separate the various metals.

In the Journal of Orthomolecular Medicine, here is a clear connection between the mercury vapor concentration and the number of amalgam surfaces as

can be seen from the reference lines. Scientific studies show that if an individual is exposed to mercury vapor from amalgam fillings through each breath, 17,000 times daily, this may result in many different symptoms, complaints and illnesses.

The mercury is quickly received through the lungs and travels through the blood stream to all organs of the body.

This is a picture which is rather stunning. I'm going to go better than that in a minute.

These are my neurological symptoms in 1995 when I was age 54. They are just the neurological symptoms. Every section of my body went under. I was in bed. I had brain fog. I was cold and had to keep going into hot baths. I collapsed regularly, constant crying fits necessitating putting me into a mental home for two weeks. Concentration difficulties, fatigue, facial strain, frozen shoulders and all my bones stopped working, and I was confined to a wheelchair eventually.

I gazed. I hyperventilated. I couldn't sleep. I had irregular heartbeats. My legs cramped all day long. I had a memory loss, a metallic taste, skin pallor, tiredness, uncertain gait, and word loss.

I think you'll find I'm a bit different now.

My stool results after the removal of all amalgam and gold caps in 1995 was sent to Schiwara Klinik in Bremen, Germany. Those are the dates. They were 1997. You should be under three units per kilo of stool. If you look in the middle of the slide, after an intravenous Vitamin C infusion in March 1998, I suddenly started excreting 170 units per kilo of stool.

Now, last year, to celebrate the tenth anniversary of the removal of this dreadful stuff and my arisal like a phoenix, I had my stools retested. Look at the difference in the levels from 30, 50, 170. I was down to 3.7 and 12, and the 12 units was, again, after an intravenous Vitamin C chelation.

This is me two weeks ago in Cambridge University. The man on the right is a well practiced technician, and he looks after the scientific labs throughout the whole of Cambridge University, and I took to him one extracted tooth, which I have saved in a plastic jar. You can examine it. It's on my seat, and one piece of gauze filling which was put in my mouth during a removal technique.

This is the result of the University of Cambridge Health and Safety Division. The

environmental monitoring report form gives its location. The date is the 24th of August 2006. The equipment used was a Sure City mercury vapor indicator, which is used throughout the university. The calibration, the last time it was calibrated was the 13th of April 2006, and the method of testing was an ultraviolet photometer.

The results. On the morning of Thursday, the 24th of August two samples submitted by myself were monitored for the presence of mercury vapor. The samples were monitored in a well ventilated room adjacent to the offices of the Health and Safety Division. The temperature within the room where the samples were monitored was approximately 20 degrees Celsius. Very comfortable.

Sample 1, the extracted tooth, consisted of a gold cap, tooth debris, and residue, and Sample 2 was the dental gauze. This is me, and the mercury vapor readings were as follows: When we closed the jar there was nothing coming out. When we opened the jar and put the probe into the jar, 367 began and it graded down to 50 on Sample 1, and on Sample 2, just the gauze, was 33 down to ten.

Then we sealed the jar and then we opened it five minutes later, and look at the results again:

418 on the initial exposure and on sample 2, 125. We filmed the whole thing. Don't tell me there's no mercury vapor coming off tooth fillings, even 11 year old ones.

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

No, no. No, you don't actually. I forgot to give you the minute warning, but having forgotten, I'll give you a minute.

MS. KILMARTIN: I'll press it again.

The University of Cambridge results came very clearly mercury is a neurotoxin despite what any of the pro amalgam dentists think. The technician said that if he found those levels from my tooth fillings in a room, he would have the room closed.

And the third point, mercury and its compounds can be toxic by inhalation, contact with the skin, that is, oral and nasal mucosa, because that's where the vapor is instantly taken up, and of course, if swallowed like the particulate.

I have been poisoned. The whole world is being poisoned, but it's to a different effect in every individual, and I seriously hope that you will take note of Congresswoman Watson because the rest of us down here think that we could just have stayed

sitting down. She said it all for us.

Thank you very much for hearing me, and it was well worth my visit.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you, Ms. Kilmartin.

Ms. Pichay.

MS. PICHAY: Good afternoon. My name is Teresa Pichay. I am employed by the California Dental Association and am the manager of policy development and analysis and the association did pay my way to this hearing.

I'm here today to tell you of the association's support for the continued use of dental amalgam based on the scientific evidence showing it to be an effective dental restorative material and based on the lack of definitive evidence showing any cause and effect relationship between the mercury in dental amalgam and any systemic illness in either patients or dental health care workers.

I am also here today to support the work done by the FDA, the Public Health Services, and other federal agencies in their ongoing review of research on the human health effects of mercury in all of its many forms.

The association in the last ten or 15 years has faced several challenges regarding dental amalgam in the public policy arena. Representative Watson referred to the dental materials fact sheet. The law she originally wrote many years ago actually required the Dental Board to distribute a fact sheet to the dentists, period. The requirement to distribute a fact sheet to patients did not come into effect until several years later when the law went into effect.

The first fact sheet produced by the Dental Board in 1993 actually was a table taken from one of the appendices in the 1993 Public Health Service report.

Other areas where we face challenges are with the Department of Toxic Substances Control, mercury report, and Proposition 65, the state's unique law that requires public notification of almost any exposure to potentially hazardous materials.

In every instance CDA relied on the 1993 and '97 reports on dental amalgam produced by the U.S. Public Health Services and the 1999 ATSDR profile on mercury.

CDA presented information from these reports at public hearings in order to counter the

sensationalized theories about dental amalgam that marked the proceedings. We learned from these reports that mercury toxicity is determined by various factors, such as the form of mercury, route and duration of exposure, and dose. We learned that measuring devices have improved over time and now allow very low levels of mercury to be detected.

Most importantly, we learned that the presence of metallic mercury in dental amalgam does not by itself mean that dental amalgam has the same human health effects as metallic mercury alone.

The work of these federal agencies help CDA make our states= legal and regulatory entities aware that recent sounds scientific information on the safety of dental amalgam is available and accessible.

Dental amalgam continues to have an important role in the oral health of Californians today. Unfortunately California school children lag behind the nation's school children in visits to the dentist and in the use of sealants. And they have more untreated decay on average.

We acknowledge that the use of amalgam has declined with the availability of other durable but more aesthetic materials and with the overall improvement in the nation's oral health. As long as

the body of science continues to show that the health benefits of dental amalgam outweigh health risks, the association will continue to support its use.

The summary of recent research on mercury, dental amalgam and human health effects that you are considering at this hearing clearly demonstrate that there is no need to further restrict the use of dental amalgam.

The association is appreciative of the time and work this panel has devoted to the subject. I thank you for your attention to my comments today.

CO-CHAIRMAN KIEBURTZ: Thank you, Ms. Pichay, for your testimony.

Next is Ms. Kerger.

MS. KERGER: Yes, and I thank you for your time.

My name is Jessica Kerger, and I have prepared a variety of remarks. The first speech, I think, was 45 minutes long and I cut it down and cut it down, and then this morning I threw it out altogether because I thought perhaps if I can even make it a little shorter you guys could ask me some questions.

I think in some ways I have a unique vantage point. But first I'll let you hear a little

bit about who I am and you can decide whether it's worthy of asking the questions.

I am somebody who has been diagnosed with mercury toxicity. I have also been diagnosed with mercury allergy and sensitivity. I am somebody who has been declared completely disabled by the Social Security Administration. I am someone who was told by an imminent physician, a man who has over a year waiting list for new patients; this was a man who sat me down and took my hands, looked me in the eyes and said, "Jessica, I don't think you have two years to worry about this mercury thing. I think you don't have that time to spend. You need to get your thoughts together on how to best spend the time you have left for my honest opinion is that you are dying of a neurodegenerative process. It's a nonspecific one. I can't give you a name for it, but I think that's going to explain the further atrophy we see on your MRIs, and it's going to explain the tremors and the seizures and all of the various problems, your memory loss, the inability to concentrate."

He said, "You know, I took the time to look up mercury." He said, "And what I found was that the ADA and the FDA say it is safe."

I am someone who struggled mightily with

chelation when I finally found someone who was willing to help me. If no pain no gain is the motto there, well, I'm deserving of all of my gains.

I am someone who when I received my APOE genotype tests was told on a piece of paper in black and white that I had Alzheimer's disease with a greater than 97 percent specificity.

I am someone who is dramatically improved with the use of glutathione. I thin you should all be aware of the glutathione connection with mercury. it has been said in reported literature that glutathione is inversely proportional -- levels of glutathione are inversely proportional to the mercury toxicity. They have a one-to-one because you need the glutathione to take it out of the body.

I am an attorney, though I haven't practiced in a while, and my license is currently inactive, but when I was, I represented clients like General Motors. They were my primary client and Emerson Electric. I was a defense attorney.

I grew up in a medical family. I have a great deal of respect for mainstream medicine. My father and all three brothers are doctors. So is my stepson and his wife is about to join them. My uncle is also a medical doctor, a psychiatrist.

I am someone who is not unreasonable. When I was an attorney I was picked to be a juror in a civil case. That's highly unusual. I was picked to be an arbitrator in various matters, as well as a mediator.

I think this all makes me an unlikely plaintiff, but a plaintiff I am. I am the plaintiff in a case against the ADA, the Ohio Dental Association, Johnson & Johnson, Densbly & Densbly, the manufacturers of dispersalloy amalgam, which was what was used in my mouth.

I may have never figured it out, except that a very fine dentist in my town performed a root canal through an amalgam filling, meaning he drilled right through the center of it. He wasn't trying to hurt me. He believed that that was the appropriate standard of care, and that was what to do.

But that escalated my neurological problem so greatly that I ended up forgetting my infant son on a changing table and going off and doing something else. I wound up in the hospital within a week with heart problems. Somebody while I was there asked me if I had any dental work done. I had said yes, and they said, "I think you ought to look into that."

I don't know if they were talking about

mercury. They were probably talking about indill -- the bacterial disease. But what I found when I started looking was just astonishing.

I read a book written by a Christian M.D. who described his experience with chronic fatigue caused by mercury amalgam. He went on to talk about what the ADA had done and how he believed that they weren't telling the full truth and how some people were susceptible.

He also went on to describe the treatment and the symptoms that I was having right then regarding hypothyroidism and body temperature. It's like he described me right in this little book.

I still wasn't convinced though. I went to see if I could find corroborating evidence on the Internet and I did. It was all of my symptoms linked in another Website by another medical doctor.

I went to see that doctor and he was the first one who told me that I could not return to health without removing my mercury filling and then trying to get it out of my body.

What I'd like you to ask me about is how you are supposed to go about this. If you are told by a doctor that you do have mercury toxicity and you are especially susceptible or hypersensitive, where is the

guidance? Where is the corroboration? What is the patient to do?

You have a doctor, and then the rest of the establishment. My family was like, "What are you talking about?" you know, and then it proves to be the right thing, but it's a very difficult issue because there's just not any agreement out there between the alternative complementary and integrative medicine folks and then the mainstream doctors.

I think that the answer lies somewhere --

CO-CHAIRMAN KIEBURTZ: One minute.

MS. KERGER: One minute? Oh, you're not going to get to ask me questions.

With Dr. Clarkson, Dr. Clarkson I think you all know is an expert on mercury toxicity. Back in 1992, he asked what are the mechanisms of tolerance in defense against mercury. Under what circumstances do these defenses fail? What makes some individuals more resistant than others?

The answer to this is key to present and future risk assessment. There is much established literature about hypersensitivity, and I would be putting that in my written statement so that you can see it.

Thank you for your time.

CO-CHAIRMAN KIEBURTZ: Thank you for your testimony.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Ms. Flowers.

MS. FLOWERS: Yes. I'm Marie Flowers, and I'm from the Roanoke, Virginia area.

I received my first amalgam fillings when I was around 12 years old. Other than having three miscarriages when I was in late 20s because I had low progesterone, I was healthy. I did not know that mercury contributes to problems with hormones and infertility.

By the time I was 46 I had accumulated 11 mercury fillings, and Dr. J., whom I liked, was my dentist. It took 34 years to experience my first neurological symptom, and that was an occasional numbness in my face.

My symptoms did not occur in a mere five to seven years like what was in the children's amalgam trials and the ADA came out stating that the children had on neurological problems, but this was only after five to seven years.

It look me 34 years to develop neurological symptoms.

I told Dr. J. about my face numbness, but

he continued to take out and put in mercury fillings, all the time allowing me to breathe mercury vapor. But my dentist didn't do anything wrong. He didn't violate the standards of care in dentistry. It's normal for dentists to expose their patients to mercury vapor while drilling out fillings because most of them do not use any respiratory protection for the patients.

I saw a neurologist in early 2001, but he had no definite diagnosis for the numbness. In June I developed Bell's palsy, which is an inflammation in the seventh cranial nerve, which I understand is in the peripheral nervous system.

The neurologist put me on 12 days of prednisone. The consumer information sheet from the pharmacist warned me that before you have any kind of medical or dental treatments, tell the doctor or dentist that you're using this medicine because it makes you more susceptible to illnesses.

Unfortunately the sheet did not warn me to stay away from mercury poisoning dentists when I had a lowered immune system. I was taking this prednisone and was on vacation in July of 2001 when I my tooth with a large amalgam filling broke off. So I went to a local dentist, and he put a patch on that tooth and immediately I started tasting metal. That is a symptom

of oral galvanism when you start tasting metal, and it occurs when dentists put dissimilar metals together in contact with the mercury. It causes a battery-like effect which forces the mercury to leak out of the filling at a faster rate.

Now I was absorbing more mercury vapor than ever before because of the broken tooth and because of this patching material causing oral galvanism.

I didn't know the metallic taste was a symptom of mercury toxicity, and neither did Dr. J. when I questioned him about it one month later, but the symptom of metallic taste is right there on the material safety data sheet for the amalgam capsule, but probably my dentist never read the material safety data sheet.

I told Dr. J. I had been on prednisone a month earlier, but that made no difference either. So he went on drilling more than usual in order to fit the crown on the tooth. He left in some of the mercury filling and some of the patching material. Then he placed the temporary crown over top of all of this mess.

I went home to experience an increased metallic taste along with nausea and feeling like I was dying. Mercury started leaking out of this tooth and

ran down into my gums making a little blue line around the gum line of that tooth and the gum started swelling.

Five days after Dr. J. drilled into that tooth and put on the temporary crown I felt movement in my brain for the first time. Eight days after Dr. J. drilled I felt a little circle of heat in the top of my head and my scalp was tingling and was filling very sore. I had a slight headache.

On the ninth day after Dr. J. drilled I woke up that morning and my whole brain was on fire. My brain was vibrating inside my skull like it was trying to jump out. My head throbbed, and it felt like someone was beating on my skull. I had electrical charges shooting throughout my body from the top of my head to the tips of my toes.

MS doctors call this Lhermitte's phenomenon. I call it mercury hitting the brain.

I became allergic to foods. When I ate vinegar, a big lump would come out on the side of my head that would burn and ache, and I would cry in pain. I didn't know that the acid from the vinegar was causing more mercury to be released from my fillings.

I became chemically sensitive, had chronic fatigue, visual disturbances, tingling in my hands and

feet, dizzy, confused. Things appeared to me like I was in the Twilight Zone. I lay in the bed for hours with heating pads. I saw seven doctors in total, including my neurologist, trying to find a diagnosis.

My neurologist said that burning of the brain was not a symptom of MS and had no idea why my brain was on fire.

I became angry and paranoid. If my husband would dare to disagree with me, I'd pick up something and hit him. I got down on the floor at church and became hysterical.

What was worse was the confusion and the memory loss, not remembering where I parked my car, not being able to make a long distance phone call to call a doctor, wandering around my home in a daze. One Sunday morning I woke my husband up at 1:00 a.m. and screamed at him for an hour, begging him to help me find out what I should do next.

When mercury is in your brain, it's very hard to make medical decisions.

Finally I found a doctor belonging to the American College for the Advancement of Medicine. He tested me for heavy metals using a DMSA urine challenge test. Even though my levels did not show up very high, there is a reason for that. I'm a poor excreter of

mercury, and Dr. Boyd Haley will talk tomorrow about how some people cannot excrete mercury very well. He has this published in a peer reviewed literature.

CO-CHAIRMAN KIEBURTZ: One minute.

MS. FLOWERS: And a study from the U.K. states that for some people, sensitive individuals, it has not been possible to set a level for mercury in the blood or the urine below which mercury related symptoms will not occur. So there is no safe level of mercury for some people.

Dr. C., my doctor that I found, said that patient's history is consistent with heavy metal toxicity. He did not say that I was allergic to mercury. He did not say I was hypersensitive. He said heavy metal toxicity, and I think it's insulting to call a poisoning an allergy. Ragweed is an allergy. If I were poisoned by arsenic, you would not say that I was sensitive to arsenic. You would say I was poisoned.

Dr. C. gave me natural hormones for my memory loss and my confusion, and because it has disrupted my hormones, and he gave me a lot of pills. I took DMSA. I did better, but I can't get all of the mercury out of my --

CO-CHAIRMAN KIEBURTZ: Sorry to interrupt

you. Thanks, Mrs. Flowers.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you for your testimony.

Next will be Mr. Reeves. If you will just click on the microphone, please.

Thank you.

MR. REEVES: I'm Bob Reeves. I'm here on behalf of the International Academy of Oral Medicine and Toxicology. Myself and my client, Dr. David Barnes, and I'm hoping we can get this PowerPoint to work.

While we're doing that, let me just say that I'm here to speak on behalf of the dentist's dilemma. If a dentist believes that mercury is toxic or can cause problems, he is in a real dilemma. He's in a dilemma if he doesn't because the manufacturers -- and there is the first slide -- the manufacturers give very explicit warnings in regard to toxicity of mercury.

This is dispersal -- well, wait a minute. I think I've skipped a slide here -- dispersalloy is the most widely used amalgam. Dr. Mackert talked about it today, and it gives these warnings: erethism and the things that go with that, hallucinations, loss of

memory, et cetera.

Now, why is this important? Well, this is important because of the learned intermediator doctrine. A dentist is obligated to pass on the warnings of a manufacturer just as a doctor is, and I'm sure all of you neurologists know about this. If you have a drug you're giving a patient, you have to warn about the side effects of the drug.

These are the side effects that the manufacturers warn of. This is an old MSDS from dispersalloy, and I"m not sure why this was taken off. It was on their Website. It was on their literature. It warned about renal deficiency, allergies, children under six, expectant mothers.

That's no longer used by them, although I'd suggest to you it probably should be.

Mercury accumulates from amalgam fillings. This is the FDA's own response to me in 1993. I filed a petition with the FDA asking that warnings be given and a number of other things, including a ban on these fillings, and their response included this fact: that mercury can accumulate, that it causes higher blood in urine levels, that it causes hypersensitivity in people, that people may respond adversely to the additional exposure.

And they said, as you'll see there, the bottom two things I've highlighted, special controls and labeling. They recommended that, and they recommended, I think, Category 2, and this is back in 1997, over nine years ago. Nothing has happened since then, except the body of knowledge implicating this has increased.

This is a quote by the toxicologist at ATSDR talking about the issue, and the reason I put this in here, there is always this statement that there is no known disease that certainly is caused by mercury from fillings, and therefore, we're going to continue to use it and it's safe.

Well, what he's saying there is that there's a lot of reasons to be careful about it because there's a lot of issues. There are a lot of -- as he says, there's not a smoking gun, but here are bullets all over the floor, and that is true for this issue.

These are the summary of mercury symptoms from ATSDR, and the reason I think this is important is that mercury obviously causes a lot of things. A woman testified earlier about flu today, and we'll see here in a minute flu symptoms. Mercury interferes with the entire biological process of the body. It interferes with self-hydrils and can interfere anywhere and cause

any kind of symptom.

And there's a quote from Clarkson that I don't have on here, but Clarkson says that's one of the reasons it's hard to deal with mercury, because there is not a signature symptom, a signature toxicity like there is for most toxins. But these are all from ATSDR and other well known references about mercury and what it can cause. Decline of intellect is one of them. Bleeding gums, and I don't have it on here, but there is a lot of dental evidence that from the dental journals that mercury causes periodontal disease and periodontal disease is being implicated in all kinds of problems now. There seems to be connections between periodontal disease and various heart conditions, strokes, et cetera.

Let's see. There are the flu symptoms: chronic headaches. Now, if mercury can cause chronic headaches, it's not a disease like MS, but it is something that can be a problem.

So where is the dentist in this? If the dentist is going to provide his patient with informed consent and follow the learned intermediary doctrine set out specifically in a case involving mercury amalgam, Barnes v. Kerr, then he has to inform the patient of this. Yet the ADA has a gag rule that they

hardly admit to, but this is applied by State Dental Boards, and for instance, in North Carolina, in 2005, the North Carolina Dental Board published something for all dentists saying you can't make a reference that mercury fillings are harmful.

Well, if you're going to give those warnings at the start for dispersalloy, you are certainly indicating there's something that may be going on with mercury fillings.

Freiberg testified in front of the FDA in 1991 that mercury was an unsuitable dental filling material. He was brought over from Sweden for that purpose, and it's logical you can see why the Swedes have taken a different attitude about this material.

The National Academy Press published a document about anecdotal reports need to be pursued vigorously, and it also talked about the inadequate training of most physicians. That's not the same as physicians are inadequate, but most physicians are not trained a great deal in toxicology, and I think that includes most neurologists at least that I know.

CO-CHAIRMAN KIEBURTZ: It's one minute.

MR. REEVES: Robert Feldman made an association between mercury and MS years ago. This is literature about it.

With that I'll close, but I'll suggest to you that the FDA should at the very least establish warnings for this substance.

Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you, Mr. Reeves, for your testimony.

Our next speaker will be Ms. Madronero. Did I say that properly?

Thank you. Please.

MS. MADRONERO: Yes. Good afternoon. My name is Dorice Madronero, and I am here not with any financial interest, but with good heart and spirit.

I am grateful to the panel members and the FDA for this opportunity, but I must ask why is it that Sweden, Denmark and Germany have restricted the use of mercury in dental amalgam and the United States supports putting mercury into the mouths of millions.

Effective May 12th, 2006, New York State mandates that mercury separators be installed at dental facilities. The New York State Dental Association questioned the science reiterating if after an exhaustive examination of the data, the New York State Dental Association were to believe that amalgam separators were justified on a cost benefit basis, it

would support such a mandate.

According to Webster's Dictionary exhaustive means leaving nothing out, covering every possible detail.

Reading volumes of journals and historic documents, indeed, simple common sense, leaves this mother and countless others asking why, why mercury is still in dental amalgam.

In our market driven society, the theme of a cost-benefit analysis leans heavily on dollars. Tradeoffs and equivalencies must be reviewed to consider the interests of all, with alternatives explicitly explained to reflect the costs of not taking action.

Clearly, New York State recognized the adverse environmental impact dental waste poses to its residents' life blood, our water, air, and marine life. So the questions about mercury and dental amalgam are not only for the placement of mercury in teeth, but resulting effects to the water, air and food.

We are advised to limit fish consumption because of mercury content, especially for women who are pregnant. There was acute understanding that the intentional termination of a pregnancy elevates emotion and debate. Can a cost-benefit analysis of dental

amalgam adequately measure the value of a fetus exposed to mercury?

Your decision imposes on the deepest debate of what causes or constitutes life. In the 1993 final report on dental amalgam, it states, in quotes, and that's from your copy up there, "Based on experiences with lead exposure, it would be prudent to minimize human exposure to all heavy metals, including mercury with the efforts underway to reduce mercury use and disposal, the continued use of mercury and dental restorations will account for an increasing percentage of the total exposure to mercury to those with amalgam restorations.

However, its health significance may decline as reductions in other environmental mercury exposures results in a decline in overall mercury exposure. Are we to believe from this statement that the totality of an individual's mercury exposure should be evaluated for body burden? Is the effect of mercury in our air what are improved factored into thresholds regarding how many fillings a person should have or who according to their environmental living conditions is exposed?

What about the most vulnerable, our children, individuals with compromised immunity, the

unborn? Expecting mothers are full of hope for the possibilities that newborn brings into this world. After a spontaneous abortion, those possibilities are shattered and one is left with lingering questions.

I am one who has had two spontaneous abortions and still those questions linger, and I must ask you why. Looking into cause and effect often leads us on a quest that reveals how very connected we all are. The impact of what is believed to be unrelated may turn out to be the very cause, and my question led me to understand just how two healthy pregnancies may have been imperiled by well intended dental work.

At the core the questions are really about the system that evaluates the efficacy and safety of an intended practice or product. Have all perspectives been exhaustively studied for interrelated effects?

Following the second spontaneous abortion I had been to the dentist just prior to losing the fetus. Dental amalgam was drilled out and replaced with new. Old dental records revealed a related pattern.

In speaking with other women who had miscarriages several also endured a similar sequence of events. A great burden rests with each of you for each of you must reflect and question whether your decision ensures that the exposure of drilling out and placing

new amalgam into the mouth of a pregnant woman poses no harm to a fetus.

There are countless studies and articles that depict related health concerns resulting from mercury exposure. What is not clear is how such a toxic substance with a known ability to cross the placental barrier can still be used in fillings. It was shown in a Swedish study that inorganic mercury in cord blood increased significantly with increasing number of maternal dental amalgam fillings. Now, that is a study I=d say is worth looking into.

Periodic tables of chemical elements list spontaneous abortion as a side effect to mercury exposure. Is your scientific data that exhaustive to refute any connection of mercury and dental amalgam causing no harm to a fetus? Has there been a review of dental records and obstetrical records following spontaneous abortions to look for a connecting pattern? Is an expecting mother given the option to choose whether she is comfortable knowing that a neurotoxin is being placed in the form of an amalgam into her mouth or advise that the water she drinks and fish that she eats is being contaminated by dental waste?

How does the life cycle of mercury used in dental amalgam impact us?

CO-CHAIRMAN KIEBURTZ: One minute.

MS. MADRONERO: Not a day goes by that we don=t hear about mercury polluting coal burning industry which ironically provides electricity for dentist=s drills to place mercury into people=s teeth. Since the first use of mercury in dental fillings over 150 years ago, technology and science have advanced. New products and understanding of science are infinitely different. Still one story remains the same, and the voices of countless people go ignored or shunned. Their lives are not anecdotal. Mercury is a neurotoxin with known adverse health and environmental effects.

Release us from this time capsule shrouded in old science. Does mercury really belong in our teeth and in the cord blood of a fetus? I urge you. Do that exhaustive study and then tell us why we, our water, air, and unborn should be subjected to mercury from dental amalgam.

And I thank you for your consideration and time.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you for your testimony.

Dr. Painter.

DR. PAINTER: Yes. I have no financial connections with anyone here.

I=m a general internist. I've been in practice about 19 years. I was in practice for five years not understanding why in the great, wonderful country we live in where we know everything, why we didn't understand certain disease processes. It took a few years to look around, get some other information and to really come to the understanding that when those professors in medical school told me that they were really ten years behind, I really came to understand what they were talking about, that there was information available for helping a general internist understand how to practice and treat people with chronic illnesses that we really did not learn in medical school.

I would like to explain the handout. I have treated approximately 84 patients with amalgam removal, and 25 of those patients wrote letters, and I just want to remind you that I've saved you two hours and 15 minutes of public testimony. Okay. Laugh, you guys.

Okay. Well, maybe to lighten you up just a little bit more, I want to give you a little historical perspective. You know, dental amalgam was not first

used in the United States. Now, I=m not sure where it was first used, but I do know it was used in Germany before it was used in the United States.

The German word for quicksilver, for mercury or quicksilver is *quecksilber*, and from that came the word Aquack.@ Now, growing up in internal medicine in a residency, I heard that word bandied about a bit, but the original historical meaning of the word Aquack@ was a dentist who put mercury fillings in patients= mouths, and that actually started a couple hundred years ago, 150 years ago. This is really a discussion and an argument that has gone on for multiple decades. This is nothing new.

I really appreciate that these two committees are asking great questions, quite honestly. I sit there listening to some of this testimony and wonder where the science is.

Being trained on the New England Journal of Medicine, I would expect to see studies, longitudinal studies, short term studies done just as we have done with aspirin, which was a drug that was grandfathered in. I have not seen any of those studies that truly show there is no toxicity to the use of mercury.

In terms of my private practice, I was trained at Creighton University, and what was very

important at that institution was that we do good physical exam. They didn't tell me what tattooing was. As I look at patients and see tattooing around a tooth, tattooing where the mercury has literally gone into the soft tissue of the gum, that was something I had to learn in my practice of medicine.

Very often teeth that have mercury restorations will be gray, and I just encourage you. I=m not sure if neurologists examine people=s mouths as much as internists do, but I just encourage you to look at teeth. You'll see very discolored teeth. That is very physical evidence that mercury doesn't stay encapsulated once it is put into a person=s mouth.

In that packet I've given you, in addition to 25 letters, 26 letters, one man was so impressed with his improvement he wrote a letter two years ago, and we wrote a follow-up for you for this meeting. The other thing that is there is I prepared a list of symptoms that have improved with the removal of amalgams. This certainly is not an inclusive list, and in fact, as I listened to some of the testimony today, I realize that there were many other symptoms I could have put on this list.

This list I put together by reviewing the letters that the patients wrote, as well as remembering

some of the more dramatic cases that I treated in my own practice. I would like to say that on this four-page list of approximately 108 dysfunctions, disorders or diseases, 33 percent of those are neurological.

I would also say that every symptom, disease or disorder or dysfunction on the list improved in one of the 84 patients that I treated.

I would also say that not all patients get better. Approximately three and a half percent of my 84 patients did not notice an immediate change or improvement in the disease I thought they might be mercury toxic with.

CO-CHAIRMAN KIEBURTZ: One minute.

DR. PAINTER: And some patients die. They are so sick by the time they get to me that they die.

In closing, I would like to say that Philip Semmelweis was a very respectable physician who discovered many years before his time that hand washing would save women from dying of puerperal fever, and hand washing took many decades to come into practice in Austria. So historically just became amalgam has been used for 150 years, that certainly does not have anything to do with safety.

I would like to say that the Lord has established your authority. In addition to your being

chosen however you were chosen to serve on B

CO-CHAIRMAN KIEBURTZ: Thanks very much for your testimony.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Dr. King.

DR. KING: Can you restart this for me, please?

Thank you.

My name is William Raymond King, III, DMD. I=m a 30 year American Dental Association member. I have no financial conflicts with any amalgam products. I myself paid for my wife and I to fly here yesterday and to stay here and return.

First, I want to thank my God in heaven above for saving my life so that I could come here and testify today. You see, I=m really not supposed to be here. I should have died a year ago and almost did.

One year and one month ago my aortic aneurism blew out in my doctor=s face as he started an operation to replace the leaky, defective aortic valve. Most people never make it. I have to praise God that I did.

Now I find out that there was a paper that was published in >76, 1976, the year I graduated from dental school, that showed a connection between chronic

low level inhalation of mercury vapor and dissecting aneurism of the aorta due to enzymatic damage. How nice. I just spent the last 30 years of my life killing myself to do my job, removing and replacing old, worn out, leaky mercury fillings.

Call me the loyal opposition. Neither the FDA nor the ADA warned me that I should have been wearing this NIOSH approved mask that they just took away from me so that I could show you what NIOSH requires miners, mercury miners to wear when they=re digging cinnabar ore out of the ground. Thank you all for taking that away from me.

Anyway, they do have a NIOSH approved respirator.

Do you not realize that all dentists who do remove mercury fillings are really mercury miners also? They use air driven jackhammers to get cinnabar ore out of the ground. We use air driven hand pieces and drills to get worn out mercury fillings out of people=s heads. We create extremely toxic aerosols in the process, and then we, the staff, and the patient breathe it all in as if we are invincible. Not so.

Today any dentist who is not protecting himself or herself at work with the mask that I=m not allowed to show you is either as ignorant of the

dangers and as trusting of the authorities as I was for so many years or perhaps they are already insane, which is another side effect of mercury poisoning, and perhaps with a death wish.

Fifteen years ago on March the 15th, 1991, I addressed this same FDA Products Advisory Panel. I presented my data proving that many of my patients were being exposed and thus poisoned by extremely high levels of mercury vapor from their mercury fillings, and that college kids who had never had a mercury filling had no mercury vapor in their mouths.

Here is my data again. I will pass it out. I hope they give it to you. Maybe someone is listening this time. I sure hope so.

There is a chart I have over here that shows scientifically the organs and systems that are harmed by mercury from dental amalgams, silver mercury fillings, and just so you will know so that you can never say again, AWell, we haven=t seen any science,@ the bibliography of all of that is on the back. Enjoy it. Study it well. You'll be amazed.

Contrary to Dr. Mackert=s disparaging remarks, the drum instruments are calibrated and they are accurate. They only measure mercury. They=re not fooled by garlic. They are so accurate they=re on the

space shuttle and nuclear submarines, and they sample for ten seconds, not the 20 he incorrectly so stated, and they also are the most accurate portable devices for measuring mercury vapor on earth.

But what is safe? Okay. What is safe? To know safety, you have to know two things. You have to know how much is coming off of the fillings, and you have to know how much is too much.

The packaging for a filling -- this is an old one here. It=s called Tytin -- has on it a warning that says Acontains metallic mercury, poison,@ skull and crossbones.

It also says ingestion may cause neurotoxic, nephrotoxic effects. Keep out of the reach of children. I reckon would that include having them lick it with their tongue? There are plenty of materials, and I have used them for years in pediatric patients, for replacing amalgams. So, no, there is no reason to have to use an amalgam on a child and nor should you, and I sure hope you inform the parents first.

I have also here two photographs of mercury vapor readings. One is over fresh dental amalgam, and it reads -- we don=t really know because it was equal to or greater than 2,000 micrograms per cubic meter of

air, 2,000 micrograms. This is a fresh mixed batch of mercury that we, all dentists, put in people=s mouths, but we don=t have machines which they took the other machine away from me, the mercury vapor analyzer. I could mix this for you and show you.

CO-CHAIRMAN KIEBURTZ: One minute.

DR. KING: The other one is air over old latex paint. One of my assistants painted her house. I gave her a latex paint, old place, and so she did. She came in with headaches, and so I said, AWell, bring in the paint can. I'll check it.@ We sniffed it. Sure enough, 920 micrograms of mercury in the air over old latex paint, which is why the EPA took phenylmercuric acetate out of latex paint about 15 years ago.

If the EPA can take mercury and cause it not to be used in latex paint for this reason, then why in the world shouldn't the Food and Drug Administration ban mercury fillings for having 2,000 times more concentration than the 300 parts C that was in the latex paint and twice the mercury vapor concentration?

It pegged the meter. We do not know. Maybe it was 10,000, but it was at least 2,000.

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

(Applause.)

CO-CHAIRMAN KIEBURTZ: The next speaker is Mr. Wehrle. Thank you.

MR. WEHRLE: Ladies and gentlemen, afternoon. My name is Johann Wehrle, and I sometimes work as a law clerk for Consumers for Dental Choice.

I=m not here as a regulator, a manufacturer, an environmentalist concerned with mercury pollution, or a victim of mercury poisoning. Instead I am here to understand how dangerous medical devices continue to find their way into the lives, homes, and bodies of people I love. This continues to happen despite hearings like these, where science based policy is supposed to find its basis.

Somewhere between the submittal of the 510(k) or an alarming number of consumer complaints or the recognition that a substance might not be generally recognized as safe or petitions from concerned consumer advocacy groups and the eventual FDA response or lack thereof, the process often corrupts. Pedicle screws, Accutane, silicone implants, Plan B, Vioxx, and, yes, encapsulated mercury in amalgam alloy come to mind.

The amalgam debate is over 100 years old, a sure testament to the unease people feel about the device. I won=t rehash the arguments or talk about how

bad mercury is. We are all familiar with them, and we know mercury kills.

No, my being here is just to make sure everyone is on the same page about one thing. Filling cavities with silver fillings is the only instance where a mercury containing device is intentionally implanted into the human body, and this is regardless of whether a particular human body is small, swollen with child, or more sensitive to mercury than luckier bodies.

Because amalgam is an implant by law, the federal Food, Drug and Cosmetic Act places the burden on this panel or at least half of this panel to explain to the Commissioner why amalgam shouldn't be subject to pre-market approval. This was never done, not in 1994 when the Dental Products Panel recommended that amalgam be accompanied with tepid safety controls and not since.

Instead, to insure that amalgam is safe and effective for its intended use as a filling material, FDA in its proposed rule to classify amalgam recommends that amalgam labeling material list ingredients and that there be labeling instructions against the use of amalgam in hypersensitive populations.

The problem is patients will never get to

see the ingredient list, and the very populations that even the manufacturers warn against using amalgam, pregnant women, children and folks with renal failure, the FDA does not include.

FDA has done some real good. They have. Food processing is a far cry from the Chicago slaughterhouse practices that gave rise to the pure food laws. FDA tests devices for both safety and efficacy. Other countries don=t do that. FDA even tried to regulate cigarettes as nicotine delivery medical devices in the >90s. The problem is with silver fillings FDA has no gold standard.

Austria, New Zealand, Germany, Canada, Norway, Finland, Australia, Denmark, Sweden, and the United Kingdom have recommended some form of real restriction on the placement of amalgam, and I can only speak English. So this list is probably short.

These restrictions range from contraindications to informed consent regimes, to eventual phase-outs. Manufacturers recommend against placement in pregnant women, among others. You would think that FDA would pay heed.

FDA considers a variety of factors when determining whether informed consent is warranted, including whether there are viable alternatives or

whether there is, and I quote, substantial public or professional controversy. I mean, placing amalgam as been controversial ever since the first ADA dentists were called quacks for using mercury in dental care. And other countries are at least discussing phase-outs for environmental reasons, as we saw this morning, and because there are good alternative filling options.

So why are we still allowing the wholesale placement of mercury amalgam in everyone without meeting core restrictions and until today, without meaningful debate?

One more thing. I=d like to point out a problem with Ms. Rosecrans= explanation of 510(k) approvals for encapsulated mercury in amalgam alloy that she gave this morning. You see, she told us that this morning that new amalgam products are substantially equivalent to amalgam alloy powder, which is classified in the 1980s.

However, amalgam alloy is not defined in Section 872.3050 was containing mercury, yet new amalgam devices do contain mercury. So how is it that new amalgam devices like silver fill, which is 26 percent mercury and was just approved by FDA in late 2005, how are devices like those substantially equivalent to non-mercury containing devices, amalgam

alloy?

Vetted against Section 360(i) of the Federal Food, Drug, and Cosmetic Act, how can a device like silver fill be considered to have, and I quote, Athe same technological characteristics as a non-mercury containing alloy@?

Indeed, reading Subsection 1(a), how can mercury amalgam, and I quote again, Anot raise different questions of safety and effectiveness than non-mercury containing alloy@? The substantial equivalence determinations are a complete sham at worst, and incompetence at best.

Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you, Mr. Wehrle.

Ms. Gallagher.

MS. GALLAGHER: Hi. I=m Kelly Gallagher.

CO-CHAIRMAN KIEBURTZ: Please turn on the microphone for us. Thank you.

MS. GALLAGHER: Hi. I=m Kelly Gallagher, and thank you for having this hearing.

I=m a five time cancer survivor, and a documented film maker, and I have been around the world on this issue for the last five years. My

interest is in the truth.

I have been sponsored for this segment of my journey by the International Academy of Oral Medicine and Toxicology. I can assure you I would have gotten here come hell or high drama anyway.

I have been the recipient of many life saving medical devices, 13 catheters, four Hickman phoresis, 67 blood transfusions, 14 months of chemo, a stem cell transplant, and most recently four pacemaker operations last September. So I do thank the FDA for your work and especially Patty Delaney from the Cancer Liaison Division.

However, I have also had 17 mercury fillings, and I can=t help but wonder if my mercury fillings, also apparently known as dental devices, could have had something to do with my diagnosis of Hodgkin=s at 20. Mercury inhibits the immune system.

I wish I could play a bunch of video, but I have a little bit. I would like to get this on the record. We have five segments.

(Whereupon, a video was played.)

MR. BURTON: Now, does the FDA take a position on the amount of mercury that accumulates in the brain and whether or not it is easily excreted from the brain?

DR. FIEGAL: The toxicology of chronic implants, like alloy, are looked at through a series of series -- series of standards that evaluate biomaterials, and most of the evidence that we evaluate biomaterials with come from animal data and come from special exposure studies in animals.

DR. LACEY: What are not valid scientific evidence on this question? They=re interesting, but animal studies don=t count.

DR. LORSHEIDER: I have two comments with regard to the address by Dr. Lacey. I was intrigued by your slide that stated that animal studies don=t count. A former dean of our medical school when he introduced the new entering class each year of our medical school, he would remind them that our medical school had admitted 72 of them, but that our medical school had admitted 35,000 animals that same year.

The point that he was trying to make to our students is that well over 95 percent of all of our knowledge base that we have in medicine, I can=t speak for dentistry, but in medicine comes almost exclusively from animal research.

And the second point that I would like to make with regard to Dr. Lacey=s address, I can=t comment on most of the papers that he raised, but the

one by Drash I would just like to read from the paper here to correct a misstatement on one of his slides. Drash says, AIn no case was an occupational exposure to mercury of the parents or an extreme fish consumption of the mother or the child reported.@ So in fact, they did got to some lengths to survey those patients.

I cannot speak for the other slides, but I=m astounded by the statement that animal research does not count. That=s one thing I felt I had to defend because that=s the fundamental B

(Applause.)

DR. LACEY: I don=t want to repeat myself, and I won=t. If you review the tapes and whatever, I think it is very clear I did not say animal research did not count for anything. I made it very clear what it counts for. It does not count for establishing cause and effect relationships between dental amalgam in humans. Human research doesn't count for animals. Animal research counts for animals in terms of establishing cause and effect. It is critically important, it is terribly valuable, we couldn't live without animal research. It gives us our starting point. It gives us information that may be useful when we don=t have or can=t have human studies.

But when we=re looking for facts and evidence related to humans, I want human studies.

DR. LORSHEIDER: If I could make just one slight rejoinder here, we=re not really in an argument, I hope.

CO-CHAIRMAN KIEBURTZ: No, that=s okay. We=re well within three minutes.

DR. LORSHEIDER: If you in dentistry were to introduce, and I realize this is hypothetical, but if you were to introduce amalgam as a new tooth restorative material in this day and age, forget about Phase 1, 2, and 3 clinical trials. You would never get it past the first stage of animal testing.

(Applause.)

DR. LORSHEIDER: So I think animal studies would be important then.

DR. LACEY: But are not valid scientific evidence on this question. They=re interesting, but animal studies don=t count. Testimonials of recovery from illness don=t count. Anecdotes, untested speculations or beliefs do not meet the aforementioned test of validity, don=t count.

CO-CHAIRMAN KIEBURTZ: Ms. Gallagher.

DR. LACEY: Religious beliefs don=t count when it comes to B

MS. GALLAGHER: I would just like to say, and this is very respectfully, I have been all over the place, and everybody keeps contradicting one another, and you know, I=m looking for a hero for the end of our film. We want to focus on solutions. There has been a lot of people that think they=re sick. There=s been a lot of data on it. There=s been a lot of scientists who have done research studies. I am buried by them. So I don=t know why the American Dental Association keeps getting up here and saying that there is no studies.

They=re a trade organization formed to protect their trade, and they=re doing their job. They=re protecting their trade, but they=re not protecting the health of the American people, and I think that many people think they are a health organization.

So we are looking for a hero, a government agency that is a hero. We hope that it is the FDA, and thank you very much for your time.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thank you for your presentation.

Dr. Grant. Oh, sorry. Very good.

DR. FLETCHER: I=m substituting. My name

is Dr. Nathan Fletcher. I am Vice President of the National Dental Association, and I am here representing that organization.

Dental amalgam has been used as a restorative material in dentistry for over 150 years. The Food and Drug Administration stated that there is more significant human experience with dental amalgam than any other restorative material.

The National Dental Association supports the findings of the FDA, the National Institutions of Dental and Craniofacial Research, the National Institutions of Health Technology Assessment Conference, the U.S. Public Health Service, and the World Health Organization that dental amalgam is a safe and effective restorative material.

The National Dental Association supports the efforts of the National Institutes of Health, Center for Disease Control, and the Food and Drug Administration to continue to study the safety of dental amalgam and to develop new alternative materials that will prove to be as safe and effective as dental amalgam.

That concludes my representation of the NDA. I stand before you now as a 20 year practitioner of the field of dentistry.

I graduated from my undergraduate institution, Morgan State University, cum laude with a Bachelor's degree in chemistry. I graduated tenth in my dental class and scientific research I did for five years with Ford Motor Company before I went into the field of dentistry.

I say all of that to give you my background as an individual standing before you with a scientific background.

I personally am for informed consent, but with my scientific background I have to be able to blend science with practicality when it comes to treating my patients. Certainly after giving the informed consent and as the representative stated, in urban centers, one, I happen to practice in, many of the young children that we deal with deal with Medicaid and medical assistance.

And when it comes to cost effectiveness, providing the informed consent to a parent with a hurting two or three or four year old child who can't sleep at night, who can't eat, can't study at school, when I ask them what is their choice after informed consent, inevitably the question is, which one does Medicaid cover?

That goes into another debate that this

panel should not have to deal with, but I would say that your decision upon whether and how you deal with dental amalgam certainly affects that debate in the broader world, certainly in the world that I practice in.

When it comes to technique sensitivity, you have had testimony that after 25 or 35 years that placing some other material makes you a better dentist. That's very far from the truth. When you have a young child who won't keep their head still and you can't isolate the tooth and they're screaming, I can tell you that it doesn't make you a good dentist just to be able to put a filling in there. It makes you a good patient manager if you're successful. Let me emphasize if you are successful because if you are not successful in placing it, you have caused more harm, certainly more harm than would be done if you placed a dental amalgam in that same situation.

The representative made the comment that dentists when asked are there other materials, certainly in my opinion every dentist should say that there are other materials, but the real question that should be asked is, are they going to be as effective?

In the scenario that I just presented to you with that young screaming child, I can tell you

from my own experience it will not be as effective.

I can also tell you that you've heard some testimony from an individual who said that you have to remove 75 percent of the tooth to place an amalgam. I'm a practicing dentist. I can tell you that any tooth that has 75 percent of it that you would need to remove, you wouldn't be removing it. You'd be removing the tooth.

So I don't want you to be misled by the things that are presented to you. No amalgam has ever caused the pain that we're talking about in a child's tooth. No amalgam has ever had the situation that it in itself caused an individual to need a root canal. It in itself has never caused an individual to need a crown. So I do not want you to be misled. I need you to understand from a practical sense, from an individual who practices dentistry, to provide for you pertinent information from personal experience.

When we have an incident, one in whatever the factor is, we understand that for that one individual who has had a negative response or a negative situation, in this particular case since we're talking about dental amalgam, we know that for that one individual it's 100 percent.

But if we take the statistics of one in

100,000, we have 99,999 who have received some benefit from it. Certainly I sympathize with those individuals who have had these types of negative situations, negative responses, but I also have to sympathizes with that young child who can't sleep, can't eat, can't study, and the best technique to use on that child is a dental amalgam. When it comes down to benefit versus harm, what are my choices?

CO-CHAIRMAN KIEBURTZ: One minute.

DR. FLETCHER: Do I leave? Do I attempt to place some other alternate material or do I place that amalgam to try to help that child based on their circumstances?

In closing, please keep those thoughts in mind. Those are the questions that you haven't heard. You should not be removing amalgam from the armamentarium of the actual practicing dentist.

Thank you.

CO-CHAIRMAN KIEBURTZ: Thank you, Dr. Fletcher.

Mr. Zimmerman.

MR. ZIMMERMAN: Hi. My name is Clinton Zimmerman, and I have no financial interests. However, I have a potential conflict of interest. My dad works for the Food and Drug Administration as a

senior regulatory chemist.

Mr. Chairman, I cannot help but note that you state on the FDA Website that this committee will be studying dental materials which include dental alloys. I hope this is an error because this committee and the dentists who compose the majority of the committee, metallurgists and engineers on it surely know by now that amalgam is no alloy, but an unstable mixture with a vapor pressure.

Contrary to the statements by the ADA spokesperson, amalgam is the number one undisputed source of elemental and, in fact, methyl mercury in all humans. The fact that the amalgam is the number one source of elemental mercury has been published in the New England Journal of Medicine.

Can you hear me if I -- okay.

As I said, my name is Clinton Zimmerman, and I was poisoned by amalgam. I live in Gaithersburg, Maryland, and I have lived here since 1975, as well as California. During the '80s and '90s I was poisoned badly by a filling installed by a dental practice formerly located just down the street. That practice ended badly with the partner who placed my filling being locked out of the office by the business owner or the controlling dental partner. The

whole affair is currently in litigation in Maryland circuit court.

You might also like to know that another lady in Germantown was poisoned by an amalgam that I know of. I learned of her when signing up for a sauna to detoxify. Unfortunately her amalgam poisoning was so severe she got worse after the sauna treatments and had to quit I hear.

I have sat back and watched the drama unfold in the amalgam issue for a while now and been flabbergasted and deeply disturbed by what I've seen, perhaps because of my scientific training. I hold an electric engineering degree, a minor in physics, and was working on my Ph.D. in physics when I was poisoned. I am also an engineer by profession, and the proximity of Consumers for Dental Choice, I am in a unique position to understand the anti-amalgam side of the issue.

Certainly, the ADA in testimony before this committee has provided no proof of safety. Yet this has not stopped them from espousing the safety of amalgam. Do they care to actually cite any studies while making grand pronouncements of safety?

Most troubling though is the mischaracterization of studies designed to detect

average exposure, which by the implications made by the ADA supposedly include determination of toxic effects for those most exposed, that is, the population most at risk from amalgam.

This kind of testimony can rightfully be construed as designed to mislead the public and the press who hold simplified notions of the complex variations in construction and variations in properties which amalgam can take and depict all amalgams as identical in formulation and Hg release.

All amalgams are not the same, and all exposure levels are not identical. Indeed, the World Health Organization has stated that no study exists with the statistical power to determine Hg exposure and effect in the top ten percent of amalgam wearers most exposed to Hg from dental amalgam, this from their expert scientist Max Berlin, and manufacturers themselves warn or have warned of the wide variety in placement and oral conditions which can lead to variability in the physical and chemical properties of amalgam.

No study done or any study cited by the ADA are capable of measuring chronic Hg burden in the one percent most exposed. They barely have any studies done with over 500 participants, and all of

their measurements use faulty urine or blood testing methods as I will explain below.

The citations of five micrograms per day by the ADA spokespeople are just ludicrous. Studies such as the Tubigon study, the largest amalgam trial ever conducted, and authorities such as the NIOM, a Scandinavian dental regulatory organization, clearly document, measured in theoretical exposure of elemental Hg for amalgam not a couple of times normal, not a dozen times normal, not 100 times normal but several hundred times normal.

For example, in an almost unknown letter from the Scandinavian Institute of Dental Materials, NIOM, the intake of metals from copper amalgam was estimated. It is concluded the intake of elemental mercury in a worst case scenario can be 350 times that from food. This is due to variations in amalgam construction and oral conditions, as well as the introduction of copper in the newer amalgams and as well documented in numerous scientific studies.

The Tubigan study also mentioned rare individuals with daily uptake exceeding 750 micrograms per day. This was verified by repeat analysis in those cases, and overall the result of the Tubigan study were in line with previous scientific

publications.

The reality is that an upper limit cannot be set to exposure. This is due to the grade variation in the final reaction of amalgam product whose chemical stability is determined by many factors, such as quality of conversation, percent of mercury added by the dentist to the mix, as well as the great variability encountered in oral conditions, which can include substantial corrosion due to factors such as galvanism, crevice corrosion, variability in saliva pH, individual immune reaction with amalgam and so on.

Phase-in stability and spontaneous mercury droplet formation on the surface of the newer copper non-gamma IIs, the new stuff which I got in the '80s, is also a disturbing phenomenon found in some amalgams, which is a very real phenomenon. See, for example, "Pleva, J - Mercury, a Public Health Hazard," Reviews in Environmental Health, 1994.

CO-CHAIRMAN KIEBURTZ: One minute.

MR. ZIMMERMAN: But boosting these underlying toxic potentials of amalgam is another even more important and sinister factor. Methylation of Hg amalgam by surface bacteria on the amalgam such as S mutans. In fact, some amalgam victims have reported

amalgam surfaces with bacterial interaction to be liquified. The ADA is blatantly lying when it says that mercury for amalgam cannot be converted to methyl Hg.

While the basic phenomenon of methylation is real and has been documented in more than one scientific paper, see, for example, AMethyl mercury in dental amalgams in the human mouth@ Journal of Nutritional Environmental Medicine, 1996, and is even warned against in manufacture data sheets discretely as surface electrical-chemical reactions. This key phenomenon is purposely ignored and for all intents and purposes not studied by established dental authorities.

And this is the key to what I believe my toxicity is and what you must address as a committee. So let me just leave it there.

CO-CHAIRMAN KIEBURTZ: Thank you very much.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Dr. London.

DR. LONDON: Yes, thank you for permitting me this opportunity to address this joint committee as you discuss peer-reviewed scientific literature on encapsulated amalgam consisting of dental mercury and

amalgam alloys, and review the scientific literature o n its potential mercury toxicity, specifically as it relates to neurotoxic effects.

My name is Steve London. I'm the Associate Dean for Research in basic sciences at the College of Dental Medicine in the Medical University of South Carolina in Charleston, and I'm here today representing the American Dental Education Association and also the American Association for Dental Research, and I happen to be the 2006-2007 Sunstar Butler ADEA, which is American Dental Education Association, Harry W. Bruce, Jr. Legislative Fellow, and that is a paid fellowship, and I'm here in that regard.

First I'd like to tell you that the mission of the American Dental Education Association is to lead individuals and institutions of the dental education community to address contemporary issues influencing education research and the delivery of oral health care for the improvement of the health of the public. So we represent all of the dental schools of the United States, as well as specialty training programs and hygiene programs as well.

And the mission of the American Association for Dental Research is to increase knowledge for the improvement of oral health to

support and represent the oral health research community and to facilitate the communication and application of these research findings.

So dental amalgam has long been an important and essential restorative option that academic dental institutions have incorporated into their educational and service missions. New practitioners need to know how to safely place dental amalgam restorations since for some patients they are the most appropriate and cost-effective treatment option available to them.

If this Joint Committee were to reverse its longstanding support for dental amalgam, it would adversely impact the ability of our member dental schools' institutions to train practitioners in the use of this restorative material and, most importantly, to provide safe, cost effective treatment for our patients, which you've heard in various testimonies from various dental practitioners in the community. They've testified that dental amalgam restorations are really an important part of the overall ability to restore dental decay.

So any decision about the use of a amalgam as a restorative material should be based on sound science and empirical evidence-based research, and

we're pleased that the National Institute of Dental and Craniofacial Research has supported two clinical studies that were recently reported in April 2006 in the Journal of the American Medical Association involving a study of amalgam placement in children, and both studies independently reached the same conclusion. Children whose cavities were filled with dental amalgam had no adverse health effect. The findings included no detectable loss of intelligence, memory, coordination, concentration, nerve conduction or kidney function during the five to seven years the children were followed in that study.

And I know you have those studies for your consideration.

As dental researchers and dental educators we will continue to investigate dental amalgam and other restorative materials. As improvements are made, the use of dental amalgam will likely continue to lessen over time, but we still believe that it has a valuable place in the treatment of patients at this time.

Your white paper which is based on the best available science corroborates the AADR, that is, a dental research association's official policy position on dental amalgam which was first written in

1996 and revised in 2004, and I think I have the time. I'm going to read what's two paragraphs, what the American Association of Dental Research says about dental amalgam.

"Dental amalgam has a well documented history of safety and efficiency, efficacy in dentistry. Its advantages include ease of handling, durability, and relative low cost. Dental amalgam has numerous indications for use, especially for restorations in stress bearing areas. That's important in the posterior teeth. Its main disadvantage are poor aesthetics and the necessity for removal of sound tooth structures in order to provide retention for the amalgam filling. Its use in restorative procedures is still indicated.

And scientific evidence indicates that currently used restorative materials, including dental amalgam caused no or very few significant side effects. Extremely small amounts of mercury may escape from an amalgam restoration during normal use, but this minute mercury exposure does not cause verifiable adverse effects on the general health of patients or the dental health personnel.

Local allergic or other inflammatory actions are rare side effects of dental amalgam. The

AADR endorses the use of -- this is important -- best management practices for the use of amalgam restorations in dental offices.@

And just on a personal note, it has been 25 years since I graduated dental school, and we handle amalgam much more safely than we did 25 years ago. The amalgam in mercury is provided in a capsule that's safer to handle. It reduces the risk of amalgam exposure, and less and less amalgam fillings, as we've heard this morning, are being placed.

So that concludes my testimony. If there are any questions I'd be pleased to answer them, and it's still green. So I did good.

CO-CHAIRMAN KIEBURTZ: Thank you for your testimony. I don't see any questions. Thank you.

Ms. Taylor.

MS. TAYLOR: Good afternoon. Thank you very much for holding these hearings.

I'm Sue Ann Taylor. I am with the Consumer Choice in Dental Care Project. I paid for my own air fare to get here.

I'm here because I was one of the founders of the Consumer Choice in Dental Care Project. I'm going to try to tell you the story. It doesn't come easily.

My own situation could be ditto, ditto, ditto to about 25 people who have spoken already. I'm not going to put you through that, but quite honestly, even though I was a medical journalist, an independent medical journalist, often on the other side of the FDA supporting alternative medicine and things like that, but the FDA has come a long way in embracing through the NIH Office for alternative medicine and things like that, a greater understanding of complementary care has come about.

That was my background. I had all of the information, and I still ignored it even when the symptoms hit me. It was a dentist that discovered all of my problems, got me immediately to a dentist in Knoxville, Tennessee. He took out all of my amalgams the same day. I don't recommend that.

However, three days after I had all of those amalgams removed, I was removed of all of my symptoms. I went from sleeping 20 hours a day to, you know, working a full and then some day.

I was going to a follow-up visit with the dentist right around Christmas time, and I said, "Can you please see my son when he comes home?" I'm sorry. "See my son when he comes home. He has a funny thing that happens with his tooth."

My son was one of three children. He is one of the Superkids. He was the kid in the play, the mentally gifted child, and he was a fabulous big brother. He had an accident teaching his sister how to run the scooter -- I'm so sorry. This is a true story. He had an accident, shattered his front teeth. I rushed him to the dentist like all good mothers do, got him to an endodontist, and he came out and he said the great news is I can save the teeth.

Well, as a mother I was just thrilled with that news. He's 13 years old. We got him patched up, got him off to school, and he goes into the ninth grade. Understand this kid has never had a B, always been in the absolute top of everything, and he failed the ninth grade. I was like what happened. Well, he's 13 so you have -- we went through every doctor and psychiatrist, psychologist. I went from, you know, waiting for the next basketball game to waiting for the principal to call every day. He became so violent. He became unpredictable. He was the best big brother in the world and all of a sudden in a single bash he would send one of his sisters across the room.

We're a Quaker family. So the big threat was if you don't straighten out, you're going to

military academy because they said he needs structure. Okay. We'll get him structure. He goes to military academy. Repeats the ninth grade. This is the hardest thing in the world for this kid and obviously his mother.

He does the ninth grade again. He does marginally better. Halfway through the sophomore year, I moved to Georgia. I had my amalgam issue. Take him to the dentist. He said, "I need to X-ray those teeth. Everything you're talking about with his behavior, rapid change in his behavior, would be indicated if he had nickel posts that those teeth were rebuilt around."

Well, sure enough, there were nickel posts in there, and I had to make the very hard mother decision to remove those teeth that day. Removed the teeth. He was violently ill for three days. At the end of those three days, he was his old self again. So he goes back to school, and I get a call from the school psychiatrist, which was not unusual. She and I had a good rapport by this time, and she said, "I need to know what drugs you put Michael on."

And I said -- oh, I'm sorry, sorry -- and I said, "No drugs. We just removed the offending material in the teeth, and actually the teeth went

with them."

She refused to believe me. Michael immediately went on the Dean's list, no behavioral problems whatsoever. At the end of the year, he goes to the Headmaster and says, "This is what happened to me. I'd like to skip the next year and graduate with my regular class," and he did with honors.

The reason that the tears is that in that period of time there were three suicide attempts, and it was just a miracle that I had inadvertently discovered this because he was on suicide watches. He was on every kind of -- they wanted to put him on every drug in the world, and I just had done so much research I wouldn't let the drugs happen, but that's what happened.

And in closing what I would like to say is just examine all of the materials. And if there was research money that would go out for anything, I would say what we need to do is back it up one more step and maybe look at testing to look at what is biocompatible for anybody.

You know, there's no short answers in any of this. You'll get 100 dentists that will say mercury is no problem and 100 that will say that it's a big problem. It's a very toxic material, but what's

wrong with material has a lot to do with what's going on with the patient, and we don't have any of those answers, and it's really under-examined.

I thank you so much for holding these hearings.

CO-CHAIRMAN KIEBURTZ: Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Ms. Tibau.

MS. TIBAU: Good afternoon. My name is Anita Tibau, and I'm here with Ugottawanna Productions, and I'm also working for IALMT, and I first would like to thank you for having this hearing and allowing the public to give some very important information that perhaps you at the FDA were not aware of.

I'm going to be presenting a short clip of footage that we had taken over the years.

Thank you.

(Whereupon, a video was played.)

DR. FEIGAL: Most of the evidence that we evaluate biomaterials with come from animal data and come from special exposure studies in animals, and manufacturers are required to know the toxicology profile of their products as part of the controls that they have over their products.

The risk is not assessed in terms of any absolute amount or characteristic of the toxicology, but in the context of the risk and benefits in clinical use.

MR. BURTON: You were here for the previous panel.

DR. FEIGAL: Yes.

MR. BURTON: And you heard some of the researchers and scientists that testified that said that when you chew, when you brush your teeth, when you have hot coffee or a hot substance in your mouth, vapors are emitted and when you chew some of it flakes off over a period of time and goes into your body.

Has there ever been a study done on cadavers, people that have had a lot of fillings in their mouth to see what the mercury content is in the brain that you know of?

DR. FEIGAL: The studies that they cited are the same studies that we reviewed in our process of looking at the literature, and how that relates to our classification is to look at the product in actual use and to look at the risk and benefit.

All implants, including hip implants, jaw implants that are made of metal have metals that leach into the body. Plastic materials have volatiles, and

we assess all of those exposures. It's not a question whether or not there's an exposure. The question is whether there's adequate evidence that the exposure causes clinical tests.

MR. BURTON: Well, these other substances that you're talking about though, steel, plastic, they're not in the same class as mercury, are they?

DR. FEIGAL: There are problematic compounds that are in very low amounts. For example, there's cadmium in the alloys of hip implants.

MR. BURTON: Cadmium, is that consistent with mercury as far as toxicity?

DR. FEIGAL: Well, my point is that we --

MR. BURTON: No, is it? Is it as toxic as mercury to the human body?

DR. FEIGAL: It has to be put in the context of the level of exposure and what the effect is and how that's offset by the benefits.

MR. BURTON: You mean to tell me cadmium is as toxic a substance as mercury? Is that what you're saying? Come on.

DR. FEIGAL: What I'm trying to do is put it in the context of how FDA regulates products. We do not assess the environment. We do not assess the effect of pure compounds and absolute toxicity.

MR. BURTON: You do agree --

DR. FEIGAL: We look at how they're used in practice.

MR. BURTON: You do agree though that mercury vapors leach out of the tooth.

DR. FEIGAL: Yes, we do agree with that.

MR. BURTON: And that it is ingested into the body in part.

DR. FEIGAL: Yes, we do agree with that.

MR. BURTON: And it gets into the blood stream.

DR. FEIGAL: Yes.

MR. BURTON: And it goes to the brain.

DR. FEIGAL: Yes.

MR. BURTON: And other organs of the body.

DR. FEIGAL: Yes, we agree with that.

MR. BURTON: And mercury has a cumulative effect in the brain.

DR. FEIGAL: That is less certain, but there's literature on both sides. It's the clinical impact, though that is the standard for taking action on medical devices, not the toxicology, not the ability to take preventive actions, but the actual observed effects.

MR. BURTON: You know, I don't understand.

Many people in this country, probably the majority, don't know that there's mercury in a silver filling in their mouth, an amalgam. Why is it the FDA doesn't at least, since mercury vapors do escape into the mouth and into the body, why doesn't the FDA at least make people aware of that? Why not publicize that?

DR. FEIGAL: The FDA's authority on information about products has to do with the labeling of the products and only rarely does the FDA actually directly intervene in the way that products are described or presented in informed consent. That's practice of medicine which the FDA is asked not to get involved in.

MS. MUDGE: I do have a response to that. There are, as was mentioned before, some European countries that have decided to err on the side of caution in combination with some environmental concerns in those countries and the labeling has been a universal labeling issue, and that because these companies sell their product worldwide, they decided to put all of those in the labeling.

I can quote from a recent FDA document that was dated March 2002 that basically says that they can no longer do that.

MR. BURTON: What about the mercury in the

vaccines that, the Thimerosal, and that sort of thing?

DR. FEIGAL: I'm afraid I'll have to get follow-up from someone else in the agency who can comment about vaccines. It's outside of my area.

MR. BURTON: Well, Thimerosal contains mercury that's injected into kids. You heard me talk about that earlier, and I think that that's been pretty well publicized, hasn't it? Hasn't the FDA talked about that?

DR. FEIGAL: Yes, but I think if you are talking about the informed consent --

CO-CHAIRMAN KIEBURTZ: Ms. Tibau, one minute.

MR. BURTON: I'm not talking about informed consent. I'm just talking about making people aware.

DR. FEIGAL: I think that is -- I think that's a reasonable -- I think that's a reasonable request to do that.

MR. BURTON: Well, I would make that request, that the FDA -- I don't know -- put a card or something in every dentist's office saying that the mercury in -- that the amalgams that you get from your dentist contain approximately 50 percent mercury. then let the people make the decision themselves.

I think people ought to be held accountable for their actions, but they at least ought to know what in the hell they're doing, and they don't.

(End of video presentation.)

MS. TIBAU: I'd like to thank the committee once again and all of these courageous people who came here in order to support more information coming out about amalgam fillings, and hopefully the FDA will agree with the proposed idea of a ban for at least, at the minimum, pregnant women.

Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Thanks for your testimony.

There are three named and numbered speakers who we have not heard from yet. Ms. Virginia Pritchett, if you're in the vicinity, going once, going twice. Okay. So may be here tomorrow.

Dr. Mark Morin.

PARTICIPANT: He's on his way here.

CO-CHAIRMAN KIEBURTZ: Okay. Ms. Nory Oakes.

PARTICIPANT: She will not be here.

CO-CHAIRMAN KIEBURTZ: She will not be

here. Okay. Great.

Then we'll go on to, as you know, people who wish to speak who are not on the agenda could speak with Ms. Williams, and we have the names of four people. We will -- I think five minutes each will get us out on about time.

So the first of those speakers is Dr. Paul Connett. Are you? Thank you.

DR. CONNETT: Thank you.

I have no economic interest in mercury amalgams, but a citizen did pay my air fare down from northern New York.

I got my Ph.D. at Dartmouth. I investigated the interaction of metals with biological systems. I mention that because my advisor was Karen Wetterhahn, who actually died from mercury poisoning. She got two drops of dimethyl mercury through her gloves and had scientists all over the world trying to get the mercury out of her body. They did largely out of her blood stream. They just couldn't get it out of her brain.

The second issue I'd like to mention is having spent 22 years on waste management, I should tell you that if you put mercury amalgams into someone's mouth and they are cremated, all of that

mercury is going to go into the environment. There's not one air pollution control device on any crematoria that I'm aware of that captures mercury. So it's destined to go into the environment, period.

Now, I would respectfully suggest to you that there is something a little bit more important than protecting the public health. I'm sure you all think that is absolutely number one, but I would put you today in 2006. There's a more important thing, and that is protecting the public trust.

You have had so much devastating information about a lack of scientific integrity in your agencies with the pharmaceutical industry running roughshod over the NIH, with the chemical industry running roughshod over the EPA, with the CDC, and I could go on and on and on. You have to restore the public trust.

Now, in that connection, let me say two things. It just absolutely astounds me that we have had prestigious agencies in this country saying it was okay to inject organic mercury into a baby's bloodstream at over 100 times the level which was deemed safe to eat. This is absolutely extraordinary.

When the people find out about that, that will demolish public trust.

Now, this afternoon I go to Case No. 2. This afternoon we've heard a whole series of people from talking about prestigious agencies from around the world, the WHO, the WDF, the FDA, the EPA. All of these agencies apparently think that dental amalgam is perfectly safe. No problems at all. The science says so. All right?

Well, I've spent ten years on another substance, and you could have saved all of that same testimony and just switched two words: fluoride, fluoride for mercury. We have had the same litany of support from the ADA and all of these organizations telling us it's perfectly safe to put fluoride in the drinking water.

But there is a difference between fluoride and mercury for me, which is I've studied the issue for ten years, and I can tell you categorically the science from the ADA on this subject is absolutely atrocious. The science on this subject from the CDC is absolutely atrocious. In fact, I would say the CDC has been captured by the ADA on this issue.

Let me give you one example. The EPA asked the NRC, the National Research Council, to review the safe drinking water standard, which is currently at four parts per million with fluoride at

one part per million.

They came back and said the standard is too high. It has to be lowered. You need to do a health risk assessment.

Immediately the ADA said this is not relevant to water fluoridation at one part per million, and within six days the CDC is saying this is not relevant to water fluoridation. They had done no health risk assessment. They didn't have time to read the report. They certainly didn't have time to read all of those references. That wasn't physical science. That was political science. They were protecting a policy.

One word we haven't heard today is liability. A lot of what you heard from the ADA is not protecting the public. It's protecting their rear ends from the liability of a lawsuit which are going to ensue the moment anybody indicates that there is a problem here.

(Applause.)

CO-CHAIRMAN KIEBURTZ: One minute.

DR. CONNETT: And as far as numbers are concerned, you heard about the safety factor of 30 that was used at some point, from the lowest observable effect level. Let me tell you the safety

factor that they used for fluoride. This is the EPA when they established the safe drinking water standard.

They took a limited amount of data for adults and they applied the safety margin to take into account the very young to the very old to the sick, with people with kidney dysfunction. Do you know what safety factor they used? Two, point, five.

Public trust, ladies and gentlemen. You're running out of time to reestablish that.

We heard today that four micrograms of mercury per milliliter of blood. Just a little bit of chemistry on that. That's 10,000 trillion atoms of mercury, 10,000 trillion atoms of mercury per milliliter when you're talking about --

CO-CHAIRMAN KIEBURTZ: Dr. Connett, I'm sorry to interrupt you.

DR. CONNETT: If I can just say one thing, I've come a long way. Just one last sentence.

(Applause.)

DR. CONNETT: I hope you will listen extremely carefully to Dr. Boyd Haley tomorrow. I think his critique of those AMA studies is absolutely solid. I think his work is solid, and it's absolutely imperative in my view that you are certain that you

are protecting the public here. You've got to be absolutely certain.

You're like building a dam above a village.

CO-CHAIRMAN KIEBURTZ: One sentence you said.

DR. CONNETT: This is just finishing that sentence. You've got to be absolutely certain, which means you look at all the evidence. You look at the biochemical evidence; you look at the animal evidence; you look at everything, and you have a weight of evidence and don't forget the Swedes. The precautionary principle is what we need here.

Thank you.

CO-CHAIRMAN KIEBURTZ: Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Dr. Isabella DeMede, are you available? Thank you.

Again, five minutes. Thank you.

DR. DeMEDE: Thank you. I'm here representing the European Commission. I'm a commission official responsible for the regulation of medical devices in the European Community.

I thank you to give me this opportunity to give you a short, very short, brief overview of where

we stand at the moment.

I won't go back to what my Swedish colleagues said about how medical devices are regulated in the European Community. Dental amalgams are regulated under the medical device legislation. They are considered a Class 2(b) product, which means that the manufacturer has to comply with essential requirements which are in the European legislation.

And I would just repeat two sentences of this essential requirements, and I think we all share the same concerns. Under the intended conditions of use, the medical device will not compromise the health, the clinical condition and safety of patients and the safety of health of users.

And also, any risk which may be associated with their use, the medical device, should constitute an acceptable risk when weighed against the benefits to the patient.

So these are part of the essential requirements medical devices have to comply with. This has been reviewed by a conformity body which we call the Notified Body.

Now, briefly I will go the situation in the member states as we are informed at the European level. We have been requested by the European

Commission to review the implementation of how dental amalgams are used in the different member states. The feedback we have is that in all member states but one, but that will be next year, dental amalgams are still used.

The trend is that there is a decrease in this use. The decrease depends on the country. If you ask me to quantify this decrease, I wouldn't be able to do it today.

Some member states as you hear today have introduced specific recommendations to use alternative fillings for specific patient groups. This you have heard today. These are United Kingdom, Germany, Austria, Denmark.

As far as Sweden is concerned, we have been informed in June this year of their intention to ban the products, to ban mercury in dental amalgam. This is for environmental reasons. The reason they give us is environmental. Due to our internal rules, this is being reviewed now by lawyers. We have to check that this doesn't infringe internal market rules, and the ruling probably should be on our side before the end of the year.

Now, as far as the European Community is concerned, we in the European Commission had convened

an expert group to review evidence regarding the use of dental amalgam in 1993. I think this was quoted this morning also.

According to this expert panel, there was no reason to restrict the use of dental amalgam at that time in view of scientific knowledge. As many of you know, we are under increasing pressure to review evidence and see whether there is a scientific ground to restrict the use.

Basically we had a Commission communication and the Community strategy on mercury, and basically the communication supports restriction of emission -- my English is -- emission and exposure of the patients to mercury. Within that framework, we, our services have been requested to review the use of dental amalgam and to ask the opinion of the appropriate scientific committee.

So there is basically this committee strategy. There is also consumer groups just like here who put us under pressure, but so far mostly for environmental concern.

So the Commission will request the opinion of the appropriate scientific committees which have been established under committee rules on the safety of use of dental amalgam and alternative fillings to

human health.

If we have to make a risk management decision or to make formal recommendations as some member states have done, we need to review the evidence on mercury and also on alternatives.

Now, very briefly someone this morning has asked the question about the legislation on waste. Although I'm not an expert in this, there is a legislation on the hazardous waste in the Commission and mercury has been listed as a hazardous compound.

Based on this legislation most member states have passed legislation for the disposal of mercury dental amalgam, and the Commission has been requested under this committee strategy to review the implementation of this legislation. So this is what I can say at the moment.

CO-CHAIRMAN KIEBURTZ: Thank you very much.

One question.

DR. AMAR: Salomon Amar.

Thank you.

You mentioned that there was a trend in the reduction of amalgam placement, but you could not quantify. Would you say that this trend results from aesthetic concerns or perceived toxicity?

DR. DeMEDE: I cannot say right now.

CO-CHAIRMAN KIEBURTZ: Thank you again.

Dr. Steven Marcus, are you available to speak?

DR. MARCUS: I am here, but I would like to be deferred until tomorrow due to technological difficulties. I was preparing my notes for today, but my battery has run down on my laptop.

CO-CHAIRMAN KIEBURTZ: I'm just repeating for the transcriptionist your desire to switch to tomorrow, but I'm looking for guidance as to whether that's possible.

Okay. Done.

DR. MARCUS: Thank you.

CO-CHAIRMAN KIEBURTZ: Dr. Andrea Brockman.

DR. BROCKMAN: Hi. I'm Dr. Andrea Brockman. I was a practicing dentist for about 25 years. Prior to that I was an intensive care, coronary care nurse.

I would like to address the FDA today on terms of labeling and in terms of exposure to female dentists and hygienists and dental assistants and office personnel that work in the dental office.

When I was a nurse I had broken a

thermometer in the hospital, and that room was quarantined until it was safely removed, and that stuck with me that this was a toxic substance, which a thermometer holds about 780 milligrams of mercury.

When I went to dental school four years later, I started working on the dental clinic floor where there were about 300 dentists mixing amalgams, squeezing it, squeezing it with squeeze cloths, dropping it on the floor, burning their instruments to get the amalgam off, no ventilation, which did not make a whole lot of sense to me if we were being quarantined for one thermometer and there was the equivalent of about 300 broken thermometers or more a day.

This concerned my exposure to myself, as I was pregnant at the time, and when I went to ask the dental professors why we are using mercury, I was quickly suppressed and said, "We don't discuss that. It gets locked into the fillings. It's safe."

And I said, "But what about me? I'm pregnant?"

And was just told that I should not make any waves. Two months later, in my third month I had a spontaneous abortion, which probably saved my life because being exposed to all of that mercury and since

it does go through the placenta, that fetus probably took a lot of the mercury out of my body.

This did not keep me from being in and out of the hospital with cardiac arrhythmias, migraine headaches, panic attacks, and I was a very healthy person prior to dental school.

When I got out of dental school, I had opened up a practice with my husband, and intuitively I felt that I did not want to use mercury in the practice, and so I had begun using composite resins, and at that time we didn't even learn about posterior composites in dental school. They weren't around at the time. We were just using two mixed paste to paste, and I was using them in patient's mouths, and I had them placed in my own mouth, which I still have some today and that's 27 years later.

There were women that were working in my office that had worked in other dental offices that had infertility problems, that were suffering from depression, that were having chronic migraine headaches, suicidal, and I thought this was kind of unusual to be in a dental office that had so many women being sick, and from what I understood from my colleagues, there were similar problems that were going on.

I was pregnant, again, and had some difficulty getting pregnant though. It took me three more years, and at the time I was not using and placing amalgams, but I was drilling out fillings. I was drilling out amalgams on the order of probably ten to 30 a day.

I had not worn masks. I had not worn gloves because this was pre-AIDS, and we did not have to protect ourselves at that time, and so I worked through my ninth month of pregnancy not wearing gloves and mask and exposing me and my fetus.

I had a very difficult delivery. My child, who did not have a nurse, my child in the office, brought him in with me until he was eight months old. He suffered from depression. He has had mercury that was on a challenge test in his urine, very high levels. He had suffered from hyperactivity, asthma, and a number of other things.

Did not connect the dots. Got pregnant again, was working through my ninth month of pregnancy, and I was realizing at this time now that maybe I should contact the American Dental Association to find out what my exposure was as a female dentist drilling out mercury amalgams.

CO-CHAIRMAN KIEBURTZ: I'm going to have

to stop you there. Sorry to interrupt.

(Applause.)

CO-CHAIRMAN KIEBURTZ: Our last speaker of the day, could you please identify yourself?

MS. PALMER: Thank you, panel.

My name is Karen Palmer from Pennsylvania. I'll probably need to apologize in advance for anybody that I may offend through what I have to say this afternoon. I'll keep it very brief.

As you know, we were able to submit letters to the gentleman from the FDA, who I thank again, about situations concerning mercury, and so I just have a couple of those that I submitted to share with you. This one was dated July 27th.

I handled mercury every day for years as a dental assistant until two years ago when I was diagnosed with heavy metal toxicity to mercury and lead. I am no stranger to neurotoxicity for I am still numb on the entire left side of my body. Chelation takes care of the detox, but what about the overall damage as a result of being toxic?

What a false sense of security all of those years of taking precautions with wearing a mask only to learn that the vapors go right through it. Much to my discredit, I now know more about mercury

toxicity than in all those years when I was working with it.

Where and when were all of the continuing education courses to warn us of the dangers? My former boss is still in denial of all that has happened to me and continues to place amalgam every day. He thinks I've been misdiagnosed and still haven't found the real cause to all of my problems.

He worships the ADA and thinks he is protected from any backlash for lawsuits because he's a longstanding member and they maintain it's safe unless you are allergic.

What I have is no allergy. It is criminal that they are allowed to cover up and mislead and misinform. What is it going to take to wake up everyone on this?

It is so sad that people are not given all of the information in order for them to make informed decisions for themselves. Mandatory informed consent would help, and it is a start and some states have it, but not all are on board.

Pennsylvania is one of the worst, lagging way behind on current information.

As crazy as it sounds, Oprah Winfrey gets quicker results and responses than the entire federal

government daily with over 40 million viewers just in this country alone. How sad.

What's in your mouth? Got mercury?

August 21st, another letter to the FDA.

I was diagnosed with heavy metal toxicity for mercury and lead in May of '03. After a full year of testing, I was told at one point that I had MS because of the sensory disturbances.

Neurotoxicity and toxic neuropathy is no allergy as the ADA would like us to believe. I gave the best years of my life in a profession as a dental assistant, taking all of the precautions with gloves and masks and glasses only to learn that the mercury vapor goes right through it.

Optimal ventilation is so key, or so I've come to learn, not minimal which is what most offices have.

Patients should be given the information on the MSDS sheets. The doctors that still insist on using amalgam silver mercury fillings because the ADA still says it's safe are causing great harm to themselves, staff, and patients.

Many months of chelation have lowered my toxic levels, thank God, and I am so encouraged. All of the paresthesia, neuropathy, and the chronic

fatigue I continue to endure. What is it going to take for all involved to wake up?

Nobody wants to be held accountable for all of the damage that has been done and allowed to occur and continues to go on. I had silver fillings in my teeth. My former employer said my levels didn't come from my mouth. Afraid of backlash, he still continues to place the mercury restorations.

Do you see and hear how huge of a crisis this is at hand? People in the environment are being ruined. Please make it stop starting with the ADA. Enough already.

There are other safer materials to use, but not as easy to place and not as quick and more costly. The dental insurance companies --

CO-CHAIRMAN KIEBURTZ: One minute.

MS. PALMER: -- want to pay for the least expensive and so the doctors are in effect letting the insurance dictate treatment, which they claim to never do.

So involving and confusing, no wonder no one wants to open this can of worms, so to speak. The deception that is allowed to continue is nothing short of criminal. Mercury is a neurotoxin, brain poison. That does not belong in any form, ethyl, methyl,

organic, inorganic, no safe amount in the human body, nor do the fish that we can no longer eat or the vaccines that are supposed to protect us.

I could go on and on. What's next? No swimming? It's in the air. It's in the water. It's in the ground, while placing it directly in the mouth two inches from the brain is just ludicrous beyond reason.

Ah, the old argument. But it has been used for 100 years without any problems. Buzz. Wrong answer. Just because the ADA says it's so doesn't make it so.

And who are we and who is their peer review? Everyone has a boss, and that is where the FDA should step in and set the high and mighty ADA straight once and for all.

CO-CHAIRMAN KIEBURTZ: I'm going to interrupt you. Thank you.

(Applause.)

CO-CHAIRMAN KIEBURTZ: I want to briefly apologize to all of the speakers I had to interrupt. I think by setting a time that everyone could stick to makes it as fair and equitable.

I'd like to thank everyone for their respectful communication of views which at times are

sharply divided, but it's one wonderful opportunity that we have a place where we can share those opposing views in a polite and respectful environment. So I appreciate everyone's contribution to that.

I'd like to thank Drs. Mackert, Conn and Philipson for their presentations earlier today, particularly to Dr. Conn and Philipson for traveling here to share with us their perspectives. To Dr. Alderson and Canady and Ms. Rosecrans, for giving us information from the FDA perspective.

I'd like to thank Representative Watson also. There are people who traveled great distances, Dr. Wilson, Ms. Kilmartin, Dr. DeMede. We appreciate them particularly.

Everyone who had the courage to stand up and tell their story, it's important for everybody to hear that. So thank you for doing that.

At this time we will adjourn for the day. We will reconvene at eight o'clock tomorrow morning with the continuation of the public hearing.

Thank you.

(Whereupon, at 4:59 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Thursday, September 7, 2006.)