UNITED STATES OF AMERICA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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JOINT MEETING OF DENTAL PRODUCTS PANEL AND PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE

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THURSDAY, SEPTEMBER 7, 2006

The meeting came to order at 8:00 a.m. in the Grand Ballroom of the Gaithersburg Holiday Inn, Two Montgomery Village Ave, Gaithersburg, MD. Richard G. Burton, DDS, and Karl D. Kieburtz, MD, MPH, co-chairs presiding.

PRESENT:

RICHARD BURTON, DDS, CO-CHAIR
KARL D. KIEBURTZ, MD, MPH, CO-CHAIR
SALOMON AMAR, DDS, PHD, MEMBER, DPP
THERESA A. COWLEY, PATIENT REPRESENTATIVE, DPP
MASON DIAMOND, DDS, INDUSTRY REPRESENTATIVE, DPP
MICHAEL FLEMING, DDS, PA, CONSUMER REPRESENTATIVE, DPP
YIMING LI, DDS, PHD, MEMBER, DPP
MAN WAI NG, DDS, MPH, MEMBER, DPP
WILLIAM J. O'BRIEN, MS, PHD, MEMBER, DPP
DOMENICK T. ZERO, DDS, MS, MEMBER, DPP
JOHN R. ZUNIGA, PHD, DMD, MEMBER, DPP
MICHAEL E. ADJODHA, MCHE, EXECUTIVE SECRETARY, DPP
LARRY B. GOLDSTEIN, MD, MEMBER, PCNSDAC
MICHAEL D. HUGHES, PHD, MSC MEMBER, PCNSDAC
SANDRA F. OLSON, MD, MEMBER, PCNSDAC
ROGER J. PORTER, MD, INDUSTRY REPRESENTATIVE, PCNSDAC
MATTHEW RIZZO, MD, MEMBER, PCNSDAC
RALPH L. SACCO, MD, MS, MEMBER, PCNSDAC
LT DARRELL LYONS, BSN, RN, EXECUTIVE SECRETARY, PCNSDAC

PRESENT (continued):

MICHAEL ASCHNER, PHD, CONSULTANT
MICHAEL DOURSON, PHD, CONSULTANT
LYNN R. GOLDMAN, MD, MS, MPH, CONSULTANT
MARGARET HONEIN, PHD, MPH, CONSULTANT
CURTIS D. KLASSEN, PHD, CONSULTANT
MICHAEL I. LUSTER, PHD, CONSULTANT
GEORGE WESLEY TAYLOR, III, DMD, DPH, CONSULTANT
NORRIS E. ALDERSON, PHD, FDA

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P-R-O-C-E-E-D-I-N-G-S

DR. BURTON: Good morning. I would again like to call this meeting back to order. The executive secretary will again read the conflict of interest statement for the meeting.

MR. ADJODHA: Thank you, Chairman Burton. This is Michael Adjodha, executive secretary of Dental Products Panel.

The Food and Drug Administration is convening today's meeting of the Dental Products Panel, the Medical Devices Advisory Committee, the Center for Devices and Radiological Health, and the Peripheral and Central Nervous System Drugs Advisory Committee, and the Center for Drug Evaluation and Research under the authority of the Federal Advisory Committee Act of 1972.

This will be a joint meeting of two committees. With the exception of the industry representative, all members and consultants of the committee are special Government employees or regular Federal employees from other agencies and are subject to Federal conflict of interest laws and regulations.

The following information on the status of the committee's compliance with Federal ethics and conflict of interest laws covered by, but not limited

to, the rules found at Title 18 U.S.C. section 208, are being provided to the participants in today's meeting and to the public.

FDA has determined that members and consultants of these committees are in compliance with Federal ethics and conflict of interest laws. Under 18 U.S.C. section 208, Congress has authorized FDA to grant waivers to special Government employees who have financial conflicts, when it has been determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Members and consultants of these committees who are special Government employees at today's meeting have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their employer, spouse or minor child, related to the discussion of today's meeting. These interests include investments, consulting, expert witness testimony, contracts/grants, CRADAs, teaching and speaking/writing, patents and royalties and primary employment.

Today's agenda involves review and discussion of the peer-reviewed scientific literature

on dental amalgam and its potential mercury toxicity, specifically as it relates to neurotoxic effects.

Based on the agenda for today's meeting and all financial interests reported by the members and consultants of the committee, conflict of interest waivers have been issued in accordance with 18 U.S.C. 208 to Drs. Larry Goldstein and Sandra Olson. The waivers allow these individuals to participate fully in today's deliberations.

Copies of these waivers may be obtained by visiting the Agency's Web site or by submitting written requests through the Freedom of Information Office, Room 6-30 of the Parklawn Building.

A copy of this statement is available for review at the registration table during this meeting and will be included as part of the official transcript.

Dr. Mason Diamond is serving as the device industry representative, acting on behalf of all related industry, and is employed by TyRx Pharma, Incorporated. Dr. Roger Porter is serving as the drug industry representative acting on behalf of all related industry and is a retired employee of Wyeth Research.

Dr. J. Rodway Mackert, Jr., who is a guest

speaker with us today, has acknowledged a financial interest in and professional relationship with a firm at issue.

We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda, for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue.

Thank you.

DR. BURTON: Thank you, Mr. Adjodha.

The first item on our agenda this morning is the open public hearing. I will relay some information prior to starting that portion. This is the second of our two open public hearing sessions for this meeting.

The first public session here was held yesterday afternoon. Repeating what was said then, public attendees are given the opportunity to address the committee, to present data or views relevant to the committee's activities. The FDA does value your

input. Members of the public have an opportunity to speak to the committee at the public meeting but practical considerations limit the time that we allocate to public speakers as a group, and therefore to any individual speaker.

For this reason, the FDA has established a docket, FDA Docket No. 2006N0352, for all interested members of the public to submit written comments of any length to the FDA.

Those will be reviewed, in addition to the oral testimony, to see what light they can shed on the questions and issues being raised at this meeting.

The FDA is especially welcoming the public comments about the peer-reviewed scientific literature on dental amalgam and its potential neurotoxicity, specifically as it relates to neurotoxic effects.

Based on the number of requests we have received and the material covered yesterday, to allow adequate time for our deliberations, we have allotted each speaker seven minutes for his or her presentation, as we did during yesterday's session.

Those of you who have registered to speak have been given a number corresponding to your order of appearance, and near your time please come to the podium area in advance, so we will reduce the

transition time between speakers and keep it to a minimum. The FDA staff will direct you to the appropriate podium. Please remain within your time constraints. There are many speakers and the time limits have been and will be strictly enforced. We will use the timer again for this meeting. The yellow light will signal you that you have one minute left to finish your presentation and we will make an audible notification as well.

The red light means that your time is up and you will be cut off at that point in time.

Both the FDA and the public believe in a transparent process for information-gathering and decision making. To ensure such transparency at the open public hearing session of the Advisory Committee meeting, the FDA believes that it is important to understand the context of an individual's presentation.

For this reason, the FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with any company or organization that may be affected by the topic of this meeting.

For example, this financial information

may include the companies or organizations paying for your travel, lodging or other expenses in connection with your attendance at the meeting.

Likewise, the FDA encourages you, at the beginning of your statement, to advise the committee if you do not have any such financial relationships.

If you choose, however, not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

I would like to remind the public observers that while this meeting of the meeting is open to public observation, public attendees may not participate except at the specific request of the chair. Also, the chair and other members of the committee may question a person about his or her presentation.

No other person may question the presenter or interrupt the presentation of any other participant.

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

Our first speaker this morning is Mr.

Michael Bender.

MR. BENDER: Good morning. Thank you, Mr. Chair, and members of the committee for the opportunity to present here this morning.

My name is Michael Bender and I'm the director of the Mercury Policy Project. We work on both domestic and international mercury-related issues to reduce both release and exposure to mercury.

In my talk today, I will be focusing on a 2005 Norwegian broadcasting documentary examining complaints by dental nurses. The reports of high mercury exposure are shocking. In fact you will see in the documentary excerpts that my assistant will be showing directly after my presentation.

The responses by dental nurses to the airing of the documentary was that their offspring were affected too. So therefore, we have two common sense recommendations. The amalgam placement during pregnancy, as a number of countries, including Canada and Britain and Germany, et cetera, have already done, and placed dental nurses on paid leave during pregnancies.

The 2005 Norwegian Broadcasting documentary investigated a number of dental nurses' complaints, including tremors, memory and

concentration problems, liver and kidney problems, and many others that I don't have time to go into at this point, but copies of my presentation will be available afterwards.

The study results that you see show that the investigation found that 25 percent of dental nurses reported having neurological problems, and many other problems as well.

There are a number of experts who claim that there is no possible way that these kind of effects could be experienced with these mercury levels, and so following the procedure used in the past in the dental office, amalgam was heated and the results were staggering.

Every time amalgam was prepared, the meter would spiked to the maximum limit the device measures.

A similar situation occurred in New Zealand during a study that was documented in 1974, when New Zealand nurses were exposed to similar levels of mercury, and they and their children experienced similar effects.

After the documentary ran in Norway, around 400 women, former dental assistants, called the television station. A pattern emerged. Many were pregnant and were also breast feeding. A high number

reported children born with birth defects, learning disabilities, immunological, muscular and skeletal problems. Mothers had severe bleedings and multiple late abortions.

The documentary was also then shown in Denmark and more than 1650 dental nurses have called the Danish trade union, expressing concerns for both their health and the health of their children.

As a result, the Danish employment agency and other Federal Government agencies in Norway and Denmark have gotten together, and they are now committing a multimillion dollar, multiyear study of neurotoxic mercury exposure effects on dental assistants and dentists as well, investigating what went wrong, who was affected, and how badly.

Norway, right now, actively discourages dentists from placing amalgam, and I did meet with, when I was over in Scandinavian countries in June, I did meet with the government authorities on dental mercury.

In Norway, it's recognized that amalgam placement takes away from the life of the tooth, and I am co-chair of the State of Vermont Advisory Committee on mercury pollution, and when we talk to our dentists, they tell us the same thing. This is common

knowledge, setting aside the toxicity issues.

Second, the levels of mercury in pregnant women and children are far too high as we know from the EPA interpretation of the CDC data. One in six or one in eight mothers, or expectant mothers, have mercury that was far above what's considered safe.

I'm sure it's important to cover the precautionary principle and the principle of product substitution. When available, use less toxic materials, and again, amalgam is banned, placement is banned during pregnancy.

While the levels of mercury in the past were much higher in Norway than they are in the U.S. today, recent research of 6000 U.S. dentists and dental assistants with exposures to low levels of mercury, below the WHO standard, still resulted in measurable neurological damage detectible in neuropsychological tests.

So Mr. Chair, an ounce of prevention is worth a pound of cure, especially when it comes to protecting the most vulnerable, the unborn who have no say over this matter. Therefore, please consider the following common sense recommendations.

While almost everyone agrees that the developing fetus is most susceptible to mercury, we

need to do more to reduce maternal exposure and the FDA is starting to do this quite well with methylmercury exposure in fish.

Except in emergencies, FDA should ban mercury tooth fillings and placements during pregnancies, and again, dental nurses should be placed on paid leave during and just prior to pregnancies.

As a result of the showing of this in Norway, the journalists who are here today were presented the most prestigious Norwegian journalistic prize for their documentaries on dental mercury exposure.

The judge's statement. "After the two journalists' impressive and extensive work, our perceptions of what 10,000 dental nurses were exposed to in their workplace has been changed forever."

There was also an award given to the dental assistant, Tordis Klausen, by the Norwegian Society for Civilian Courage. She was recognized for her tireless work to acquire and spread information about health damage resulting from exposure to dental amalgam and mercury in dental clinics.

Ms. Klausen lost her civil law suit in 1997 and 1999 for compensation, then appealed all the way to the Norwegian Supreme Court and was then

denied.

She has since appealed to the European--

[Bell]

DR. BURTON: You have a minute left.

MR. BENDER: Okay. --has since appealed to the European Court of Human Rights in Strasbourg. The Zola Prize winner is awarded to persons who, quote, openly and courageously have revealed or opposed conditions in Norway that threaten basic values in Norwegian society--human rights, democracy and legal protection.

I'd like to acknowledge the following, and also in your handouts is information. I do have a copy that I'd like to submit for the record of both Mercury Girls and also Mercury Children, and you will be seeing excerpts primarily from Mercury Girls next. Thank you very much.

DR. BURTON: Thank you.

Our next presenter is Dr. Rachel Obbard.

DR. OBBARD: Good morning. My name is Rachel Obbard and I'm a science advisor working for the Mercury Policy Project. I have no financial conflicts of interest.

Michael Bender and I obtained the film, Mercury Girls, from Tordis Klausen, a former dental

nurse, and one of its subjects, while in Norway this past June. The film, as Michael tells you, was produced by independent film makers in Norway and shown on public television there.

The original 29-minute film has been cut to the seven minutes I will show you, and as a result has a rather abrupt ending.

[Video playback]

DR. OBBARD: Seventy percent mercury. We're making amalgam the traditional way. When heated, the mercury appears. The most dangerous element is invisible, the vapor. Eighty percent is absorbed by the lungs and distributed around the body. Some of it ends up in the brain, where it is accumulated. This program is not about teeth. It's about those who handle mercury daily in dental offices.

At least 10,000 women worked as dental nurses from 1960 to 1990. What they did on a daily basis, no one would dare today.

In Stockholm, we see Mathis Berlin, environmental medicine professor. His special field is mercury. He has contributed to establishing the WHO limits. Berlin confirms the difficulty of settling on a diagnosis.

Physicians have little knowledge of the hazards of mercury, he says. If you are poisoned, they tend to think you have mental disorders. And mercury does lead to an unbalance in the brain.

Berlin is well aware of the dental nurses. He thinks many have inhaled too much mercury. He thinks even today's limits are too high. Zero exposure is best, he says.

Our biological organisms are sensitive to mercury. In Seattle, we find some of the world's leading mercury experts.

I'm going to want the sound back on for this, please.

They're associated with the research organization, Battelle. In the USA they carry out a lot of assignments from the authorities. The dental personnel examined here were exposed to very low doses of mercury, ten times lower than what was common among personnel in Norway until the '90s. Even so, there are damages.

Can you turn the sound back on for the film.

A person's capacity to hold something steady, very firmly in their fingers, and not jiggle, and not move this way or this way, is impaired, when

someone has a fair amount of exposure to mercury.

A person's ability to recall numbers is worse. So their attention is lower. We see increased symptomology, not across the board, mostly in complaints of memory loss and concentration, okay, and anxiety.

We see some mood, some depression.

This is Nils Rigyerdet, professor of urbanology in Bergen. Deep inside a cupboard, he has found copper amalgam. We'll try to find out how much mercury released when we do what the nurses did several times a day. The difference is we've got gloves and a hood.

We've brought an occupational hygiene expert to the survey. In Norway, 50 micrograms during a workday is permitted. Thirty-six micrograms per cubic meter is the reading. Measure now, with the mercury on the surface. Then I will transfer this to a mortar. This is beyond the level I'm able to measure. It's more than a 1000 micrograms per cubic meter. Why don't we blend it here. Yes. Every time the meter said high level. More than 1000 micrograms. We don't know how much more.

The section for occupational medicine in Bergen has carried out a study on initiative from

Brennpunkt. All the nurses who were tested worked between 1960 and 1990. Twenty-five percent report frequent or very frequent neurological problems.

They are compared with a group of nurse assistants of the same age. The dental nurses score more than the nurse assistants in four fields. tremors, dental nurses 36 percent; nurse assistants, eight.

Heart and lung problems, dental nurses, 21 percent; nurse assistants, five.

Depression. Dental nurses, 18 percent; dental nurse assistants four. And loss of memory, 14 percent. Nursing training. The girls radiate joy and awe. They are dental nurse students and their future is secured. They will learn a modern trade. For two years, they are taught how to knead mercury and boil copper amalgam. They do not know that alarmingly, many of them will develop uterine problems.

(Video shown)

DR. BURTON: We'll need to stop at this time. Thank you.

DR. BENDER: The part that you missed was that the dental hygienists, 25 percent of them had hysterectomies versus 6 percent in the control group. Thank you for your attention.

DR. BURTON: Thank you for your testimony.

Our next speakers are Mr. and Mrs. Michael and Phyllis Burke.

MR. BURKE: Good morning, everyone. I'm Michael Burke. This is my wife, Phyllis. We have no financial contributors. Phyllis was diagnosed on July 29th, 2004 with Early Onset Alzheimer's disease by a traditional neurologist, M.D. Most recently, our M.D. in Chicago, Dr. Thomas Stone, a very famous doctor there, agreed with that assessment. However, his root cause diagnosis was in fact heavy metal toxicity.

Thus far, in an attempt to save her life, I have studied over 3000 plus hours on the subject. It is my firm conviction that the bioaccumulated mercury vapor coming off of one's mercury fillings over the course of many years is in the fact the primary causative trigger for Alzheimer's disease.

Following are but four crucial interlocking puzzle pieces I uncovered.

Alzheimer's disease is most prevalent in industrialized nations. These are countries where dentistry using mercury amalgam fillings is common practice. Alzheimer's barely exists, if at all, in third world nations. There are many sources that back this up.

In 1993, a groundbreaking study by Duke University revealed that the presence of just one APO-E4 gene significantly increases Alzheimer's risk and also lowers the age of onset.

My wife took a blood test and it confirmed as being the worst case scenario, APO- E4/4. Both her APO-E genes are fours.

According to Dr. Boyd Haley, the unprotected APO-E4 form as has four arginine amino acids located on the potential mercury binding positions as opposed to the very protective APO-E2 in which there are two cysteine amino acids present, or the semi-protective APO-E3 where there is one cysteine and one arginine.

It is no more than basic chemistry we are talking about here. Mercury loves sulphur. Mercury binds preferentially; to sulphur over almost any other element.

The cysteines present in the protective APO-E2 and semi-protective APO-E3 are sulfur-based amino acids and thus readily attract, bind and excrete mercury on a continual basis, 24/7.

An APO-E2 status would easily explain why someone might be 70 years old and have a mouth full of amalgam fillings but never reach a state of

intellectual compromise.

Conversely, there is absolutely no chemical affinity for mercury by the arginines on APO-E4.

APO-E4 genes only allow individuals to hyper-bioaccumulate mercury 24/7. this more than adequately explains Duke's previously mentioned findings.

Every aberrant, diagnostic physiological change that occurs in the brain cells and neurons of Alzheimer's's victims has been identically recreated by Dr. Boyd Haley and colleagues in strict laboratory settings by exposing live nerve cells to very low levels of mercury.

Please note. Many other metal have been tested, including aluminum, but none of them reproduced any of the hallmark diagnostic changes.

In my wife's particular case, this next point is critical. Mercury fillings can and do carry electrical charges. The higher the negative electrical charge, the more mercury is being released from the amalgam.

While having only two amalgam fillings, Phyllis had one filling that registered a negative 316 microamp charge on a device called the Rita Meter,

specifically for measuring the charges on amalgam fillings. When I spoke personally to Dr. Hal Huggins and relayed this fact to him, he was incredulous with disbelief. He had never heard of, seen anything remotely close to this high a reading for a negative charge being registered on an amalgam surface.

Both he and Dr. Boyd Haley personally conveyed to me that because of this high negative electrical charge, this particular amalgam was extremely toxic and it was giving off tremendous amounts of mercury.

Dr. Huggins stated also that perhaps even in the form of more deadly methylmercury.

I'd like to share a few items with you that I call my reasonably intelligent person's top ten list, why mercury should not be used in dentistry and medicine, and I'm going to do a few of the highlights.

On this planet, mercury is second only to the radioactive element plutonium in its ability to do neurological damage. Pink disease was from the late 1880's to about 1950. It killed thousands and thousands of babies worldwide, when it was discovered, finally, yet reluctantly accepted in late 1940's, early 1950's, that mercury was in infant teething powders and it was in fact the cause of pink disease.

When they took it out, no more babies died.

When a dentist fills your teeth with mercury, he or she must handle the excess scraps as a hazardous waste material in accordance with EPA guidelines. Why, then, is the load of mercury left behind to weather the stormy and turbulent conditions of your mouth any different? What makes it so safe and special?

On the flip side of the coin, you then become an EPA-approved toxic waste receptacle.

A study done in Glasgow, Scotland, evaluated 180 dentists and 180 volunteers off the street. The dentists, as a group, scored much lower on the cognitive memory issues as well as physically. Hugh Fudenberg, M.D., a world leading immunogeneticist and biologist, with nearly 850 papers published in peer review journals, has reported that if an individual has had five consecutive flu shots in a 10 year period, his or her chances of getting Alzheimer's disease is ten times higher than if they had zero, one or two shots. He attributed this to mercury and aluminum present in vaccines.

The original dental association in the United States was called the American Society of Dental Surgeons. They refused to use mercury amalgam

fillings because they knew they were extremely toxic.

However, because many dentists wanted a piece of the mercury amalgam financial pie, they abandoned ship and started using mercury amalgams in patients. As a result, the American Society of Dental Surgeons died on the vine. In 1859, the ADA was formed from these same individuals.

The initial statement of the ADA as regards the use of mercury in fillings was that the compound was perfectly inert and mercury does not leach off or vaporize.

This is a statement that was made with absolutely no scientific evidence to back it up either way. They blatantly disregarded any and all caution as regards mercury. Even the name "silver fillings" was deceptive, as by composition, the amalgams contained a much higher mercury content than silver. This was a foot in the door for mercury.

The American public trustingly and unknowingly allowed a silently creeping, deadly monster into its everyday world.

Unfortunately, subsequent, well-meaning dentists were also inherently desensitized by the status quo. Heavy metal, toxic metals, and soft, pink, human flesh are simply not compatible.

In conclusion, I am asking you today to hear my message and do the right, decent, honorable, God-loving thing.

There needs to be an immediate embargo upon the placement of mercury fillings in this country, if not for everyone, at least for pregnant women and children because they represent our future.

We need to understand my wife as a worst case scenario, yet it took 35 to 40 years to manifest. It clearly puts the--

DR. BURTON: Thank you very much for your input.

MR. BURKE: --children's studies into perspective. Thank you.

DR. BURTON: Thank you.

Our next presenter is Dr. Howard Bailit.

DR. BAILIT: My name is Howard Bailit. I'm a professor in the Department of Community Medicine at the University of Connecticut, and I'm a dentist and a health services researcher by training.

And today I want to present a study that was done on the economics of regulating amalgam restorations.

The investigators that are listed here, including myself, are a mixture of economists,

epidemiologists, and people with expertise in operative dentistry.

This is sponsored by the California Dental Association and American Dental Association, but we had complete academic freedom. I have no financial ties to these organizations. They have not reviewed this presentation. This represents our own view of our analysis, and we have prepared a paper that is now being reviewed by a national public health journal.

So our objective was this--to estimate the financial impact of banning the use of amalgam restorations and we did it for three cohorts of the population. Children and women of child-bearing age in the entire population.

There is no national data set that's available, that gives the number of amalgams being received by every individual, so we had to make some approximations.

We used data from, claim data from Delta Dental of Michigan, which is a carrier based in Michigan but also in surrounding states, that has large market share, so we're talking about close to a million people in the study, each year of the study.

And we ran this data from 1992 to 2004. But obviously this is a problem because we have people

here who only have insurance, so we know that insurance does affect use.

So we looked at another data set that came from the American Dental Association where they survey a sample of dentists, and obtained from these dentists the services they provide to their patients, so this is to all patients, insured and non-insured, and we know from this analysis that these two data sets are in close agreement.

A third big methodological issue is coming up with an estimate of the relationship between the price of services and the response in terms of quantity. As price goes up, obviously, the quantity goes down.

And we used the elasticity estimate for all dentistry, which is well-known because restorative dentistry includes, is such a large component of dental services, and we did sensitivity analysis to determine how different elasticity estimates would affect our results.

Then we calculated the rate of change in amalgams and fees for the last 12 years. We estimated the per capita amalgam use and then projected that to our national estimates using census data, and then looked at the impact of the ban on these sub groups

from 2005 to 2020.

Amalgam trends first. In 2005, we project 166 million restorations, about 31 percent of them would be amalgams, 47 percent resin composite restorations, and the rest, the various kinds of cast crowns.

Interestingly, for all sub groups and all ages, amalgam is declining about 3.7 percent a year. So, we've seem, you know, over that period a fairly dramatic decline in the use of amalgam, which we assume will continue.

The ban is going to have an effect on fees. It's going to increase fees, obviously, because the substitute services, resin composites and crowns are going to be more expensive than amalgams and require more visits.

As price goes up, you're going to have fewer restorations and it's going to increase costs.

Let me give you an example for the total population. If the ban was for the total population, the average restoration would increase in fees by $52. You'd have 15 million fewer restorations provided in this country. That's about 10 percent of all restorations.

And in the figure on the right, you see

the impact in the first year of the cost of the ban. For the total ban, it would be about $8 billion and that constitutes about 10 percent of total dental expenditures this year.

For children and women, it would be about 4 billion, and for just children it would be about a billion.

In addition, there's an unmeasured impact that we could not measure but it's important to understand it. First is the announcement effect. Clearly, if you ban it for one sub group of the population, you're going to cause some patients and some dentists to decrease the use of amalgams and use these substitute services, which will probably increase overall fees for restorations even at a greater rate. Plus, you'd have a significant impact, detrimental impact on all health, because as price goes up and expenditures go up, you'd find people using fewer services, and this is associated with pain, missing teeth, disability, what have you.

And of course this would increase disparities in access to care because it's the lower-income families that would be most affected by these increased fees and expenditures.

And dentists' incomes would increase about

$3 billion if it was banned on the total population. That's approximately, in gross income, about $20,000 per dentist.

So from our view, the amalgam ban is going to increase dental expenditures. I don't think there's any doubt about that. It's going to reduce access in oral health. Based on the New York Times report on your findings yesterday, there's no evidence of amalgams causing ill health.

So our recommendation is do not ban the use of amalgams. Thank you.

DR. BURTON: Thank you for your input.

Our next speaker is Dr. Boyd Haley. You ready, Dr. Haley?

DR. HALEY: Yes.

DR. BURTON: Thank you.

DR. HALEY: I would say that I have "no dog in this fight." I'm nothing but a hard-core scientist that believes in numbers and measuring things, and this first slide is a slide that comes off the Internet, that's been made several times. It's something that we do in the lab.

I teach at the University of Kentucky, called Mercury, Science and Politics. Freshmen students do it. And I would point out that if the

mercury level came out as estimated by the American Dental Association, you would not be able to see a vapor coming off an amalgam filling in this form.

We've also measured this in much more rigorous scientific ways and sealed the containers, and the mercury comes off quite rapidly, and it's very simple, a freshman chemistry student can do it.

And this begs the question of how much mercury emitted from amalgams and why hasn't the FDA demanded that somebody, an uninterested party, do this and estimate--or not estimate but actually tell people how much mercury comes off of one amalgam spill.

It hasn't been done. Why is it critically important? If you take neurons in culture and you treat them to nanomolar, that's ten to the minus ninth molar levels. In a study published in the JADA, the Journal of the American Dental Association, they showed that mercury in the brain of people with Alzheimer's disease, and certain controls, is in the micromolar range. That's a thousand to ten thousandfold higher level than causes neurons to die in culture. It is important.

Now I want to question the thing about the Alzheimer's Association that says mercury in amalgams have no contribution to this disease. This is a

neuron and the neuron's axon is held together by tubulin, as shown in this slide. I don't have a lot of time to go through and tell you all the details.

But this is disintegrated in Alzheimer's disease and it is caused to be disintegrated in any tissue, in animals, et cetera, that you expose to mercury vapor, and this slide shows the technology that we developed, used by NIH, even today, to look at the GTP binding to tubulin and what you can say is that mercury, and only mercury, will cause the same biochemical photolabeling profile as you see in an Alzheimer's disease brain. Lead won't do this; copper won't do this. Nothing but mercury will do this.

If you take a dental amalgam and you soak it in water for just an hour, as I show on this slide, and you take a sample of that and you add it to the same brain homogenates, you get exactly the same effect as if you're adding pure mercury to that system. This indicates that amalgams do release toxic mercury and this mercury, if it gets into the brain, can cause an aberration, similar as you find in Alzheimer's disease. All of this data has been published in refereed journals.

If you look at mercury in Alzheimer's disease, we can say that mercury has been shown to

cause the following disorders. This is in a handout you'll get. I won't go through it but if you look at this, it is Total Publications where we see it.

It can produce nerve fibrillary tangles. It can affect the tau hyperphosphorylation, and it can increase the synthesis of beta amyloid protein which makes the senile plaques. In other words, mercury and only mercury will do these things, and yet it's ignored by the NIH, and several other people, and say mercury can't be a contributor.

What I would submit to you, that while I would not make the claim that dental amalgams cause Alzheimer's disease, I would absolutely state that anyone that's carrying a significant number of amalgams for 30, 40 or 50 years, would cross that thin red line into Alzheimer's dementia quicker if they had amalgam fillings. There's absolutely no doubt about that.

It is a toxin. It has never been put into a biological system without it showing severe toxicity at the nanomolar level. And we have these slides, it's all published, and there's a protein called glutamine synthetase that's seen elevated. I published this first. It's been repeated, now, by two different groups. It's considered one of the leading

markers for Alzheimer's disease, if they can get the diagnostic test reliable, and what you can say is that mercury, and only mercury, will inhibit this enzyme at the levels we're talking about.

In addition to the glutamine synthetase, creatine kinase, an enzyme that is well known to biochemists to be exquisitely sensitive to mercury, is 95 percent inhibited in a Alzheimer's disease brain. This has been published in Molecular Brain Research.

The genetic susceptibility, as Mr. Burke talked about earlier, they have "beat this protein to death," to try and find out why the APO-E4 is a risk factor. You understand? The second highest concentration in the body is in your cerebral spinal fluid. The EPO-E2 is a mercury buffer. The EPO-E4 loses that buffer and capacity and that protein is being transported out of the CSF into the serum, to be cleared by the liver, to get rid of oxidized cholesterol.

So it is a countercurrent movement to take mercury out of the brain, out of the cerebral spinal fluid. A publication from Germany shows that the blood level of mercury is three times higher in AD patients versus unmatched controls.

This is a paper that was published in

JADA, has kind of an unusual history, was rejected by the Journal of the American Medical Association and the New England Journal of Medicine, but it was published.

It had some conclusions that I disagree with. But one of the conclusions I look at if you look at the level of the mercury in 6 percent to 15 percent of these people, they're in the 10 to the minus 6 molar range. If you measure the mercury in the brains of certain people, that's a thousand to 10,000 pole times higher than is necessary to cause a neuron to die within a few minutes.

So you can't say that there isn't proof, that mercury can't get in the brain and can't cause problems, And you have to ask the question where does this come from? Why does it only appear in certain people?

Because these were all nuns that lived in the same convent, ate the same food, used the same dentist as far as I know, that's the reason the study was done that way, and you look at this and you say, How come a certain percentage of these people can't keep mercury out of their brain? And it's genetics.

This other disease, idiopathic dilated cardiomyopathy. That's the one we find young high

school athletes drop dead, playing football. Happens every year. You'll read about it several times. They have 178,400 nanograms of mercury per gram of tissue. That's 22,000 times higher than is in the muscle tissue or is in the heart tissue of other people. And why hasn't NIH or the FDA jumped on this and said, Where does this mercury come from and how does this contribute to the disease? Is it the cause? Is it an exacerbating factor? Or is it something that's there.

But what we can absolutely say--

DR. BURTON: One minute.

DR. HALEY: The other proof. Here's a paper that was in--the white paper they talked about. They said persons, about two and a half years after amalgam, had about the same level of mercury in their blood as those with existing amalgams, which was significantly much, much higher than people who had never had amalgams before.

And what that's telling you is that the human body retains a lot of mercury. It doesn't go out in the urine and feces. It's retained. When they chelated these people, using Dr. Vasapozhen's technique, the levels dropped 30 to 40 percent, but within two hours it was back up. Now the DMPS takes it out of the urine. So where did the mercury come in

that replaced it?

And what I'm telling you, this paper shows, absolutely, that there is a high level of mercury retained in the human body, and you can take it out of the blood for two or three hours. When you quit, it comes right back in because it's re-equilibrating, and this is absolute proof that we have mercury stores in the body that we don't talk about. This is the much ballyhooed--

DR. BURTON: Thank you very much, Dr. Haley.

DR. HALEY: Yes. Fine. Thank you.

DR. BURTON: Thank you.

Our next presenter is Dr. James Adams.

DR. FACTOR-LITVAK: No.

DR. BURTON: No. I'm sorry. Your name, please?

DR. FACTOR-LITVAK: Good morning. My name is Pam Factor-Litvak. I'm associate professor of clinical epidemiology at the Mailman School of Public Health, Columbia University in New York.

I am here today to speak about my research pertaining to mercury-containing dental restorations, also known as mercury dental fillings.

I have been asked to speak here by the

American Dental Association, and they have paid for my ticket and expenses at this meeting. I have received no other compensation from them and they have not seen this presentation before I am giving it here today.

As a epidemiologist, I'm trained to evaluate all aspects of research on a particular topic. There are certainly roles for both animal and human studies in the evaluation of possible adverse associations between substances, any substances and health outcomes. Indeed, there's ample evidence from both the animal and human literature regarding elemental mercury exposure related to dental restorations, and I'm not here to quibble with that. There's clearly evidence that there is exposure from dental restorations, especially during chewing or the consumption of hot liquids.

The question that remains is whether such exposure is related to the wide variety of health effects reported in both scientific and lay literature.

I might add that the evaluation of safety is a little bit different from the evaluation of an adverse effect.

In fact, if you want to evaluate safety it's much more difficult and it's due to a statistical

subtlety regarding testing of null hypotheses. In fact, you need sample sizes much, much larger than the evaluation of adverse associations.

As an epidemiologist, I am also trained, in particular, in the conduct of observational research, and observational research, as opposed to experimental research or randomized clinical trials, is key in evaluating health effects in humans, as for many substances such as cigarettes, it's ethically inappropriate to expose humans.

But observational research also has a very key role in evaluating the health effects of substances that are not deemed to be harmful, because you get to study people in natural environments, rather than selecting a group of people for clinical studies, and, in fact, that gives it more what we call external validity, or validity to a wider range of people.

Between 1997 and 2000, I received funding from the National Institute of Dental and Craniofacial Research to conduct a cross-sectional observational study evaluating the potential harmful effects--and they were harmful effects in terms of subtle neuropsychological and neurological effects of mercury-containing dental restorations in otherwise

healthy adults.

The study was approved by the Institutional Review Board of Columbia Presbyterian Medical Center and full informed consent was obtained from all participants.

My colleagues and I evaluated 550 healthy employees at Columbia Presbyterian Medical Center. They were ages 30 to 49. Well, we evaluated both exposure and outcomes at the same point in time, so that we couldn't actually say for sure, that exposure preceded outcome. We assumed that most of the amalgams had been placed in the teens and twenties of these people. Thereby, exposure had occurred for at least 10 to 20 years. That was a key assumption of this study and we felt that it was a very reasonable assumption of this study.

Approximately half of the sample was in the 30 to 39 age range and half in the 40 to 49 age range. And additionally, approximately half the sample were professional staff and half were support staff, and this sampling strategy assured a representative sample of medical center employees, across a wide range of sociodemographic characteristics.

Well, we called a random sample of these

employees into our general research clinic and during the approximate 90 minute visit to this clinical research center, my colleagues and I administered several examinations.

First, we had trained dentists doing a noninvasive dental examination. So what they did, using just a tongue depressor and a lamp, they looked in their mouths and ascertained each tooth, and we charted the size, the type of restoration, the size and the location of each restoration on the tooth. We did it for both amalgams, for composites, and for other resins.

We also administered a battery of neuropsychological tests which measured verbal and nonverbal memory, attention, planning, executive function and motor coordination.

We asked the participants to fill out self-administered checklists to measure symptoms of anxiety, depression, and other symptoms that had been reported in some of the anecdotal literature on dental amalgams.

We also administered a lengthy questionnaire to obtain information regarding current and childhood social circumstances, demographics, lifestyle habits, dental habits, fish consumption and

medical history.

We administered a very sophisticated measure of neurological integration, postural sway in which the subject stood on a platform under a variety of different conditions, and it measures how much you sway while you're standing still.

We took a urine sample to obtain spot concentrations of inorganic mercury, which we then adjusted for creatinine, to adjust for the urine concentration, and we also took a blood sample in which we measured blood exposure as a possible covariant and serum creatinine as a measure of renal function, and I won't talk about those results today.

Our results indicated no adverse associations between any of the measures of mercury exposure, meaning urinary mercury adjusted for creatinine, number of total amalgams in the mouth and number of occlusal amalgams in the mouth, and any of our outcome variables.

And these null associations persisted after sophisticated--

DR. BURTON: One minute.

DR. FACTOR-LITVAK: --statistical adjustment of potentially confounding variables in the analysis. We did, as expected, find significant

associations between the number of total amalgams and the number of occlusal amalgams and urinary mercury concentration, sort of bolstering what I said before, that there is exposure and measurable exposure. However, the amount of exposure was tiny and, indeed, only 5 of our 50 subjects had urinary mercury concentrations over 10 micrograms per gram of creatinine.

So from this--

DR. BURTON: Thank you very much. Your time's concluded. Have you published your results, and where?

DR. FACTOR-LITVAK: These results have been published in Environmental Health Perspectives in 2003.

DR. BURTON: Thank you.

Our next presenter, could you state your name, please.

MR. LAURENS: My name is David Laurens. I am a staff consultant to the American Association of Public Health Dentistry. I am a staff consultant to the American Association of Public Health Dentistry. I have no other interest in this particular issue. I would apologize for Dr. Watson's inability to be here due to family obligations and we thank you for the

opportunity to provide this statement.

The primary mission of the American Association of Public Health Dentistry, AAPHD, is to improve the oral health of the public. For almost 70 years, members of the association have dedicated their professional work to improve the oral health of all citizens, and, in such a way, contribute to the overall health of our nation.

Our specialty focuses on preventive oral diseases and assuring that the best possible treatment options are available to citizens. We accomplish this by keeping ourselves abreast of the most important scientific findings and using the best scientific evidence available in deciding preventive and curative options and formulating policies and recommendations.

We agree with Brown and Wells' assessment of the scientific evidence, that there is no causal association between dental amalgam restorations and health problems. In the absence of compelling evidence that dental amalgam causes or contributes to health problems, it is important to consider the benefits of its continued use in dental practice in the U.S.

AAPHD is strongly committed to the use of effective measures for the primary prevention of

dental caries. But this is not always possible. Tooth decay, dental caries, can lead to the loss of dental function, pain, disability and tooth loss. Timely restoration of decayed teeth, with durable restorative filling materials, can prevent the loss of dental function and tooth loss, thus enabling a person to regain oral health.

Tooth decay remains an important health problem in the U.S. The most recent published national data revealed that more 16 percent of adolescents, ages 12 to 15 years, and 23 percent of adults, aged 20 years or older, had decay lesions in their teeth that have not been treated. More importantly, there are significant health disparities.

Twice as many children and adolescents from families with lower incomes have lesions that remain untreated compared with those families with higher incomes.

The disparity by family income is even greater among adults and seniors. Part of the problem is that despite societal efforts, more than 108 million Americans do not have dental insurance. Thus, the cost of dental treatment is a barrier to timely receipt of dental care.

Because of its durability and other

clinical characteristics, dental amalgam restorations are less costly than other alternatives. Were dental amalgam not available, the costs of dental care would indeed be higher, thus the barriers to treatment would be greater.

In consequence, the American Association of Public Health Dentistry is concerned that eliminating dental amalgams as a restorative option for tooth decay will, in fact, increase the proportion of U.S. citizens not being able to regain oral health status and suffer from its sequelae.

It is clear that the continued use of dental amalgams will have an important health benefit at the personal and society level and should remain as a restorative treatment option.

The final decision regarding its use should be left to patient and provider. Thank you.

DR. BURTON: Thank you for your input.

Our next speaker is Mr. Jay Grant.

MR. GRANT: Thank you. My name is Jay Grant. I am the legislative counsel to the National Association of Dental Plans. I thank everyone for the opportunity to speak today. On a personal note, being in the Air Force and having my entire mouth full of amalgam, I duly hope that it's okay.

ANDP is a nonprofit trade association focused exclusively on the dental benefits industry. The membership comprises over 70 companies, 111 million Americans with dental throughout the United States.

The dental benefits industry relies on the scientific literature, along with the experience of the dental profession in setting dental benefit levels for its policies.

Dental directors and consultants who have been practicing dentists, and broad-based dental advisory committees, are key contributors of recommendations regarding dental benefits coverage for particular procedures or materials.

NADP has voluntary groups that include dental directors and other professional relations staff of dental plans, indicate that amalgam is the most studied material in use today for dental fillings. The historic scientific literature from the Food and Drug Administration, the Centers For Disease Control and Prevention, the U.S. Public Health Services, the National Health Institute, supports the efficiency of amalgam fillings, as well as a recent study published by the journal of the American Medical Association which focuses on different aspects of

child health, including neurobehavioral, neuropsychological and kidney function, concluded that there are no measured adverse effects of dental amalgam fillings on children.

Amalgam is also the most common material covered by dental benefits for posterior fillings since the inception of dental benefit programs in the early sixties. This is because dental amalgam is durable, resistant to wear, relatively inexpensive in relation to other materials.

Thus, it is the most effective material for posterior teeth, where the chewing loads are the highest and the area of restoration is difficult to keep dry. Largely for cosmetic reasons, other less-stringently-tested materials such as composite resins may be covered by benefit plans for interior teeth.

However, the costs of these materials range across the country from 40 to 60 percent more than the cost of similar amalgam fillings.

NADP recognizes that the ultimate decision on the type of filling material to use is between the patient and the provider. The dental benefit industry role is to facilitate access to care by relieving some of that cost.

The Surgeon General's report, Oral Health

2000, concluded that the cost was the top barrier for assessing dental care reported, that dental benefit coverage increased the percentage of the population seeking dental care by 20 percent. Thus reduction in dental benefits coverage result in reduction of dental care.

The 2005 NADP purchaser behavioral study showed that 71 percent of employers offer dental benefits, with the largest number, over 90 percent, among employers with over one thousand employees. The following year, the dental benefit report on enrollment found that 97 percent of all dental benefits are provided through group policies.

However, the rising costs, particularly for medical coverage, are pushing more of the costs, including dental coverage, to employees. NADP member company surveys show that more than two-thirds of groups and individuals cite the cost as the primary factor for selecting a particular dental benefit plan. No other factor, even personal dentist participation, ranks as high.

For this reason, expanding dental benefits with new coverage or higher annual maximums, or eliminating lower cost treatment options such as dental amalgams, can have an adverse effective on

coverage decisions and ultimately access to consumer care.

Providing dental benefits for the lowest cost effective treatment, which includes amalgam fillings, keeps cost affordable. In 2005, approximately 10 percent of the 21 billion in claims, 21 billion in claims, paid by dental benefit carriers were fillings. These costs were roughly equally divided between amalgam and composite fillings.

But the costs of these composite fillings, averaging 50 percent higher than amalgam, the elimination of amalgam as a filling material, absent reduction in coverage levels, would increase the overall costs of claims for dental procedures by 2.5 percent. That would equate to more than a half a billion dollars annually.

If these costs were passed on to the consumer through premium increases, it would be more than the total dental premium increases levied upon the industry in the last two years, with cost being the top factor in selecting dental benefits. Costs increase at a level that could easily reduce dental benefit coverage below 55 percent of the covered population. With that and the time, I believe the rest of my testimony has been submitted. Thank you

very much.

DR. BURTON: Thank you very much, Mr. Grant, for your input.

Our next speaker is Dr. Felix Liao.

DR. LIAO: Good morning. My name is Felix Liao. I'm a dentist with 29 years of clinical experience. I paid my own way here, and I represent only that ideal to have patients get well and stay well--mouth, mind and body.

Unlike other ADA dentists, I got out of the box. Inside that box is the old world of ADA's mercury amalgam dentistry, with its disregard for the fetus and the environment. Outside that box is the brave new world of biological medicine-dentistry. One word. Because the body no departmental or party line. I'm here to share with you that view from outside that old box, which includes letters from--well, I will also include letters from patients who have recovered their health by going down a mercury-free path, using safe mercury practices of International Academy of Oral Medicine and Toxicology.

My patients and I wish to salute the FDA for revisiting mercury amalgam issue now, and to thank all of you panel members for considering mercury amalgam's toxic effect on the human peripheral and

central nervous system.

As a mercury-free, mercury-safe biological dentist, I see many patients who have struggled long and suffered horribly. These mercury do not want to return to the ADA dentist. That's why they never see them in their office.

These patients are often at the end of their ropes as well as their hope.

Mary Puff from Minneapolis is a typical example. She writes this letter to be entered into the record of this hearing as part of my statement, exhibit one.

As you listen to this abbreviated version, please ask yourself, What needs to change to avoid more of these, more of the same? Mary Puff.

"I was diagnosed with "multiple sclerosis," in quotes, by three neurologists at The Mayo Clinic and Minneapolis Clinic of Neurology after MRIs revealed multiple lesions in my brain's frontal lobes. I asked one neurologist if he ever read any research on the link between amalgam fillings and autoimmune disease. He summarily dismissed me. I don't have to do any research. Amalgams toxicity is a fact, just like bee venom.

At 42, I am forever relegated to a

wheelchair? I don't think so.

"I took immediate action. I fired my Mayo Clinic neurologist and hired a mercury-free biological dentist. On the first day of amalgam removal from my lower right quadrant, a week after declining a wheelchair, my paralyzed right hand suddenly opened while I was still in the dental chair. On the first day of chelation, upon getting a DMPS injection, my proprioception and balance snapped back, and I tossed my cane into a corner. I never retrieved it again.

"From bedridden paralysis to the bathroom on my hands and knees, I now give speeches about mercury recovery around the world, in Europe, U.S. and in the Arab Gulf. Literally back from the dead, I, Mary Puff, do not intend to remain silent about this iatrogenic poisoning."

How can this happen? And that's the end of quote. How can this happen? A published study concludes that mercury amalgam is safe. Is Mary Puff simply an inconvenient exception for the old box of mercury is safely in use for the last 150 years? If Mary Puff's case is too far out of the average, maybe this next case of JT of Centerville, Virginia, will be closer to home.

I will just read the highlights from her

letter.

"As a result of childhood trauma, heredity, and who knows what else? I have always been a highly sensitive person, mood-wise. This condition intensified in my adolescence, especially at age of 15 when I had five or so mercury fillings put in my mouth all at once.

"I remember being very depressed, starting around that age. I was a good student, so I was able to muddle through somehow; but I certainly wasn't a happy person. At midlife, 46, I had been through 20 years of interventions such as therapy, meditation, medication, and many alternative holistic approaches such as bodywork, holistic psychiatrist, trauma work, energy psychology and so on.

"Over the years, I've evolved to a highly organic lifestyle that by all counts will be considered well above the average in terms of health and fitness. However, I still have recurrent gloom and pessimistic thoughts that obsessively were in my head. I could work on them and get temporary relief but they'd always ebb back in. I struggled with mood issues continually, and most recently, before getting my mercury fillings out, I experienced mood instability, irritability and recurrent, obsessive

gloomy thoughts, such as people I love getting hurt.

"The changes I've experienced from getting the mercury fillings out of my mouth have been subtle and yet profound. Even after half of my mercury fillings was removed, I felt immediately as if a charge has been turned off from my nervous system. The benefits continued with the rest of the mercury removal. I find that I'm no loner obsessing over worrisome thoughts.

"This isn't to say that I still don't have such thoughts in reaction to expected circumstances. However, they don't plague me or swirl in my head. It's like now I can't even make myself obsessive anymore, even though I do try.

"The other mood improvement I've noticed is that I don't feel irritable. Even when circumstances irritate me, I find myself shrugging it off. It just doesn't stick. In the very recent past, I would get so irritated and I'd be clenching my fist and muttering under my breath, almost screaming internally. The reaction is simply gone.

"No matter what conventional medical experts say--

DR. BURTON: One minute.

DR. LIAO: --mercury is not good for the

human body. Okay.

What can we conclude from the living proof of these cases, and of those who have testified as survivors? Time only allows me a few bullet points. Please keep these in mind.

One. Mercury-free dentistry is good medicine, as Dr. Huggins pointed out yesterday on cholesterol, and as Mary Puff's case comeback shows. Shouldn't the medical community and the FDA sit up and pay attention?

Two. Mercury amalgam dentistry is catastrophic medicine and catastrophic economics, as you have heard testimony from recovered and suffering patients alike in the past two years.

Three. Mercury-free dentistry can help reduce and even reverse neurological deficits without side effects and without relapse, as living testimonials have shown. Isn't that good medicine?

Four. Mercury amalgam--

DR. BURTON: Thank you very much, Dr. Liao.

DR. LIAO: Thank you.

DR. BURTON: Thank you for your time.

Our next presenter is Ms. Freya Koss.

MS. KOSS: My name is Freya Koss. I am

one of untold numbers of consumers who have sustained neurological and other illnesses resulting from placement of amalgam dental fillings.

In March of 1998, I was among the majority of dental patients, unaware that their silver fillings are 50 percent mercury. Seven days after having an existing amalgam filling drilled out and replaced with a new one, I was suddenly struck with double visions and within weeks I developed drooping eyelids, loss of equilibrium and ataxia, symptoms I had never experienced before.

The double vision progressively worsened and nine days after the onset, my optometrist, alarmed by my condition, referred me to an neuro-ophthalmologist, stating that, quote, "the sudden onset of double vision indicated emergent neurological problems."

I later found out that she suspected a brain tumor or multiple sclerosis.

Although lesions weren't apparent in brain scans, I was diagnosed with MS, lupus, and then myasthenia gravis, based on clinical symptoms, a 10,000 ANA titer, and elevated rheumatoid factor and liver enzymes.

Having been told that there were no known

causes, no cures, only steroids to, quote, fix my eyes, I began the solitary journey to find out what caused this sudden onset of life-threatening autoimmune diseases.

I was unwilling to accept a lifetime of chronic debilitating illness as I had seen friends of mine suffer for years, and die of these diseases.

Having received no hope from the medical profession, I spent 20 hours a day searching the Internet, searching for answers. A woman from England gave me the answer. She had MS for ten years, had two amalgams improperly removed by a dentist who exposed her to lethal amounts of mercury vapor, and was struck with double vision seven days later.

That was my answer. I had had an old amalgam filling drilled out and replaced, seven days prior to the onset of double vision.

Working through the nights, for months, I read hundreds of scientific studies and governmental documents. That's one of them. There was no mistake. I had been mercury poisoned. I learned that mercury, in the form of vapor, is constantly released from dental amalgam fillings. The fillings that I had been told were silver.

I learned that MS, lupus, myasthenia

gravis, and other autoimmune diseases, had been linked to mercury exposure from amalgam dental fillings. I learned that heavy metals, such as mercury dental fillings, can impair function of the skeletal muscle acetylcholine receptor and calcium channels to the motor nerve terminal, compromising the neuromuscular transmission, often diagnosed as myasthenia gravis.

This information was never given to me by a physician. I had to find it myself.

I learned from the research of Swedish neurologist, Patrick Storetebecker, that the route for transport from the upper teeth to the brain amounts to less than 10 centimeters, and that neurotoxins from the oral cavity can cause neurological symptoms such as ptosis or drooping eyelids, sclerosis, epilepsy, and myasthenia gravis.

Dr. Storetebecker's book is available, if you're interested in reading it.

I had my amalgam fillings removed slowly and safely by a mercury-free dentist, and within a few weeks the muscle pain in my neck and shoulders disappeared, leg rashes began to fade, and I slowly regained my equilibrium.

It took three years for my eyelids to lift and other functions to return. However, I still

experience occasionally balance problems and have neuropathy of my feet and brow area, Raynaud's syndrome and occasional leg cramping. I also have some double vision. I was mercury poisoned, and in all likelihood will be affected for the rest of my life.

We are here today with the hope the FDA will listen to the public and examine the role they have played in fostering the belief that the benefits of using amalgam outweigh the risks, while not acknowledging that any risk exists, despite the plethora of research supporting the dangers. The FDA has allowed the continued implanting of mercury in the body, the second most non-radioactive metal, solely based on the anecdotal claim of its 150 years of use, without classification or proof of safety or efficacy.

Neither the FDA nor the ADA have done actual research on the safety of amalgams but claim they are safe. One must wonder, is the mouth the only safe haven for mercury?

In deference to the FDA drafters of the white paper with regard to the World Health Organization's position on dental amalgam, WHO has never taken a position on the adverse health effects of dental amalgam. However, they have reported that

dental amalgam is the largest human exposure to mercury.

In their mercury policy report of 1991, and again, in 2005, WHO, quote, confirmed that mercury contained in dental amalgam is the greatest source of mercury vapor.

In summary, there is no need to use mercury in dentistry, considering safe alternatives, and the mounting evidence of harm.

It is incumbent upon the FDA to protect the public, at once mandate informed consent, accurately classify mercury amalgam as a class 3 implant. Give warnings for children and women of childbearing age. Ban mercury fillings for pregnant women. And uphold the precautionary principle: Do no harm. Abolish mercury in dentistry. Thank you very much.

DR. BURTON: Thank you for your presentation.

Our next speaker is Ms. Sandra Duffy.

MS. DUFFY: I'm president for Consumers for Dental Choice. I am a Government lawyer from Portland, Oregon, and I have no financial interest in this matter.

The FDA is telling you that your job is to

decide to agree with its white paper, or to tweak it in some minor way. FDA is apparently trying to resurrect its 2002 proposed rule. The draft rules proposed special controls, date from 1991, and therefore--and I'm not making this up--warn patients of amalgam=s zinc content, not its mercury content. That's shocking for a health agency, isn't it?

But that 2002 proposal is dead, legally dead. It requires a legal panel recommendation before classifying and it has none.

The one done in 1993, before all the bans and limitations on mercury products were done is obsolete and did not follow FDA rules when it was done. Repeat. Before FDA classifies, you must recommend. If FDA staff thinks otherwise, they need to get legal advice.

If they had gotten legal advice before, we would not have needed to sue them earlier this year for failing to classify amalgams. We urge you to call a meeting promptly, to take up the classification issue, and the only one you can do, with the state of the science today, is a class three. Today, you can act on a narrower question. Ban mercury fillings for pregnant women.

FDA's failing to act on this issue is

scandalous. FDA refuses to classify. It has never classified encapsulated mercury amalgam. It has never done an environmental impact statement on this, the largest source of mercury in wastewater treatment plants,

It refuses to require proof of safety by manufacturers, a step that one of them has admitted to shareholders it cannot meet. It adopts a sham substantial equivalence test and the Department of Justice has now admitted, in court, that FDA is applying a substantial equivalence test that it has never adopted.

The Commissioner never made an order of substantial equivalence, says the Justice Department. The FDA is approving the product as if there were one. Why? Any one of these steps, environmental impact statement, classifying, group of safety, all leads directly to the end of amalgam. So FDA ignores its legal duty to do any of them. Small wonder that the FDA "jumped the gun" last week, rushing to press, the announcement mercury fillings are safe, even before you have met.

Are they saying the fillings are safe for pregnant women who live near power plants or who are raised on tuna fish.

Michael Creighton, the physician-turned novelist, said, quote: "The system works against problem solving because if you solve a problem your funding ends." End of quote.

The ADA is using a product in the 21st Century that medicine abandoned in the 19th Century.

The Consumers for Dental Choice Council, Charlie Brown, proposed to ADA counsel, Peter Sfikas, last April, an exit route for amalgam. ADA would say, due to environmental reasons only, it would stop endorsing the product, after, say, January 1st of 2007. Brown offered a meeting and asked for no money at all. ADA refused. ADA remains the only health group in the nation endorsing mercury in a health product, and again, an unnecessary product.

If this panel review will be used by the FDA for a new proposed rule, FDA cannot limit your literature review to just the last ten years.

All of the literature which receives a prior review, the FDA is trying to lock up. FDA is desperately trying to avoid having you consider the Vimmy studies of sheep and monkeys, showing radioactive mercury amalgam dispersed throughout the body within 30 days of implantation.

The ADA says animal studies don't count.

That is a scientific foolishness. As Dr. Feigel of the FDA stated in the testimony film clip you saw yesterday. He admits animal studies are used to set policy and safety levels.

Certainly we aren't going to experiment on pregnant women to determine the percentage of mercury-damaged babies.

In 28 years of trial work, my job was to marshal evidence, to show a fact had been proven or that it had not been proven. You heard evidence that mercury vapor is emitted from amalgams far in excess of Government safety levels. Dr. Haley testified about this. Studies show there is no safe level of mercury. For example, Kazanskis's work. FDA always cites the 1993 USPHS report on mercury to support its claim of amalgam safety, but even that report states that amalgam is one of the two largest sources of mercury.

And the 1999 report, which they never mention, states that there is no scientific proof of safety for amalgam. You've heard evidence here, yesterday and today, that mercury is absorbed into the body, the Vimy studies show that, and that one out of eight women giving birth have so much mercury in their bodies, that their babies are at risk of brain damage.

One-third of dentists are mercury-free, which is proof that amalgams are completely unnecessary.

Consumers For Dental Choice conducted a survey about Medicaid payment. Every state responding said it would pay for alternative, but patients just aren't informed of this.

I am going to be giving these four CDs to the person who takes the submissions, and I'm going to place them in the record. They are scientific study submissions from experts and the public in the 2002 proposed rule process, to make them of record.

I specifically want to point out that since 1957, studies have shown amalgam causes--

DR. BURTON: One minute, please.

MS. DUFFY: --periodontal disease. I'm just going to sum up, then, here, and say that the testimony of the last two days make clear that change is needed in government's untrammeled approval of mercury fillings. The only group still supporting it is pro-mercury dentists. Of course changing work habits isn't easy for any of us but mercury fillings simply aren't needed to fill cavities.

The starting point to phase out these products that pose a risk to human health, and ruinous

to the environment, is to protect pregnant women now.

Amalgam exposes pregnant women to mercury. On that, every federal agency, CDC, U.S. Public Health, even FDA, agree. The health of unborn children must come before dental economics. Please ban mercury fillings for pregnant women. Thank you.

DR. BURTON: Thank you for your testimony.

Our next speaker is Dr. Steve Marcus.

DR. MARKUS: I'm Dr. Steve Markus. I've been a practicing dentist for 31 years in Haddon Heights, New Jersey, and I'm here on my own nickel. I've been a member of the ADA for those 31 years also. Hopefully this conference will mark the fulfillment of a quest that has taken more than 15 years. That quest is to be proven prudent in erring on the side of caution.

We have heard that expression, "erring on the side of caution," several times yesterday, from the Canadian and the Swedish speakers. Let me tell you about my quest.

While at the University of Pennsylvania School of Dental Medicine, my mother got into the habit of sending me clippings from the Sunday Times. Once a month, I got a big fat envelope of clippings. Then, probably early '90s, I got one envelope that

changed my professional life. In it was an article about the Vimy study in Calgary.

When I read the words of Alton Lacey, president of the ADA, as you recall hearing yesterday, that this was not a human study, I wondered what the ADA's agenda was. I stopped placing mercury fillings that day and have not done so since.

I began thinking about the storage of mercury scrap. The ADA told us we had to seal it in a glass jar under antifreeze or another high specific gravity fluid. But the ADA also told us, out of the other side of their mouth, that it was totally safe to put in an American's mouth.

So why did that amalgam scrap eat a hole in the metal lid of the jar that had the antifreeze in it. What was it doing to my patients? I thought about the environmental impact of mercury that was going through my suction and out into the sewer system. I installed a separator on my building and now every year, we proudly recycle between 3 and 5 pounds of mercury that otherwise would have become an ecological bio-burden.

At the beginning, it took a lot of time to explain the whole issue to my patients. The Vimy study, the story about amalgam scrap, and that I

preferred to err on the side of caution.

When properly educated, who in their right mind would choose mercury?

About 20 years ago, the profession underwent a major paradigm shift when autoimmune deficiency syndrome came on the horizon. We had to treat everyone as if they were an AIDS patient--gloves, sterilizable, or disposable instruments. Now another shift is in order. We must treat everyone as if they are one of the susceptible to mercury toxicity. We have heard repeatedly about the myriad symptoms and syndromes that are part of the diagnostic equation. The A to Z, from Alzheimer's to zygote abortion and everything in between.

A member of the panel on this side, I forget who it was, yesterday, asked a very salient question of Dr. Philipson. What did he expect the epidemiological impact of eliminating the placement of dental amalgam to be in Sweden. Many pro-mercury dentists argued yesterday, and then again today, about the cost of eliminating mercury from their armamentarium.

But nobody asked what the financial burden is on the medical system for symptoms resulting from the use of mercury implanted in people's skulls.

Hopefully, if this body deems it correct to take the appropriate stance, we may see serious decreases in the amount that medical insurance has to pay for the treatment of chronic illnesses that physicians might otherwise attribute to factors other than people's fillings.

Pro-mercury dentists argued yesterday, and then again today, that composite fillings are less durable and that dental schools can't teach it. This is all ludicrous. Dental schools teach dexterity and they teach technique. They also insist on the use of the rubber dam for all students.

That makes the placement of composite resins a non-issue. It can be trained and it should be done. It's the training of the faculty that is going to take a little bit of time because there are a lot of "dinosaurs" still teaching in dental schools.

The image of the fighting and screaming welfare child is the exception and not the rule, it is certainly not the reason you have to approve the use of mercury in children's heads, a substance that has no known half-life, as we have heard, and cause symptoms 35 years later, not five to seven years later, as the limitations of the study presented yesterday indicated.

What needs to be done is that parents need to be educated, that what they allow their children to put into their mouths is going to affect their spending money. The schools need to reform the foods that they offer. Soda machines need to be banned. Warnings need to be placed on Mountain Dew. Not to get off the topic, but if anybody has ever seen what "Dew mouth" looks like. "Dew mouth" is as disgusting as "meth mouth," and we really need to educate the public so that the children don't get decay.

I mean, we thought decay was going to be eliminated by this point in time, but you go into any convenience store and people are just hitting the Big Gulp machines and drinking soda.

So the issue isn't how much is it going to cost to put amalgam fillings in people's heads versus composites. The issue is prevention. How do you give informed consult that says--

DR. BURTON: One minute.

DR. MARKUS: --here is a list of 105 symptoms you might develop as a result of this filling I'm placing. Keep it in your wallet. It might be 30 years until they develop but if they do, they're going to be tremendously debilitating.

On the basis of the information provided,

how many of you are willing to take the risk to have a large mercury filling placed in your mouth, in your child's mouth, in the mouth of the woman who's about to deliver your grandchild? In the mouth of somebody who doesn't even know that they're pregnant? How, therefore, can you allow it in the mouth of any American?

I encourage you to consider taking a cautious and courageous approach. The ADA won't do it, the state boards of dentistry won't do it, and the dental profession isn't going to do it voluntarily. The act of placing mercury in the head of anyone, not just a pregnant woman or a young child, must be banned. How do you, the FDA, listen to all this information and apologize to future mercury cripples.

DR. BURTON: Thank you for your input.

We're attempting to get the public portion done. I'd like to clean up the list that we have here.

Is Dr. James Adams here?

DR. HALEY: He couldn't make it. He asked me to fill in.

DR. BURTON: All right. And you're Dr. Haley?

DR. HALEY: Yes.

DR. BURTON: We had a discussion between the chairs on that. I mean, I would be happy to have a substitution for him but someone who has not previously spoken. It could be from your group, would be fine, but we would have to have--you know, it would then be allowing you to have a second opportunity, which we have not allowed anyone else to have. But if you had someone else from your group who would like to speak for him, that would be acceptable.

So if you want to take a moment, I would be happy to consider someone else, but just not you because you've already had an opportunity to speak.

Yes, could you come--well, give me a moment and let me see if some of the other people we have listed here are here. I'll get back to you in just a moment.

Dr. David Sarrett. Is he present?

[No response]

DR. BURTON: Okay. We'll move on.

Ms. Karen Burns. Okay. Would you like to come forward.

MS. BURNS: Hello. I am here--

DR. BURTON: Could you state your name and--

MS. BURNS: Oh, yes. My name is Karen

Burns, and I was a dental assistant for 24 years, until I couldn't work anymore. But I'm here to represent myself, to talk to you people, to ask you to please listen, and please study this material, so that other people won't have to suffer, so people in your family who might have this sensitivity might not have to suffer, like the dentist before me just said. Let's treat everyone as though they had the sensitivity, like we treat AIDS patients, so that we don't cross-infect the whole public.

Nobody knows who has the sensitivity, or not. Nobody knows why they get this, or not. But we do. This is a real thing. I've been sick for eight years. If I could tell you what my life is like. It's really hard, to even talk about it.

Even the cure, with cancer, going to chelation treatments, not having any veins left. I've gone through 12 chelation treatments and I'm still very elevated.

When I first started dental assisting, we didn't wear masks or gloves. We had a vial of mercury and silver pellets that we put together by hand. And you want to talk about vapors being in the room. Back then we even had rugs in the rooms because we didn't understand that these vapors were everywhere.

This is a great opportunity for you people to consider this issue, even though they've been saying for 150 years that this has been a safe product. You must see the damage that it's doing. Even if it's doing it to ten people. Why should ten people--which it's not, it's much more--why should anyone have to suffer this illness when it can be totally eradicated? We don't need to use dental amalgam fillings.

So what if it costs the dentist another $20,000 on his practice. I'm sure he could absorb that cost, like the guy was saying from the ADA. You know? And why do poor children have to get stuck with amalgams? Is that right, too? Why can't Medicaid pick up the difference in the cost?

And this last dentist that spoke, too. We need to educate children about soda and things. My children don't have cavities, you know, and if they did, I would never put amalgam in. I hope you people just listen and find it in your heart to really consider all of this. It's a real thing. Thank you.

DR. BURTON: Thank you for your input.

Again, some people who had asked today. Is Virginia Pritchett here?

[No response]

DR. BURTON: Mark Morin?

[No response]

DR. BURTON: Nory Oakes?

[No response]

DR. BURTON: Dr. William Duncan?

DR. DUNCAN: Yes.

DR. BURTON: Okay. Would you come forward. Thank you.

DR. DUNCAN: I'm Dr. William Duncan. I served for ten years for Congressman Istook from Oklahoma as the Appropriations Committee associate on the Labor, Health and Human Services, and Education bill, overseeing the Centers For Disease Control. Today, I'm a lobbyist and I have no interest whatsoever in the issue, in any financial way, other than as a former public servant, and I used to do FDA issues as well.

My testimony is from a 2004 hearing, the last official hearing I covered for CDC, and I have a quote from Julie Gerberding, the CDC director, that is quite significant.

We were talking about mercury in vaccines and she stated: "Let's get to the basics. The basics are that mercury is a heavy metal. It is not something that anyone wants to have in their body, if

they don't have to.

"The steps that we have taken, we've all recommended removing Thimerosal, which is 25 percent mercury, from vaccine supplies as quickly as possible, as a prudent common sense approach to the situation because we cannot prove a null hypothesis that it is not harmful.@

Further, I worked with Dr. Jim Pirkle who is the chief toxicologist at the Centers For Disease Control, Environmental Health Sciences Lab, and he told me that the more he has studied mercury and arsenic and lead, the more concerned he has become over the public health impact of these metals and mercury is the most toxic.

I've been asked to cover the release rate for mercury, from newly-made mercury amalgams, they created mercury amalgam using commercial single-spill samples under supervision of a board-certified dentist and stored samples appropriately.

And the composition of the two alloys tested showed a significant increase in the amount of chemical composition. Of the two alloys studied, the old one, at 50 percent mercury, had a much higher release rate--excuse me. The high copper alloy releases significantly more mercury than the old-

fashioned, low copper alloy, as the slides show on the screen. The analyzer showed that only mercury is present in the emitted vapor and it exactly matches the signature of pure mercury on the slides on your screen.

Therefore, the amount of this is from a single-spill filling, and most fillings are one to three spills, and the actual release rates in the first four hours could not be measured, so release rates on one day are presumably higher than reported.

The mercury amalgams emit much higher levels of mercury during the first few weeks than reported in the literature, for fillings, placed years ago. High copper alloys, primarily released today, release much more mercury than older style, low copper alloy fillings. The amounts emitted during the first week are far in excess of the FDA guidelines for exposure to methylmercury. In vitro studies are needed to more exactly quantify the release rates from new fillings, and presently, there is no data on vapor release rates for newly-made fillings except for this study.

This was funded by the Wallace Foundation and was a master's thesis paper for Jamie Aguilar at Arizona State University and there's an article now in

preparation on that basis.

I would urge the committee to follow Julie Gerberding's recommendation, the head of the Centers For Disease Control, and come to the conclusion that nobody wants mercury in their body if they don't have to have it there. In my years of doing public health for Congress, and overseeing the public health service, avoidance of mercury poisoning is one of the number one areas that the entire schools of public health, all twenty-nine of them continually work on, to try to limit the exposure, because getting it out of somebody's body, as you've heard testimony here today from people who are poisoned with it, is very difficult, and very expensive in the process, and usually not paid for by insurance.

So it's important, when one out of eight children, as Dr. Pirkle discovered, he's the one who did that study that EPA published, when one out of eight children of women of childbearing age are toxic from mercury, it's having a direct impact on the entire education system.

We're spending $60 billion a year to educate people, children in schools, many of whom are damaged with neurological disability from mercury poisoning. Thank you for this opportunity to testify.

DR. BURTON: Dr. Duncan, could you clarify one thing. You weren't clear. You said you were a lobbyist but who do you represent?

Dr. DUNCAN: I'm not here representing anyone except my own experience.

DR. BURTON: Okay. I'm sorry. You stated you were a lobbyist and I--

DR. DUNCAN: Yes, I just stated I was a lobbyist because that--you know. I'm not working for Congressman Istook any longer.

DR. BURTON: Okay.

DR. DUNCAN: But I did that issue for him, for ten years, and this is something that I learned in ten years. That it's--see, I saw all kinds of people with all kinds of chronic diseases come to me for NIH funding for this problem and that problem, and they were all kind of puzzling things.

You can imagine my shock, as I prepared for the 2004 hearing on mercury, to realize that many of the symptoms that people were coming to me with were the exact same symptoms that showed up in mercury-poisoned patients, where there was documented evidence directly from Harvard School of Public Health, and other places.

You know, you look at the symptoms of the

people and all of a sudden you see psoriasis and you see neurological problems, and you see chronic fatigue syndrome, and you see autoimmune diseases show up, and these are all directly related, according to the case reports I was reading, to the mercury poisoning they received in a known dose, and we knew how much mercury they got.

I can tell you, I have had all my mercury fillings out and I'm very glad to have done so, and did the same for my wife, and our grandchildren are next.documentary

So prudence on the part of the FDA--you guys have already removed mercury from teething powders, you took Thimerosal off the market as mercurochrome because it wasn't safe to put it on topically. If you can't put it on topically, as an occasional thing for a cut, why would you put something in your mouth that you just leave there for years?

DR. BURTON: Thank you for your input. Thank you for your clarification.

Mr. John Rowe.

MR. ROWE: Good morning. I'm John Rowe from Oxon Hill, Maryland. I'm here as a individual but in the interest of full disclosure, I did use to

work for the House Committee on Government Reform and Oversight. I coordinated three congressional hearings on the subject of dental amalgam.

On a personal note, several years ago I was being treated at the University of Maryland Dental School, received seven amalgams. There was no discussion about what kind of restorative material to use. It was just mix the amalgams, put them in. At that time, I had no idea what that was. Two years later, I was diagnosed with chronic myeloid leukemia.

Now I can't tell you with absolute certainty that the mercury poisoning from the amalgam was the trigger for my leukemia, but I also, after reading thousands of documents, I can't tell you with absolute certainty that it was not the trigger. It very well could have been.

But, you know, all that experience makes me wonder, where's the informed consent? Why wasn't there some kind of a discussion of here are the alternative materials, the pros and cons of what are your choices?

And then during the congressional hearings, this issue of the gag rule came up constantly, and while the ADA denies that there's a gag rule, there most certainly is in the eyes of many

state dental boards, and various dentists have lost their licenses or were in jeopardy of losing their licenses because of discussions about the alterative materials and the mention of the fact that mercury is in the amalgam.

Informed consent is an honored tradition in every other facet of medicine; every other facet of medicine. Why isn't it a tradition in dentistry and why, in fact, is it actually prohibited in many states, in dentistry? That's a very puzzling question to me.

It recently came to my attention that there's controversy in the European Union about the transport of amalgam from the manufacturer to the warehouses and to the dental offices. Restrictions on the transport of hazardous materials is interfering with the free flow of the amalgam to its place of use because it's so hazardous.

Many good brains in the European Union don't want it on the public highways. They don't want it on the aircraft. And of course there are workplace rules for storing that amalgam until it gets used, and as you've heard several times, once amalgam comes back out of a mouth it has to be handled as a hazardous waste.

But yet it's safe while in the human mouth. That's another thing that just defies logic and defies common sense. I cannot reconcile that. And finally, and to be brief, the Institute of Medicine, part of the National Science Foundation, as you've heard before, estimates that at least, at least 60,000 babies are born a year, every year in the United States, with the risk of learning disabilities because they've been mercury-poisoned through the placenta from their mother and from their mother's amalgams. Sixty thousand a year.

Now it's not like we're giving these kids the common cold and they're going to feel bad for a week and get over it. We are imposing life-long disabilities on these children that are going to adversely impact their quality of life, and the quality of life of their extended family for many, many years.

As a father of four, a grandfather of ten, I'm a great-grandfather of one with another great-grandchild on the way, this just tears my heart out. If nothing else comes out of this conference today, and yesterday, please, please act responsibly so we stop poisoning our babies. Please.

DR. BURTON: Thank you for your input.

Mr. Ernest West?

[Pause]

DR. BURTON: Are you speaking for Dr. Adams?

DR. DUNCAN: Sir, I spoke for Dr. Adams.

DR. BURTON: Okay. Thank you very much.

DR. WEST: Ladies and gentlemen, my name is Ernie West. I'm here from Gillette, Wyoming, supporting my wife, Dr. Painter, and I would like you to watch this little video of the videos that were seen yesterday.

[Video played back.]

DR. BURTON: Thank you for your presentation. I'd like to take this opportunity to thank all the public presenters over the last two days for their input and all your materials that have been presented will be fully considered by the panel in our discussions, which will begin this afternoon.

Per our agenda, we'll go ahead at this point and take our break. We'd like again, try to keep this to about ten minutes, so we will reconvene at 10:15, and we'll be continuing with our literature review portion of the meeting. So we'll take our break now. Please return and be ready to start at 10:15. Thank you.

[Break from 10:03 a.m. to 10:19 a.m.]

DR. BURTON: As we start this next portion of our agenda, we'll be having a literature review, and this is the FDA white paper review of recent scientific studies, and our presenter will be Dr. Meryl Paule, director of the Division of Neurotoxicity, NCTR.

Dr. Slikker, are you going to be introducing him?

DR. PAULE: I am Meryl Paule.

DR. BURTON: Yes.

DR. PAULE: By point of order, I think that Dr. Canaday, in responding to questions yesterday about uncertainty factors, has passed out some information describing exactly how that goes on. So in response to those queries, please look at the information that Dr. Canaday has passed out.

DR. BURTON: Thank you. I believe each of the panelists should have that in front of them. I believe it was handed out during the break. If they'd care to review that, we'll consider that in our discussions later.

Dr. Paule.

DR. PAULE: It will also be released to the audience and posted for anyone who's interested in

getting a copy of that.

Distinguished panel and guests, it's a pleasure to be here today to talk about the review that we've conducted on mercury amalgam, and by way of introduction, I would offer the outline that follows. I would like to first give a brief introduction and charge for the current review, talk about other U.S. Government agency evaluations of mercury, speak about the strategy and process that we went through in this current updated review, and then for the review, discuss assessments of previous Government agency literature reviews conducted by the Agency for Toxic Substances Disease Registry and the Environmental Protection Agency, reviews by nongovernment public health organizations, the World Health Organization, and then close with our review of additional scientific literature which includes a summary of 34 studies that we highlighted for this white paper, and then close with an overall review of our conclusions.

So to address recent concerns expressed by some members of the public related to adverse health effects of dental amalgam and consistent with the FDA's ongoing commitment to monitor the state of the science regarding the safety of dental amalgam, the FDA's National Center for Toxicological Research which

is charged to prepare review of the state of the science regarding the potential health risk of mercury in dental amalgam.

In 1997, as you've heard before from Dr. Canaday, the U.S. Public Health Service last reviewed mercury in mercury amalgam. The purpose of the 2006 review is to determine whether peer-reviewed scientific information published since 1997 substantially changes our comprehension of the health risk of mercury in dental amalgam.

The specifics for the charge for this review were to build upon previous reviews by public health agencies. There were extensive reviews conducted, previously. You've heard about a lot of them.

We felt that there was no need to duplicate previous effort. We were to identify peer-reviewed studies important to the comprehension of health risk for inorganic or elemental mercury, or to mercury in dental amalgam since 1997.

Continuing on with the specifics of the charge, we were to provide a critical review of each of the identified studies or refer to other public health agency reviews, as appropriate.

We were to provide an overall assessment

and summary conclusions, specifically what contributions have peer-reviewed scientific literature published after 1997 made to our understanding of mercury-containing dental amalgam and its potential risk to human health?

We've already mentioned that other U.S. Public Health Agency evaluations for mercury have been conducted. The Agency for Toxic Substances and Disease Registry, ATSDR, in 1999, formulated a toxicology profile for mercury.

They published a detailed peer review evaluation and established minimal risk levels.

Since that time, and on an annual basis, ATSDR has undergone literature searches to identify studies that might affect conclusions regarding the risk and require a profile update.

The Environmental Protection Agency, in 2002, conducted an integrated risk information system screening level literature review for both mercury vapor and inorganic mercury. They used this review to decide whether to update their health-based reference values used in environmental regulatory programs for mercury.

The review and strategy process was to identify relevant peer-reviewed articles published

from May 2003 to May of 2006. This period overlaps recent reviews by the Agency for Toxic Substances and Disease Registry and coincides with the publication of a 2003 World Health Organization document and the EPA's 2002 literature review.

We utilized search terms that included dental amalgam, mercury vapor, elemental mercury, and metallic mercury, with a focus on adverse effects and toxicity in animal and human studies.

Initially, we identified 911 citations that met some aspect of these search criteria. Out of an initial review, we requested 200 of those for further assessment, out of which 24 were judged to provide the most significant new information.

You have in your packets, as an appendix A to the white paper, the exact acceptance criteria that we followed for, including these papers in the scientific review.

None of the studies were excluded based upon their conclusions. In addition to the 24 papers that were new publications, we identified ten more that were selected from the ATSDR update in the 2002 EPA/IRIS literature reviews.

Assessments of previous Government reports of literature reviews provide health effects-based

exposure reference values for mercury vapor and inorganic mercury. Those reviews compare reference exposure values in urinary mercury concentrations and they're applicable to making safety assessments for dental amalgam.

Health-based comparison values help regulatory and public health agencies make decisions. EPA, and the Agency for Toxic Substances and Disease Registry values, have been derived, that are useful for our review. The EPA generates reference concentrations and reference doses. The Agency for Toxic Substances and Disease Registry generates minimal risk level values.

Minimal risk levels are defined as estimates of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects, in this case particularly with respect to noncarginogenic end points, over a specific duration of exposure.

Although the term "minimal risk level" may seem to imply a slight level of risk, MRLs are in fact considered to represent safe levels of exposure for all populations, including sensitive sub groups.

Minimal risk levels are derived when reliable and sufficient data exists to identify the

target organ or organs of effect or the most sensitive health effect or effects for a specific duration within a given round of exposure.

With respect to EPA's RFCs and RFDs, in general, reference concentration is an estimate with uncertainty spanning perhaps an order of magnitude of a daily inhalation exposure of the human population, including sensitive sub groups, that is likely to be without an appreciable risk of deleterious effects during a lifetime.

In general, the reference doses of estimate with uncertainty spanning perhaps an order of magnitude of a daily exposure to the human population, including sensitive sub groups, that is likely to be without an appreciable risk of deleterious effects during a lifetime.

It's important to remember that minimal risk levels, reference concentrations, and reference doses do not represent thresholds for toxicity.

Exposure to a level just above the minimal risk level or the reference concentration or reference dose does not mean that adverse health effects are expected. These values are derived by identifying a no observed effect level, or lowest observed effect level and dividing by uncertainty factors to

protectively account for what is not known, and again the information that Dr. Canaday handed out, specifics of how those uncertainty factors are used are described.

In 1999, the Agency for Toxic Substances and Disease Registry derived a minimal risk level for chronic inhalation exposure to elemental mercury vapor of two, zero point two micrograms per cubic meter, 24 hours a day, seven days a week.

Exposure at this MRL is estimated to result in a dose of about 4 micrograms per day. This approximates the general population exposure to mercury, inhaled or swallowed from dental amalgam, which is estimated to range from one to five micrograms per day.

The ATSDR has evaluated the mercury literature since 1999, with the last assessment occurring in 2005.

These reviews are totally independent of the reviews conducted by either the FDA or the EPA, and those reviews have not identified any new studies that would warrant an update of their 1999 toxicological profile, and thus determined, at that time, that there was no need to change the minimal risk level for chronic exposure to mercury vapor.

From the Environmental Protection Agency's 2002 IRIS screening literature used, it was determined that the literature published since the inhalation reference concentration for elementary mercury was derived in 1990, that there were in fact publication that could potentially produce a change in the reference concentration.

However, after further consideration of those publications, the EPA chose not to initiate a new evaluation of the reference concentration, which remains today at 0.3 microgram per cubic meter, 24 hours a day, seven days a week.

For the reference dose, the literature published since its derivation in 1998, there was no additional pertinent studies that could potentially produce a change in the RFD and therefore it was left as was.

You see this slide before, indicating where the EPA's and the ATSDR's reference values fall with respect to air mercury concentrations, and those values encompass the estimated mercury exposure range as determined by the United States Public Health Service in 1993.

The Agency for Toxic Substances and Disease Registry and the EPA reviews are relevant to

FDA needs because of several reasons. The ATSDR minimal risk level and the EPA's reference concentration for mercury vapor have remained unchanged through the present.

They have been derived to be protective of human health, including sensitive populations, subpopulations, and they provide additional insurance that the FDA has not overlooked peer review studies relevant to its assessment of the potential for health effects from dental amalgam exposures.

Reviews have been conducted by nongovernment public health organizations, one of which was performed by the World Health Organization in 2003, who commissioned the generation of the concise international chemical assessment document, Human Health Effects of Elementary Inorganic Mercury.

An Agency for Toxic Substances and Disease Registry expert was the lead author on that, and that product was peer reviewed by an international panel of experts.

The conclusions from that report were that the estimated exposure to mercury from dental amalgam is less than 5 micrograms per day for most persons in the United States and Canada. That the central nervous system is considered to be the most sensitive

target for long-term exposure to mercury vapor.

That subclinical effects have been reported to occur at workplace concentrations of greater than or equal to 20 micrograms per cubic meter, and that the tolerable concentration for elemental mercury vapor is 0.2 micrograms per liter squared, again, 24 hours a day, seven days a week.

Now for our review of the scientific literature that we identified as relevant to this topic.

Initially, there were several reports that dealt specifically with mercury toxicokinetics and exposure characteristics. In several studies, it was again reiterated and demonstrated that background levels of mercury in urine, in persons with no amalgams, ranged from 0.54 to 1.4 micrograms per gram of creatinine.

Persons with dental amalgams that are not occupationally exposed to mercury range from less than one microgram to about three micrograms per gram creatinine.

And studies reported that for each ten mercury amalgam surfaces, urine levels increased by approximately 0.8 to 1.4 micrograms per gram creatinine, adults. That increase is actually less in

children.

It was known before, and again redemonstrated, that approximately 70 to 80 percent of mercury is absorbed when it's inhaled, and airborne levels of lower than 10 micrograms per cubic meter are not accurately reflected in urine mercury levels.

So at very low ambient levels of mercury, those values are not reflected in urinary concentrations. It was also demonstrated in one paper that after removal of mercury amalgam restorations or fillings, there was no large decrease in blood mercury levels. In fact a marginal blood level decrease in mercury, even two to three years after the mercury amalgams were removed.

In utero, that is, fetal exposure to mercury via placental transfer, while much less than maternal levels, is actually greater than it is post-natally, were neonatal mercury levels actually continue decreasing after birth, even with continued exposure, presumably via breast milk from the mother.

In studies concerning occupational exposure to mercury vapor and neural behavioral outcomes, we considered studies, or most of the studies were based upon observation to high levels of mercury in the environmental situation at work.

Concentrations of mercury vapor that exceed occupational exposure guidelines or psychological effects are the most sensitive end points. Workers exhibited neurological deficits at the end of chronic exposure when urine mercury values were about 21 micrograms per gram of creatinine at the time of testing, yet five years later, those effects had gone away and were no different from controls.

It's also important to point out that there was a series of extensive neurobehaviorial workups in these same subjects, that showed absolutely on effect, even when their urine mercury levels were at 21 micrograms per gram.

Workers occupationally exposed to extremely high levels of mercury, resulting in mean peak urinary levels of more than 460 micrograms per gram of creatinine, or which is more than one to two hundred times greater than those observed in persons with dental amalgams, do in fact have long-lasting effects on peripheral nervous system function.

Most measures, from an extensive neural behavioral test battery showed no residual effects, even after exposure to these very high levels, and there were no findings of effects on tests for dementia or cognitive function.