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MERCURY IN DENTAL AMALGAMS: AN EXAMINATION OF THE SCIENCE

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

NOVEMBER 14, 2002

Serial No. 107–159

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpo.gov/congress/house
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U.S. GOVERNMENT PRINTING OFFICE

84–699 PDF WASHINGTON : 2003

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CONTENTS

Page

Hearing held on November 14, 2002 1

Statement of:

Haley, Boyd E., professor and chair, Department of Chemistry, University of Kentucky, Lexington, KY; G. Mark Richardson, director and risk assessment specialist, Risklogic Scientific Services, Inc., Ottawa, Canada; Richard D. Fischer, past president of International Academy of Oral Medicine and Toxicology; J. Rodway Mackert, professor of oral rehabilitation, Medical College of Georgia Dental School, Athens, GA, on behalf of the American Dental Association; Gregory Stoute, president, National Dental Association, Cambridge, MA; and Michael Bender, director, Mercury Policy Project, Montpelier, VT 25

Tabak, Lawrence A., Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD; and Dr. David W. Feigal, Director, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD 108

Letters, statements, etc., submitted for the record by:

Bender, Michael, director, Mercury Policy Project, Montpelier, VT, prepared statement of 88

Burton, Hon. Dan, a Representative in Congress from the State of Indiana, prepared statement of 5

Feigal, Dr. David W., Director, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD, prepared statement of 118

Fischer, Richard D., past president of International Academy of Oral Medicine and Toxicology, prepared statement of 47

Haley, Boyd E., professor and chair, Department of Chemistry, University of Kentucky, Lexington, KY, prepared statement of 29

Mackert, J. Rodway, professor of oral rehabilitation, Medical College of Georgia Dental School, Athens, GA, on behalf of the American Dental Association, prepared statement of 56

Richardson, G. Mark, director and risk assessment specialist, Risklogic Scientific Services, Inc., Ottawa, Canada, prepared statement of 37

Stoute, Gregory, president, National Dental Association, Cambridge, MA, prepared statement of 83

Tabak, Lawrence A., Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD, prepared statement of 110

Watson, Hon. Diane E., a Representative in Congress from the State of California, prepared statement of 12

MERCURY IN DENTAL AMALGAMS: AN EXAMINATION OF THE SCIENCE

THURSDAY, NOVEMBER 14, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 11:13 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Otter, Norton, and Watson.

Also present: Representatives Norwood, Simpson, and Linder.

Staff present: Kevin Binger, staff director; David A. Kass, deputy chief counsel; S. Elizabeth Clay and John Rowe, professional staff members; Blain Rethmeier, communications director; Allyson Blandford, assistant to chief counsel; Robert A. Briggs, chief clerk; Robin Butler, office manager; Joshua E. Gillespie, deputy chief clerk; Nicholis Mutton, deputy communications director; Susie Schulte, legislative assistant; Mindi Walker, staff assistant; Corinne Zaccagnini, systems administrator; Sarah Depres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. Good morning. A quorum of the committee being present, the Committee on Government Reform will come to order.

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

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

I ask unanimous consent that Congressman Norwood, Linder, and Simpson, who are not members of the committee, be permitted to participate in today's hearing. Without objection, so ordered.

Sorry I am a little bit late. I appreciate all of you being here.

Over the last 3 years, the Government Reform Committee has looked at health and safety issues related to mercury-containing products.

In July 2000, we held a hearing entitled, "Mercury in Medicine—Are we Taking Unnecessary Risks?" We focused on why mercury is put into vaccines that are given to children. We received a report during that hearing that indicated that the symptoms of mercury toxicity are similar to the symptoms of autism.

That was followed up by a hearing on April 18, 2002, entitled, "The Autism Epidemic—Is the NIH and CDC Response Adequate?"

We found out during our investigations over the past several years that to our knowledge there has never been a real test of whether or not thimerosal and mercury in vaccines is a problem. In the 1920's, when they first started using thimerosal, which contains mercury and is used as a preservative, it was tested on I think twenty-some people who had meningitis, all of whom died, and because they didn't die or have any reactions to the thimerosal before they died, they said that it really did not have any adverse effect and it was a good preservative.

To my knowledge, there has never been any blind study, double blind study, or anything else done on thimerosal or mercury in vaccines since the 1920's. If that is the case, and we believe it is, that is a real failure of our health agencies because that should have been checked out.

We have conducted numerous hearings on the Vaccine Injury Compensation Program. I am pleased that Dr. Dave Weldon and our ranking minority member, Congressman Waxman, joined me in co-sponsoring legislation to improve the compensation program. I believe through our oversight activities that we have made it absolutely clear to the Department of Justice and the Department of Health and Human Services that the intent of Congress was and remains that the National Vaccine Injury Compensation Program should be a no-fault compensation program, not a contentious tort system. I really regret that we have not been able to get this bill passed because it would really help a lot of people, and there are an awful lot of people who have suffered who have not been compensated because of vaccine related injuries.

Today's hearing will focus primarily on the science regarding mercury-containing dental amalgams.

Early in our investigation, I was accused of being "anti-vaccine." Now that we are examining the science behind the use of mercury in dental amalgams, I suppose I will be characterized as anti-dentistry. And after all the money I have spent on my teeth, that cannot be the case. [Laughter.]

Neither charge could be further from the truth.

Immunizations have been portrayed as one of the greatest advances in public health during the past century, second only to clean water and improved hygiene. I think that is true, although we need to make sure that vaccines are as safe as possible. I am for vaccines, I am for good dentistry, but we want to make sure we are not putting toxic chemicals into our bodies and into our children. Dentistry is a noble profession that has contributed to Americans' overall health and quality of life. While immunizations may offer a great benefit, they also carry risks. And while dentistry offers great benefit, the continued use of a toxic substance such as mercury needs to be examined.

Mercury is mercury, whether it is methyl or ethyl, organic or inorganic. There is no one in this room or in all of science who can say with any level of credibility that any form of mercury is safe. While many people have absolutely no problem with being injected with thimerosal-containing vaccines, and while mercury-containing dental amalgams have been used for over 150 years, we have a responsibility to protect those who are pregnant women, infants and

young children, those who have autoimmune dysfunction, and the elderly.

And with dental amalgams, I am also talking about economically disadvantaged people of all ages who depend upon Medicaid for dental care. They either get fillings with mercury, or they get no fillings at all.

Are we giving them short-term relief by helping pay for their dental work, only to set them up for disaster, for long term problems down the road? We do not know.

The simple fact is that mercury is one of the most toxic minerals on earth, second only to radioactive materials.

The fillings that typically are called "silver" fillings because of their color probably should be called mercury fillings. They consist of 50 percent or more of mercury. And a lot of people do not even know that. When the mercury is mixed with an alloy of powdered metals, it becomes Dental Amalgam.

For many years dental schools taught that when the amalgam hardens it becomes inert. They taught that there was no further risk from the mercury. However, from research, we now know that mercury vapor continues to leech from amalgams for as long as it remains in the mouth. The fumes are inhaled into the human body and minute particles chip off and are ingested into the stomach as fillings wear out.

This has important health implications, since mercury has a long half-life and has the potential for doing significant damage to the kidneys and brain. For reasons that are not well understood, some individuals seem to hold on to the mercury absorbed by their body, leaving them at risk for neurological or renal damage.

In 1999 the U.S. Agency for Toxic Substances and Disease Registry published the "Toxicological Profile in Mercury." That was in 1999 that it was published. This report stated that poisonous mercury vapors are constantly emitted from amalgam, that these vapors go first to the brain, and that children are most at risk because their brains are still developing. The report further states that the mercury crosses the placenta into the developing fetus, and that it is transmitted through a mother's milk to the infant.

The Food and Drug Administration has taken what appears to be a bipolar approach to protecting the public from mercury. While denying that thimerosal in vaccines or mercury in dental amalgams poses any health risk, it has taken a stand against mercury in other products.

The FDA has repeatedly issued strong warnings cautioning the public, and in particular pregnant women and young children, to restrict their consumption of tuna and other fish that is known to contain mercury.

The FDA has determined that mercury compounds used as active ingredients in over-the-counter drug products were not "generally recognized as safe." Mercurochrome had mercury in it. When we were kids we used to put it on our skin to heal wounds. It is a topical dressing. You cannot sell it anymore, you cannot use it anymore because it has mercury in it and they said it might leech through the skin and into the body and into the brain. And yet we inoculate our kids with thimerosal in it, and have for years, and we put metal amalgams into their mouths.

They also have not approved any mercury-containing compounds as food additives.

The FDA also states that lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels.

I have asked before, and I will ask again, how is it that mercury is not safe for food additives and over-the-counter drugs but it is safe in our vaccines and in our dental fillings?

There are alternatives to mercury-containing amalgams. Shouldn't we exercise an abundance of caution and hasten the use of these alternatives?

Before I conclude, I want to commend Congresswoman Diane Watson of California for her initiative in sponsoring H.R. 4163, the Mercury in Dental Filling Disclosure and Prohibition Act.

As I have already stated, the Federal Government must exercise special care for vulnerable population groups. Physical and in particular neurological damage from mercury is an issue that crosses all boundaries—geographic, economic, ethnic, religious, age, and gender—all boundaries.

It is said that you cannot stop an idea whose time has come. Hasn't the time come for us to really examine this and whether or not exposing people to mercury through medical interventions is something that we should do away with.

I look forward to hearing from our witnesses today, to learning about the scientific research that has been conducted and to learn about what research still needs to be done.

The Record will remain open until November 28, 2002.

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

Opening Statement

Dan Burton (R-IN)

Chairman

Committee on Government Reform

**"Mercury in Dental Amalgams and Vaccines:
An Examination of the Science."**

November 14, 2002

2154 Rayburn House Office Building

Washington, D.C.

Over the last three years, the Government Reform Committee has looked at health and safety issues related to Mercury-containing products.

In July 2000, we held a hearing titled, "Mercury in Medicine – Are we Taking Unnecessary Risks?" We focused on why mercury is put into vaccines that are given to children. We received a report during that hearing that indicated that the symptoms of mercury toxicity are similar to the symptoms of autism.

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Today's hearing will focus primarily on the science regarding mercury-containing dental amalgams.

Early on in our investigation, I was accused of being "anti-vaccine." Now that we are examining the science behind the use of mercury in dental amalgams, I suppose I'll be characterized as anti-dentistry. Neither charge could be further from the truth!

Immunizations have been portrayed as one of the greatest advances in public health during the past century, second only to clean water and improved hygiene. I think that's true—although we need to make sure vaccines are as safe as possible. Dentistry is a noble profession that has contributed to Americans' overall health and quality of life. While immunizations may offer great benefit, they also carry risks. And while dentistry offers great benefit, the continued use of a toxic substance such as mercury needs examination.

Mercury is mercury, whether it is methyl or ethyl, organic or inorganic. There is no one in this room or in all of science who can say with any level or credibility that any form of mercury is safe. While many people have absolutely no problem from being injected with thimerosal-containing vaccines; and while mercury-containing dental amalgams have been used for over 150 years, we have a responsibility to protect those

who are pregnant women, infants and young children, those with autoimmune dysfunction, and the elderly.

And with dental amalgams, I'm also talking about economically disadvantaged people of all ages who depend upon Medicaid for dental care. They either get fillings with mercury, or no fillings at all.

Are we giving them short-term relief by helping pay for their dental work, only to set them up for disaster – for long-term problems down the road?

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The fillings that typically are called "Silver" fillings because of their color probably should be called mercury fillings. They consist of 50% or more of mercury. When the mercury is mixed with an alloy of powdered metals, it becomes Dental Amalgam.

For many years dental schools taught that when the amalgam hardens it becomes inert. They taught that there was no further risk from the mercury.

However, from research, we now know that mercury vapor continues to leech from amalgams for as long as it remains in the mouth. The fumes are inhaled into the human body and minute particles chip off and are ingested into the stomach as fillings wear.

This has important health implications, since mercury has a long half-life and has the potential for doing significant damage to the kidneys and brain. For reasons that are not well understood, some individuals seem to hold on to the mercury absorbed by their body, leaving them at risk for neurological or renal damage.

In 1999 the U.S. Agency for Toxic Substances and Disease Registry, published the Toxicological Profile in Mercury (Update). This report stated that poisonous mercury vapors are constantly emitted from amalgam, that these vapors go first to the brain, and that children are most at risk because their brains are still developing. The report further states that the mercury crosses the placenta to the developing fetus, and that it is transmitted through a mother's milk to the infant.

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- The FDA has repeatedly issued strong warnings cautioning the public, and in particular pregnant women and young children to restrict their consumption of tuna and other fish that is known to contain mercury.
- The FDA has determined that mercury compounds used as active ingredients in over-the-counter drug products were not "generally recognized as safe."
- They also have not approved any mercury-containing compounds as food additives.
- The FDA also states, "Lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels.

I've asked before, and I'll ask again. How is it that mercury is not safe for food additives and over-the-counter drugs, but it is safe in our vaccines and in our dental fillings?

There are alternatives to mercury-containing amalgams. Shouldn't we exercise an abundance of caution and hasten the use of those alternatives?

Before I conclude, I want to commend Congresswoman Diane Watson of California for her initiative in sponsoring H.R. 4163, The Mercury in Dental Filling Disclosure and Prohibition Act.

As I've already stated, the federal government must exercise special care for vulnerable population groups. Physical and in particular neurological damage from mercury is an issue that crosses all boundaries – geographic, economic, ethnic, and religious, age, and gender – all boundaries!

It is said that you can't stop an idea whose time has come. Hasn't the time come to exposing people to mercury through medical interventions?

I look forward to hearing from our witnesses today, to learning about the scientific research that has been conducted and to learn about what research still needs to be done.

The Record will remain open until November 28, 2002.

I now recognize my colleague, Mr. Waxman for his opening statement.

Mr. BURTON. I now recognize Ms. Watson for her statement, and after that we will go to our guests.

Ms. WATSON. Thank you so much, Mr. Chairman. I would like to thank you for your leadership and your hard work on this important issue. Above and beyond your diligence as chairman of the Government Reform Committee, I applaud your vision and compassion on public health issues. Your ability to reach across the aisle and co-author H.R. 4163 is a tribute and is a testimony to your dedication to, and your concern for the public well being. I truly believe that elected public officials are the stewards of public health. I also want you to know that the importance of this issue is highlighted by your decision to have this hearing before stepping down as Chair. So thank you and your staff again. I look forward to this and other work we will do together in the future.

As a former Chair of the California Health and Human Services Committee for 17 years, I was given constant testimony as to the status of Californian's health, especially those in the lower socioeconomic sector of our population. In the medical professions, including dentistry, professionals have sworn to "do no harm." Dentists have stood behind a long history of utilizing mercury; however, a long history of use is no excuse.

Mercury in any form is as much of a health risk as lead in paint and asbestos. Mercury is being taken out of other health care products as well as disinfectants, thermometers, childhood vaccines, and even horse medicine. With mercury, a highly toxic substance, as the main ingredient in dental amalgams, I can only ask a very simple question—why take the risk?

In 1991 I wrote a law, Section 1648.10 of the California State Business and Professions code, that mandated a fact sheet be produced by the California State Dental Board stating the risks as well as the efficacies of dental materials. Over the next 9 years, the board did not comply. But I am pleased to see that our Governor has installed a new California Dental Board. For the first time in California history, the legislature closed down a State board before its authorization time had run its course.

Of biggest concern to me when I wrote the law was amalgam, because it is composed of approximately 50 percent mercury, a very pervasive and persistent toxic element. Mercury has been placed on the list of reproductive toxic substances in California's Proposition 65. I found that most consumers did not know amalgam contained mercury, and it is easy to see why. The filling is simply called "silver" by organized dentistry—a very deceptive misnomer.

Mercury must be removed from the last known use in the human body. Again I ask, why take the risk? Consumers have not been informed about the differing properties of various dental materials—for example, resin, gold, porcelain, and mercury amalgam—and they have certainly not been told of the possible risks to their health and the environment. The public has a right to know. The public has a right to be informed and to make choices.

Regrettably, the American Dental Association has a provision in its code of ethics to stop dentists from initiating communications with patients about the risks of mercury dental fillings. I would say shame on them. This what I call "the gag rule" has unfortunately been enforced by many dentist-dominated State dental boards. I

am happy to report that yesterday the Iowa Dental Board repealed its gag rule, and that earlier this year Oregon did likewise. The dental board in my home State of California repealed its gag rule in 1999. It is now time for the American Dental Association to stop blocking communications from dentists informing their patients about amalgam. It is time for every State dental board to stop enforcing this gag rule and to do the right thing.

This current legislation, H.R. 4163, introduced by Chairman Burton and I, is an extension of my California State disclosure law. The bill has three main goals: One, to ban mercury amalgam for children under 18, pregnant women, or nursing mothers, effective immediately; two, dental disclosure and a health warning for all consumers, effective immediately; and three, a phase-out of all mercury amalgam use in the United States by January 1, 2007.

The provisions of the bill reflect the fact that mercury poses a particular risk to children, lactating and pregnant women. The U.S. Agency for Toxic Substances and Disease Registry states that poisonous mercury vapors are constantly emitted from dental amalgams, that these vapors go first to the brain, and that children are most at risk because their brains are still developing. The report further states that mercury can go through the placenta to the fetus, and through the mother's breast milk to the infant. The two most common occurrences of mercury toxicity in humans are from dental amalgams and fish. It is time pregnant women learn as much about the amalgam risks as they do the risks from mercury-laced fish. The fact that mercury vapor is continually being emitted from the mercury amalgam fillings is not disputed by anyone. Again I ask, why take the risk?

There is a growing international movement in both scientific and dental communities that now disapprove of amalgam, and the government of Canada advised in 1996 against its use for pregnant women, for children, and people with kidney problems, orthodontic braces, or mercury allergies. Indeed, the major manufacturer of amalgam warned back in 1997 that amalgam is contra indicated, meaning not to be used, for those five vulnerable population categories. Sweden, Germany, Austria, and now Norway have announced plans to go mercury-free, and the U.K. says pregnant women should not get mercury fillings.

What is happening in the United States? We hope that we will see a movement starting with this bill, because mercury is an environmental poison and listed as the No. 1 environmental poison by the World Health Organizations.

I am very pleased to inform you that the National Convention of the NAACP endorsed H.R. 4163. And I tell you how significant that is, because I had a group of minority dentists come to me and they said, "How dare you scare people into thinking that they do not want to come in because we are putting poisons in their mouths." I said, "You as medical people, are you saying to me that you do not want to inform your patients about what is in that amalgam, if there is a risk? I do not understand, if you are sworn to do no harm."

So to be able to convince the NAACP, and all these dentists who are members, that there is a considerable threat to lower socioeconomic people and people that they serve, because they are the

ones that go in and get the fillings and they are the ones who are at risk and they should be able to know, and we should be able to inform them, then they can make the choice. The dentists said to me, "Well, it is cheaper. You know, people do not like to go to the dentist anyway." That does not prevail. That is not a compelling argument when a person's health is at risk. So we have the NAACP's endorsement, and I am very, very pleased to announce that.

And last, the subject of the Food and Drug Administration classification of dental mercury amalgam must be addressed. The FDA must come forward and be open and honest with Americans.

And so we are hoping that this bill, Mr. Chairman, will be a beginning. I look forward to the testimony that is going to be presented here this morning. I am pleased to have the opportunity to hear the scientific and regulatory testimony on this issue. I think there is a lot to be learned, a lot to go public, and a lot for Americans to consider.

So thank you for your leadership, and thank you to the presenters. If I slip out for a moment, I have business in another building but I will have heard your testimony. So thank you, Mr. Chairman, for the opportunity.

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

Opening Remarks of Diane E. Watson, M.C.
Government Reform Hearing on November 14th, 2002
"Mercury in Dental Amalgams:
An Examination of the Science"

****

Thank you Mr. Chairman.

I would like to thank you for you leadership and hard work on this important issue. Above and beyond your diligence as Chairman of the Government Reform Committee, I applaud your vision and compassion on public health issues. Your ability to reach across the aisle and co-author H.R. 4163, "Mercury in Dental Filling Disclosure and Prohibition Act ", is a testament to your dedication to, and concern for the public well being. I truly believe that elected public officials are the stewards of public health. I also want you to know that the importance of this issue is highlighted by your decision to have this hearing before stepping down as Chair. Thank you again. I look forward to this and other work we will do together in the future.

As former Chair of the California Health and Human Services Committee for 17 years, I was given constant testimony as to the status of Californian's health, especially the lower socio-economic section of our population. In the medical professions, including dentistry, professionals have sworn to "do no harm". Dentists have stood behind a long history of utilizing mercury. However, a long history of use is no excuse. Mercury in any form is as much of a health risk as leaded paint and asbestos. Mercury is being taken out of other health care products including disinfectants, thermometers, childhood vaccines, and even horse medicine. With mercury, a highly toxic substance, as the main ingredient in dental amalgams, I can only ask a very simple question, "Why take the risk?".

In 1992 I wrote a law, Section 1648.10 of the California State Business and Professions code, that mandated a fact sheet be produced by the California State Dental Board stating the risks as well as the efficacies of dental materials. Over the next 9 years the Board did not comply, and I am pleased to see that

Governor Davis has installed a new California Dental Board. For the first time in California history, the Legislature closed down a state board before it's authorization time had run.

Of biggest concern to me when I wrote the law was amalgam - because it is composed of approximately 50% mercury, a very pervasive and persistent toxic element. Mercury had been placed on the list of reproductive toxic substances in California's Proposition 65. I found that most consumers did not know amalgam contained mercury - and it is easy to see why. The filling is called "silver" by organized dentistry - a deceptive misnomer.

Mercury must be removed from the last known use in the human body. Again I ask, "Why take the risk?" Consumers have not been informed about the differing properties of various dental materials --for example, resin, gold, porcelain, and mercury amalgam -- and they have certainly not been told of the possible risks to their health and the environment. The public has a right to be informed and to choose.

Regrettably, the American Dental Association has a provision in its code of ethics to stop dentists from initiating communications with patients about the risks of mercury dental fillings. This gag rule has unfortunately been enforced by many dentist-dominated state dental boards. I am happy to report that yesterday the Iowa Dental Board repealed its gag rule, and that earlier this year Oregon did likewise. The dental board in my home state of California repealed its gag rule in 1999. It is time for the ADA to stop blocking communications from dentists informing patients about amalgam, and it is time for every state dental board to stop enforcing this gag rule.

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A growing international movement in both the scientific and

dental communities now disapprove of amalgam, and the government of Canada advised in 1996 against its use for (1) pregnant women, (2) children, and people with: (3) kidney problems, (4) orthodontic braces, or (5) mercury allergies. Indeed, the major manufacturer of amalgam warned back in 1997 that amalgam is contra indicated (meaning not to be used) for those five vulnerable population categories. Sweden, Germany, Austria, and now Norway have announced plans to go "mercury-free," and the U.K. says pregnant women should not get mercury fillings.

Mercury is an environmental poison. Mercury is listed as the #1 environmental poison by the World Health Organization. The Environmental Protection Agency has listed mercury as #1 of the 19 most persistent and bio-accumulative toxic metals. Dentists are responsible for serious mercury pollution. In a recent article in *The Los Angeles Times*, dentists were called the biggest mercury polluters in the United States. In the U.S., dentistry might be the only unregulated major source of mercury discharge to the environment. Dental fillings

constitute the largest source of direct mercury pollution in wastewater. Due to unmitigated mercury dumping by a factory into Minamata Bay, Japan, signifcantly higher than normal rates of birth defects and brain damage found in a population of 10,000+ is an appalling testament to the dangers of mercury. Another environmental danger arises when mercury dental fillings are removed from a patient's mouth; the removed filling is improperly discarded, thus releasing poisonous mercury in soil and water sources. "Why take the risk?"

Increased attention to mercury risk is apparent around the nation. I am pleased to inform you, that the national convention of the NAACP endorsed H.R. 4163. Also, the National Black Caucus of State Legislators has called for legislation to protect children and pregnant women from mercury dental fillings. Alternatives to mercury based dental filings exist -- porcelain and resin fillings for example --but many publicly and privately financed health plans do not allow consumers to choose alternatives to mercury amalgam fillings.

Upper-income consumers are increasingly choosing non-toxic alternatives, and low-income families are generally forced to choose mercury fillings or no fillings at all. Medicaid should pay for the alternatives, and not pay for a substance that contains mercury. "Why take the Risk?"

Lastly, the subject of the Food and Drug Administration classification of dental mercury amalgam must be addressed. In 1976, Congress gave the authority to the FDA to regulate devices. The FDA has had 26 years to classify the mercury amalgam capsule. In 1987, the FDA initially classified 110 devices, including all other dental filling materials. The FDA inexplicably skipped classifying encapsulated mercury amalgam. The FDA thus gave privileged status to the makers of a mercury product. I have a list of seven such products approved between 1980 and 1995. This action by the FDA raises fundamental questions of ethics, public safety, and complying with the laws written by Congress. At the same time, the FDA was disapproving other products containing mercury, because mercury is of course so toxic.

To understand the classification of amalgam it is important to understand the "old way" and the "current way" dentists make amalgam. The "old way" utilizes #1 Amalgam alloy--silver, copper, zinc and tin (no mercury) - designated as a Class II product by FDA and #2 "dental" mercury from a jar - designated as a Class I product by the FDA. The two components are mixed by the dentist. In the "current way" the manufacturer makes a capsule which contains mercury and the amalgam alloy as one product. No mixing is performed by the dentist. This device has never been classified by the FDA and never proven safe by the FDA's process of regulation.

For the past 15 years, while admitting it is not classified, the FDA regulates encapsulated mercury amalgam as a Class II device. The arbitrary classification of encapsulated dental amalgam is not acceptable. The FDA treats encapsulated mercury amalgam like "amalgam alloy" even though one has mercury and the other does not. Without proper protocol and due process, the FDA permits approval without proof of safety. In our system of classification, the burden of proof is on the

manufacturer, not the federal government.

Mr Chairman, I look forward to the testimony of everyone on the panel today. I am pleased to have the opportunity to hear scientific and regulatory testimony on this issue. Again, I thank you for your leadership and hard work. Mercury in Dental Amalgam: Why Take the Risk?

I Yield back my time.

Mr. BURTON. We will go next to Mr. Otter, who is a member of the committee, and then we will go to our guests, Mr. Linder and Mr. Norwood.

Mr. OTTER. Thank you, Mr. Chairman. It had been my intent when you offered me the microphone to defer to my colleagues, all three of which are guests here in our committee room today. But knowing that they are dentists, it does not bother me to have the dentists wait on me for once. [Laughter.]

So I am going to go ahead. Dentists have used amalgam fillings safely for over a century. As my dentist colleagues can and will attest to, I believe, dentists have come to rely on the use of amalgam as a harmless, dependable, and cost-effective material with which to treat their patients. In fact, numerous studies have already been conducted, apparently not for the benefit of those who would wish to ban amalgam. An assortment of health organizations, including the World Health Organization, the U.S. Public Health Service, the Food and Drug Administration has issued an opinion on this, the Center for Disease Control and Prevention and National Health Institute, all conducted and concluded that "with the exception of rare personal allergic reaction to amalgam components, there is no evidence that the use of amalgam in dental fillings causes consistent health problems in our population."

Given these conclusions, H.R. 4163 simply fixes a problem that does not exist, and therefore unnecessarily eliminates I believe a very cost-effective treatment option for dentists and for their patients.

The very function of the Department of Health and Human Services is to protect our population from health risks. This Congress and many Congresses before it continue to fund these organizations. Why then does Congress ignore the research studies and continue to second-guess and undermine the conclusions of these very organizations that we fund?

This country enjoys the most accurate and comprehensive state-of-the-art medical research institutions in the world. We should heed the advice and conclusions of these health professionals. The use of amalgams should remain a viable option for dentists and for their patients. Simply put, Mr. Chairman, I hope we are not pulling the wrong tooth here today. Thank you.

Mr. BURTON. Thank you, Mr. Otter.

Mr. Linder.

Mr. LINDER. Nothing, Mr. Chairman.

Mr. BURTON. No opening statement? Mr. Norwood.

Mr. NORWOOD. Thank you, Chairman. I would like to particularly thank you for extending the courtesy of us participating in today's hearing. I for one am very grateful for this opportunity.

I practiced dentistry for 25 years and I have placed thousands and thousands of dental amalgam restorations in my patients. And you know what? If I have been hurting my patients, I want to know about it. But I want to know about it with good science. I want to know about it from people who are trying to look at this issue for all the right reasons.

I have always known this material to be safe and effective and safe for me. If you think my patients have been around amalgam very much, I have been around it many, many greater hours and

times than any patients that I have. Now I will grant you, there are some Members of Congress who might say that it has affected me greatly. [Laughter.]

But my wife seems to think it is OK. And I want you to know that I today believe it to be OK.

I am very worried about hearings like this and what it can do to the dental health of the people of this Nation. Misinformation is very, very dangerous. Those of us who have been trying to serve our patients and improve the dental health of this Nation and have been on the front line of this, the greatest majority agree that this is a very safe restoration. The reason we call it silver is very simple—it is silver. It is not mercury. Mercury is toxic; I agree that it is toxic, particularly in some doses. So is chlorine, but salt is not deadly unless you inhale too much of it, I suppose. Mercury is not the same thing as an amalgam. We need to make that very clear in this hearing today.

We must put our emphasis on good peer reviewed science so as to not harm our citizens and keep them away from seeking dental care. I have spent my life trying to get patients to come and be treated so that in this Nation we can have the best dental care in the world. And this is not the way to go about improving dental care in America. If we are going to take action on the use of dental amalgam, we better be darn right or we are going to affect a large part of our population's ability to access care. And that should be very much part of our concern here too.

Mr. Chairman, I look forward to this hearing more than I can ever tell you. I am grateful for you allowing us to be here. I yield back my time.

Mr. BURTON. Thank you, Dr. Norwood.

Mr. Simpson, my buddy from Idaho.

Mr. SIMPSON. Thank you, Mr. Chairman. I, too, want to extend my appreciation for allowing us to sit with your committee today to explore this issue. And I also want to thank you for actually holding this hearing on H.R. 4163. I appreciate your sincere concern about this subject, and Congresswoman Watson's concern about this subject. Even though I am opposed to the bill, it is important to hold these hearings I think to be able to put forth the science concerning amalgam and other mercury-containing medical treatment.

Sometimes in this job, in fact most often in this job, we react to public concerns. Sometimes we over-react to public concerns. And let me say without equivocation that if there were any credible and supportable evidence that amalgam was unsafe to the patient, I am certain that the ADA, joined by Dr. Norwood, Dr. Leonard, and myself, would immediately call for its removal from the approved products list. I would also have the amalgam fillings removed from my mouth, of which I have a few.

What concerns me is some of the implication that was stated during the testimony of Congresswoman Watson that somehow this is a money issue with dentists, that they are less concerned with their patients' health. I can assure you that is not the case. I am not sure what she meant by stop enforcing these board-enforced gag orders that prevent dentists from communicating to their patients the effects of amalgam. I was always free in the 22 years I

practiced dentistry to communicate whatever I wanted to to my patients. In fact, not only was I free to do so, I had an obligation to communicate with them the effects of the treatment that I was going to render them. So I do not know what gag order she is specifically talking about.

It is important to remember that mercury and amalgam, as Dr. Norwood said, are not the same thing. Amalgam remains an important restorative material in dentistry, and I think will so in the future. Yes, we are developing other types of restorative material. Those are not appropriate in all circumstances and oftentimes amalgam is the best restorative material that you can use in certain circumstances.

So I believe, as everyone has said, that our decisions, and I am sure you would agree, should be based on science and not over-reacting to public concern, while we should take public concern into consideration. I do appreciate your holding these hearings today so that we can put the science forward concerning amalgam. Thank you.

Mr. BURTON. Thank you.

We will now go to our witnesses. I would submit to my colleagues who are dentists, the March 1999 study, I do not know if you have seen that or not, does have some interesting things that might be illuminating for you.

I would now like to call to the dais Dr. Boyd Haley, Ph.D., Professor and Chair of the Department of Chemistry, University of Kentucky, Lexington, Kentucky; Dr. G. Mark Richardson, Director and Risk Assessment Specialist, Risklogic Scientific Services, Inc., Ottawa, Ontario, Canada; Dr. Richard D. Fischer, a good friend of mine from Annandale, Virginia, past President of the International Academy of Oral Medicine and Toxicology; Dr. J. Rodway Mackert, Professor of Oral Rehabilitation, Medical College of Georgia Dental School, Athens, Georgia, who is here on behalf of the American Dental Association, your colleagues; Dr. Gregory Stoute, Cambridge, Massachusetts, President of the National Dental Association; Mr. Michael Bender, Director of the Mercury Policy Project, Montpelier, Vermont.

Would you all please stand and raise your right hands.

[Witnesses sworn.]

Mr. BURTON. Be seated. We will start with you, Dr. Haley. I would like to, since we have such a large number of witnesses, I would like to have you confine your remarks to as close to 5 minutes as possible so we can get to questions, because I think there is going to be an abundance of questions for all of you.

Dr. Haley.

STATEMENTS OF BOYD E. HALEY, PROFESSOR AND CHAIR, DEPARTMENT OF CHEMISTRY, UNIVERSITY OF KENTUCKY, LEXINGTON, KY; G. MARK RICHARDSON, DIRECTOR AND RISK ASSESSMENT SPECIALIST, RISKLOGIC SCIENTIFIC SERVICES, INC., OTTAWA, CANADA; RICHARD D. FISCHER, PAST PRESIDENT OF INTERNATIONAL ACADEMY OF ORAL MEDICINE AND TOXICOLOGY; J. RODWAY MACKERT, PROFESSOR OF ORAL REHABILITATION, MEDICAL COLLEGE OF GEORGIA DENTAL SCHOOL, ATHENS, GA, ON BEHALF OF THE AMERICAN DENTAL ASSOCIATION; GREGORY STOUTE, PRESIDENT, NATIONAL DENTAL ASSOCIATION, CAMBRIDGE, MA; AND MICHAEL BENDER, DIRECTOR, MERCURY POLICY PROJECT, MONTPELIER, VT

Mr. HALEY. If I could have the first slide. We will go to the science. This is what people are wanting to see. This is research done where we looked at the mercury level in a birth hair of babies, those that have become autistic and those that are controls are normal. And if you look at this slide and you look at the level, if you look at the top line that is controls, and below that, on the abscissa of that is the number of dental amalgams that the birth mother had. And in control children, you see an elevation in the birth hair with increasing number of amalgam fillings. However, with the autistics, the bottom line, no matter how many amalgam fillings the mother has, they have less on average of about 0.5 parts per million in their hair.

A reasonable interpretation of this is that autistic children represent a subset of the population that cannot effectively excrete mercury. One thing you cannot disagree with is that autistics handle mercury different than children who are born and who do not become autistic.

This slide shows the severity of the disease. As you go across, as the level of mercury in parts per million in the hair of these children decreases, the severity of the autism increases. And what you will notice is the female to male ratios are quite different in the different categories. On the far left, where the mercury levels are on average higher, you will see that the females almost all fall below the average amount of mercury in their hair, whereas the males are in the top and the females are roughly 50 percent. If you go to the next one, you see the female population disappears, drops dramatically. And as you go to the higher level, it is even more pronounced. There is only one female in the severe autism case. This fits into the situation where boys get the disease about four to five times more often than girls and they are the ones that get the severe cases of autism by far the most.

Could I have the next slide. If we look at the synergistic toxicities, and this is my major disagreement with the dental association, you cannot tell somebody what level of mercury is safe. A person that is exposed to lead, or aluminum, or a number of other things that is then exposed to mercury will have a totally different reaction than that individual who is not exposed, the same individual, if he were not exposed to other toxic metals, etc.

The thing that is very interesting here—this is with neurons in culture, the mammalian neurons, and the top line is the control—if you look at the green, that is the one that is critical, if we take

testosterone, which has no effect on the neurons when it is added alone, if you add it to a level of 15 nanomolar thimerosal, which takes several hours to kill the neurons, it will kill all the neurons 100 percent in the first time point. So, logically or reasonably speaking, the presence of testosterone enhances the toxicity of ethyl-mercury from thimerosal by over 100-fold. This fits into the data by Dr. Barren Cohen in London where he measured the testosterone level of the amniotic fluid of females that give birth to autistic children, compared it to controls, and the one consistent feature was that their amniotic fluid contained high levels of testosterone, the highest levels.

So we have a gender risk factor here that is put in by a hormone. I would also point out that estrogen has exactly the opposite effect. It is protective. If we add estrogen to this study, fewer of the neurons die out at 12 hours. And this fits into the model where you see that people say women on estrogen therapy are less likely to become demented with Alzheimer's disease.

Could I have the next slide. This is the one that amazes me that our Government, the American Medical Association, the National Institutes of Health seem to totally ignore. This is a disease called idiopathic dilated cardiomyopathy. This is young athletes that drop dead during high school athletic events. They have 22,000 times more mercury in their heart tissue. Most of these kids are inner-city kids or kids from the countryside, they are not people that eat shark, tuna, or mackerel. Where does the mercury come from? And is it causal, or is it just a happenstance? This needs to be addressed. If you want science, why don't you have NIH go look at this.

Could I have the next slide. This is the fact about neurons. If you take neurons in culture, you see significant death at five nanomolar, 5 times 10 to the minus 9th molar, that is roughly 100fold less than what you find in the brain of the average person. They have concentrations around 10 to the minus 7 molar, although it varies dramatically. So we can say this compound mercury itself is extremely neurotoxic if it gets into the brain and if you do not have the reducing equivalence to effectively chelate and remove it by the natural process.

Could I have the next slide. This is the problem with neurons.

The major protein in neurons is a protein called tubulin, it is the one at the bottom, and it forms into something called mycrotubuls, which you see at the very bottom. It is the major protein in there and when one atom of mercury binds to one molecule of tubulin, it disrupts that entire structure. Our studies have shown that mercury mimics the effects that we see in Alzheimer's disease. And so we are going to be talking about this protein for just a few minutes.

Could I have the next slide. This is what we do with our research, and I cannot explain photofendelabeling except to say that NIH funded it for about 27 years in my laboratory and this technique is used by NIH, Mayo Clinic, and everyone else that do roughly the same thing that I do. When you look at an Alzheimer diseased brain, you will find that on the average about 80 percent of them have a dramatically lowered or totally abolished

photolabeling or viability of this protein called tubulin. This is significantly found only in Alzheimer diseased brain.

Could I have the next slide. When you take heavy metals, all of them, we tested all of them, most of them are toxic but if you chelate them with the normal compounds that exist in your body, citrate, glutamate, or add EDTA, a common food additive which is used to chelate and render heavy metals less toxic, it stops the toxicity of every one of the heavy metals except mercury and it makes the mercury more toxic. So we do not have the level of protective compounds in our brain to render mercury less toxic or non-toxic. It just does not work. We did not evolve with any protective mechanisms except for glutathione and metalthien, but definitely other compounds do not work. And you will see that mercury exactly mimics the profile that you see in an Alzheimer diseased brain and that it does not affect the actin which is the bottom band below that.

Could I have the next slide. This is the take home lesson. We have two controls on the right with zero mercury, it is not all showing on your format here, and two Alzheimer diseased subjects on the left. The bottom line is as you add low levels of mercury—and you need to understand that this is done in a test tube and it is done within a few minutes, it is not letting it sit there for days, weeks, years at constant low level exposure. You can make a control brain look like an AD brain by the mere addition of mercury.

Could I have the next slide, please. This is an enzyme. We published this in Molecular Brain Research called creatine kinase in Alzheimer's diseased brain. It is over 97 percent inhibited. I have done a lot of biochemistry on this, way before the mercury issue ever came up, it has a very reactive sulfur in the active site. If you take an amalgam filling, drop it into distilled water, let it sit there, as we show here, 15 minutes, you see significant inhibition of the ability of that enzyme to make creatine phosphate. So you cannot tell me that breathing mercury vapor, having it going into your brain, if you are a person that is going to become Alzheimer's diseased is a good idea. It is a risk factor that we do not need to take.

Could I have the next slide, please. This is the last slide. If this were any other metal, it would have been kicked out and named as a cause of Alzheimer's disease a long time ago. It causes all the aberrant biochemistry, based on the simple process it inhibits thyroreactive enzymes. If you take neurons in culture and you add mercury to it, you generate neurofibrillary tangles, the diagnostic hallmark of the disease. You see the level of glutathione drop dramatically, which is also found in these type of diseases. You see the hyper-phosphorylation of protein called Tau which is only seen in Alzheimer's disease, and it increases the production and secretion of beta-amyloid protein which makes the senile plaques, which is the other major diagnostic hallmark of the disease. So if you have all of the scientific evidence behind it, this is where most people in medicine would look at it and say, hey, this is kind of conclusive evidence. But it is done on animals, it is done on a thing. So unless we take somebody and do it on a human, the dental association does not want to believe that this is something that is relevant. Most medicine fits into this category.

And I would like to point out one other——

Mr. BURTON. Doctor, if you could summarize.

Mr. HALEY. Sure. OK. Mercury is classified by dentistry as a Class I material, totally safe. If I order that and it comes into my chemistry department, it is placed in the most toxic of categories. So there is the difference; the cavalier attitude that it is safe, it is not toxic, and the attitude that, no, this is one of the most toxic chemicals known. I think they need a wake-up call. Thank you.

[The prepared statement of Mr. Haley follows:]

Boyd Haley, Ph.D.,
Professor and Chair of the Department of Chemistry, University of Kentucky
Testimony Before The Committee on Government Reform
"Mercury in Dental Amalgams: And Examination of the Science"
14 November 2002

DANGERS OF MERCURY BASED AMALGAM DENTAL FILLINGS

The major contributor to mercury body burden of American Citizens comes from dental amalgam (1). This belies the propensity of many spokespersons in organized dentistry to compare the safety of mercury in amalgams to sodium in table salt and hydrogen in water. Checking with any university level department of chemistry would immediately elucidate the chemical ridiculousness of their opinions on this issue. Amalgams leak vaporous mercury constantly into the oral cavity and this ends up in the cells of the body causing damage.

Organized dentistry is filled with statements that vastly underestimate the amount of mercury released from dental amalgams. Note the term "underestimate" as they rarely give values obtained by direct, scientific measurements using acceptable chemical protocols. The most widely accepted and taught "estimated" claim by a dental authority is from a manuscript that states it would take 450 to 530 amalgam surfaces to produce 30 micrograms mercury/g creatinine of urine mercury per day (roughly estimated as 0.067 to 0.057 g/day/surface) (15). This claim has failed numerous scientific examinations, does not remotely explain the microgram level of mercury found in urine and feces in amalgam bearers, yet is taught as fact in many of our nations dental schools.

The absolute truth could be arrived at by the simple process of making numerous, identically sized copies of today's utilized amalgams of know weight and surface area, outside of the mouth. These could be sent to appropriate unbiased laboratories for the determination of the amount of mercury vapor release from these amalgams under controlled conditions. This is simple to do and would resolve the issue of how much mercury would one minimally expect to be exposed to from an amalgam filling. I find it hard to believe that organized dentistry has not done this and knows the answer, it is the first thing a logical scientist would do. When this was done by my students using a popular amalgam material the amounts released were 7.54 g/cm2/day when undisturbed and increased to 45.49 g/cm2/day when brushed twice for 30 seconds using a medium bristle toothbrush. However, all that is released by organized dentistry is based on "estimates" that are fraught with vague interpretation and exaggerations. Whom to believe, organized dentistry or those opposed to amalgams, is a reasonable question. I recommend to this committee that it commission a simple study to scientifically measure the release of mercury from dental amalgams by a competent, independent set of laboratories. This testing should measure the release at body temperature, with and without appropriate abrasion to replicate chewing and tooth brushing. Starting with hard, scientific truths is a good way to resolve such disagreements.

A July 2000 report from a National Academy of Sciences study states that 60,000 children are born at risk for adverse neuro-developmental effects each year due to their mothers' exposure to methyl-mercury. A Center for Disease Control and Prevention

study in March 2001 (in Morbidity and Mortality Weekly Report) indicates that about 10% of American women of child-bearing age are at risk for having a baby born with neurological problems due to *in utero* mercury exposure (statistically representing about 375,000 babies/year). The fact that amalgams are most likely the major contributor to the mercury levels in American citizens should be clearly presented to the public. Yet all the American public hears is concerns about mercury in fish.

Mercury in the oral cavity is capable of creating a class of more toxic organic-mercurials. It is well known that oral and intestinal bacteria can methylate mercury to methyl-mercury increasing its uptake by fetal tissues (2,3,4). Further, it is obvious that one of the major neurotoxins produced during gingivitis and periodontal disease, methylthiol (CH_3SH), reacts immediately with Hg^{2+} creating a new class of toxic, organic mercury-thiol compounds, (CH_3-S-HgCl and CH_3S-Hg-S-CH_3), that are extremely dangerous. These compounds would behave similarly to methyl-mercury (CH_3HgCl) in that they would easily pass the gastrointestinal and blood-brain barriers. Such compounds formed in the mother's mouth may be the major cause of periodontal disease being the major risk factor for pre-term low birth weight babies.

It has been shown that mercury from amalgams placed in rats distribute to fetal tissues (6). In a comparable human study it was shown that mercury levels in mothers fluids versus that found in similar fetal materials showed increased levels in fetal materials (meconium and cord blood) that correlated with maternal and infant risk factors (7). This additionally adds to the danger of mercury from dental amalgams to babies, pregnant mothers and small children as well as adults. The well-known toxicity of mercury to kidneys makes this especially important to those patients with renal difficulties requiring kidney dialysis.

Youngsters that die of idiopathic dilated cardiomyopathy (IDCM) have 22,000 times more mercury in their heart tissue than comparable controls (8). These are the young athletes that die in high school on exertion during athletic events. It is a critical question why this observation has not received any significant attention from our NIH and AMA. Doesn't any responsible group want to know where this mercury comes from and if it is causal?

Data on the level of mercury in the birth hair of autistic versus normal children shows that a subset of the population, the autistics, are not effective at excreting mercury (5). In normal children the level of mercury in birth hair goes up with increasing amalgams in the birth mother. In contrast, in autistic children there is very little excretion of mercury in their birth hair no matter how many amalgams the birth mother has. Yet, exposing these children to a mercury challenge test to determine toxic exposure to mercury shows that the autistic children have retained higher amounts of toxic heavy metals. These observations demonstrate that autistics represent a sub-set of the population that do not physiologically handle mercury excretion like normal individuals. Autistics are therefore much more susceptible to neurological damage through exposures to mercury. It is important to note that it is the mercury retained in the body's cells that cause toxicity, not that that is found in the urine, hair and feces.

Studies on the toxicity of mercury to mammalian neurons in culture demonstrate that low nanomolar levels can have lethal effects. Experiments using this system have also demonstrated, in agreement with published literature, that many antibiotics, other heavy metals and chemicals increase the toxicity of mercury and thimerosal (ethyl mercury).

Additionally, in this same system the female hormone estrogen decreases thimerosal's toxic effects. In contrast, the male hormone testosterone greatly increases the toxicity. This may explain the 4 to 1 ratio of boys to girls that become autistic and the observation that boys represent the vast majority of the severe cases of autism.

Considering the variances in human health, age, sex, genetic diversity and exposures to toxins unknown the universal scientific truth is: "We do not know what the tolerable level of mercury is for each individual as it can vary dramatically from person to person".

It is quite plausible that neuronal impairment, as occurs in autism, would happen in the human infant exposed to mercury compounds unless the mercury was rendered harmless by the body's protective compounds such as glutathione and metallothionine. However, pre-exposing unborn children to mercury from the mother's amalgam would reduce the availability of such protective compounds and exacerbate the toxic effect. The observed toxic nanomolar level is much less (about 100-fold) than the concentration found in the brains of aged patients in many studies. It is important to note that it is not just the level of mercury that determines toxic effects! It is the level of mercury in relation to the level of the body's protective compounds, and these compounds decrease with age, disease, other toxic exposures, oxidative stress and genetic susceptibility.

Autism appears to represents a damage caused by an exposure to ethyl mercury in an infant with a developing nervous system and other organ immaturity that decreases their ability to excrete and decrease the toxicity of mercurials. This is not surprising at it is similar to what happened in the mercury caused diseases acrodynia and Minamata Bay disease.

One has to consider what is the likely danger to an aging population that is chronically exposed to mercury for 40 to 60 years from dental amalgams? The data regarding *'the specific ability'* of mercury (a known neurotoxin, found in gram quantities in many American mouths) to cause much of the aberrant biochemistry found in the brain and to produce many of the widely accepted diagnostic hallmarks of Alzheimer's disease (AD) is unquestionable. It is also easy to explain, mercury reacts with the most readily available, thiol-reactive proteins it encounters and inhibits their functions that are necessary for cell function and life. The axon of the nerve cell is very dependent on a protein called tubulin to maintain its structure and function. Tubulin is adversely affected in dramatic fashion by very low concentrations of mercury.

It is only the value and popularity of amalgam material by organized dentistry that keeps mercury from being regarded by medicine as a major exacerbating factor, if not causal, for AD. For example, mercury dramatically inhibits the functions (among others) of the brain proteins tubulin (greatly inhibited and abnormally polymerized in AD brain)(9), creatine kinase (over 90% inhibited in AD brain) (10), and glutamine synthetase (greatly inhibited, extruded into and elevated in the cerebrospinal fluid, blood in AD) (11). The latter enzyme is used in the brain to remove the excito-toxic amino acid, glutamate. If glutamate builds up in brain tissues it would cause neuronal death.

Other studies on neurons in culture have demonstrated that low nanomolar levels of mercury (sub-lethal doses) effect the production of pathological hallmarks of AD. These are greatly decreased glutathione levels, neurofibillary tangles (12), abnormally aggregated tubulin (13), increased hyper-phosphorylation of protein-Tau (14), and increased production of beta-amyloid protein (the constituent of amyloid or senile plaques) (14). In light of these results it seems unreasonable to accept amalgams, the

major contributor to mercury body burden, as a safe dental filling. If mercury from amalgams is not causal for AD it, at the very least, would have to be considered a major exacerbating factor.

Addressing the initial issue of concern by the National Academy of Science, the grave concerns expressed about mercury by the OHSA and EPA agencies, and the identification of amalgams as the major contributor to human body burden by the NIH and WHO. Doesn't common sense tell us that it is time to remove the mercury exposure from amalgams from all citizens? If doubt persists in legislative minds then you have the power to have amalgams tested by an unbiased, set of credible laboratories to determine how long it takes a half-gram amalgam to make a gallon of water unsafe to drink by OHSA and/or EPA standards. It is common to find blood or urine mercury levels in the 2 to 30 micrograms per liter level. In my department sewage water must be many folds lower at 0.5 micrograms per liter of water to meet EPA standards. I agree with this EPA standard as I don't want to see our lakes and tributaries polluted by a build up of retained mercury. However, it begs the question why we don't hold medicine and dentistry to a similar, reasonable standard with regards to pollution of our citizen's bodily fluids.

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Mr. BURTON. Thank you.

Dr. Richardson.

Mr. RICHARDSON. Thank you. Ladies and gentlemen of the committee, it is an honor and privilege to address you this morning. Dental amalgam is the single largest source of mercury exposure in the U.S. population. This is acknowledged by the U.S. Environmental Protection Agency, amongst other agencies in this country. While an employee with the Canadian Federal department of health, I was directed in 1994 to undertake an assessment of mercury exposure and risks from dental amalgam on behalf of that country. Subsequently in 1996, I was commissioned by the government of Sweden to contribute an updated assessment of those risks for their review of this issue.

As you might expect, the work received considerable criticism from the dental establishment, in Canada, the United States, and internationally. Interestingly, however, my work is not unique. At least 14 journal articles and government reports have evaluated mercury exposure from dental amalgam, and that is what is presented in this slide. The horizontal bars show the different estimates of exposure ranging from the minimum to the maximum. The green circles represent the average as estimated by the different authors in those studies. The four studies at the top have been authored by what I will term "pro amalgam" authors who want to support the continued use of amalgam. They are totally out of step with every other study that has been done on mercury exposure from amalgam, including a committee of the U.S. Public Health Service, my own study for Health Canada, the World Health Organization, Tom Clarkson, who is one of this country's foremost mercury researchers, and other authors from Europe.

Therefore, the fact that mercury exposure occurs and the likely levels of that exposure throughout the population are not in doubt.

Other than my own work, what every other report or article on mercury exposure from dental amalgam failed to do was ask the question: So what? What does that exposure really mean? One answer to that question is achieved by comparing the levels of amalgam related exposure to what is deemed to be a "safe" or reference exposure level. These are represented by the red vertical bars in this graph. Such toxicological benchmarks are routinely prescribed by the U.S. EPA, again amongst other agencies. And when the mercury exposure from amalgam is compared to what is deemed to be a safe exposure level by the EPA, it is apparent that dental amalgam leads to excessive exposure in a very large proportion of the United States and Canadian population. All exposure represented by those horizontal lines that go passed the red bar to the right are exposures that exceed what the U.S. EPA calls a safe dose. And in fact, if a Superfund site is contaminated with mercury, the exposure to residents around those sites cannot exceed a dose equivalent to that red bar. So the exposure that occurs from dental amalgam exceeds what would be permitted at a Superfund site.

In my own assessment of risks on behalf of Health Canada, I concluded that a more appropriate safe or reference dose is some 4 times lower than the reference dose established by the EPA. Further, from the analysis prepared on behalf of Sweden, it was appar-

ent that the frequency of both neurological impairments and subtle kidney effects increases with increasing dose, but still well within the range that results from the presence of dental amalgam fillings.

The science upon which the U.S. EPA based their safe or reference exposure level for elemental mercury is quite dated. The most recent article on neurotoxicity that is cited on their IRIS data base is 1993. The keystone paper dates from 1983. This agency has so far failed to update that reference level to reflect and include any new science on the neurotoxicity of mercury vapor that has been published since 1994, and there are a lot of studies. In my submission I have listed many of them. It is apparent from that literature that neurological effects occur at levels of exposure much lower than believed 7 years ago.

Mercury from amalgam crosses the placenta and contaminates the unborn fetus, in proportion to the number of amalgam fillings in pregnant women's teeth. Yet, no research has attempted to identify a safe dose, if one exists, for elemental mercury in an unborn child. Mercury from amalgam contaminates breast milk, in proportion again to the number of amalgam fillings in nursing women's teeth, and amalgam fillings may be placed into the teeth of children as young as 3 years old. Young children are a population group whose central nervous system is still developing and in whom neurological toxins such as mercury are more harmful than in adults. Again, however, we do not know what effects this exposure might be causing.

Several countries, including Canada, Sweden, Norway, Germany, and Austria, have now taken or initiated steps to reduce or eliminate the use of amalgam as a dental restorative material. Canada has identified an obligation of informed patient consent and has made a series of recommendations regarding in whom amalgam should not be used. Identified groups include pregnant women, children, and persons with kidney diseases, among others. In Sweden, with a national socialized dental health care program, the placement of amalgam fillings is no longer funded.

The Superfund program in the United States does not permit as much mercury exposure to residents living near those sites, as I have said previously. Yet the place of dental amalgam into the human body is still permitted, if not promoted, despite the fact that those exposures exceed what a Superfund site would be permitted to occur from what is classified as a hazardous waste.

In both the United States and Canada, efforts are now underway to force major industries, particularly coal-fired electrical generators, to spend hundred of millions or perhaps billions of dollars to reduce or eliminate mercury emissions. The reduction in mercury emissions to the environment is a worthwhile cause worthy of your support. However, the reductions in mercury emissions that will result from those massive expenditures will do nothing to reduce mercury exposure in the population, not as long as dental amalgam, the primary source, is still in use. Industrial emission reductions will reduce slightly mercury levels in the atmosphere and, with time, the environment in general, but exposures in the general population will change only marginally, if at all, since their main source of exposure is planted directly in their teeth.

If the desired goal is to reduce mercury exposure in the U.S. population, then massive action on minor contributors to that exposure will be totally ineffective. Dental amalgam use must be reduced or eliminated if a significant reduction in mercury exposure in the U.S. population is to take place. Thank you very much.

[The prepared statement of Mr. Richardson follows:]

TESTIMONY BY G. MARK RICHARDSON, Ph.D.,

BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

"MERCURY IN DENTAL AMALGAMS: AN EXAMINATION OF THE SCIENCE"

November 14, 2002

Ladies and Gentlemen of the Committee, it is an honor and privilege to address you this morning. I am here to discuss mercury exposure from dental amalgam. Dental amalgam IS the single largest source of mercury exposure to the general population[1]. This is acknowledged by the U.S. EPA[2]. While an employee of the Canadian federal department of Health, I was directed in 1994 to undertake an assessment of mercury exposure and risks from dental amalgam on behalf of that department. The results of that investigation are available from Health Canada and their departmental Internet site[3] and have also been published in a peer reviewed scientific journal [1]. Subsequently in 1996, I was commissioned by the government of Sweden to contribute an updated assessment of the risks of dental amalgam[4] for their review of this issue. Due to time limitations, I will not go into the details of these investigations. They are appended to my written submission. But as you might expect, that work received considerable criticism from the dental establishment, in Canada, the U.S. and internationally. Interestingly, however, my work was not unique. At least 14 journal articles and government reports exist on mercury exposure from dental amalgam [5] (Figure 1). One of those reports was authored by a committee of the U.S. Public Health Service[6], a report that, in

[1] see Richardson, G.M., 1995 (Addendum 1); Richardson and Allan, 1996 (Addendum 2). The average adult has 8.65 amalgam fillings that contribute an average 3.4 g of mercury to the body per day. Adults can have as many as 25 filled teeth, with such an amalgam load often contributing more than 30 g of mercury per day. In children, mercury doses from amalgam are more significant due to children's lower body weight and developing nervous system.

[2] The US EPA admits that "people are most likely to be exposed to metallic mercury from mercury released from dental fillings" (Mercury In the Environment: Sources, Health Impacts, & What can be done. US EPA, Washington. http://www.epa.gov/region02/health/mercury.htm)

[3] http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/publicat/richards-scan_e.pdf

[4] Richardson, G.M. 1999. Mercury Exposure From Dental Amalgam: Re-evaluation of the Richardson Model, Standardization by Body Surface Area, and Consideration of Recent Occupational Studies. In: Chapter VI. Expert Commissions, *Amalgam and Health - New Perspectives on Risks*, FORSKNINGSRÅDSNÄMNDEN (FRN; Swedish Council for Planning and Coordination of Research), Report 99:1, Stockholm, Sweden. (attached as Addendum 3)

[5] see Figure 1and citations thereto

[6] Evaluation of Risks Associated with Mercury Vapor from Dental Amalgam. Appendix III in: Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation. Subcommittee on Risk Management, Committee to Coordinate Environmental Health and Related Programs, U.S. Public Health Service. January, 1993.

fact, concluded that the exposure to mercury occurring from dental amalgam was the same as what I concluded. Therefore, the fact that mercury exposure occurs and the likely levels of that exposure throughout the population are not in doubt.

Other than my own work, what every other report or article on mercury exposure from dental amalgam failed to do was to ask the question: SO WHAT? (WHAT DOES THAT EXPOSURE MEAN?) One answer to that question is achieved by comparing the levels of exposure to what is deemed to be a 'safe' or reference exposure level[7]. Such toxicological benchmarks are routinely prescribed in the U.S. by the Agency for Toxic Substances and Disease Registry [8] (a branch of the Centers for Disease Control), as well as the U.S. Environmental Protection Agency[9]. When the mercury exposure from amalgam is compared to what is deemed to be a safe exposure level by the U.S. EPA (see Figure 1), it is apparent that dental amalgam leads to excessive exposure in a large proportion of the population. In my own assessment of risks on behalf of Health Canada, I concluded that a more appropriate safe or reference dose is some 4 times lower than the reference dose established in 1995 by the US EPA, and which has not been updated since. Further, from the analysis prepared on behalf of Sweden, it was apparent that the frequency of both neurological impairments and subtle kidney effects increases with increasing dose, at doses well within the range that result from the presence of dental amalgam fillings.

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[7] These risk assessment methods are described as "Tools of the Trade" and are described in detail in documentation published by the U.S. EPA (http://www.epa.gov/superfund/programs/risk/tooltrad.htm) and numerous other state agencies that must manage chemical exposures and risks.

[8] see ATSDR minimum risk levels at http://www.atsdr.cdc.gov/mrls.html

[9] U.S. EPA reference doses (RfD) and reference concentrations (RfC) are published as part of toxicological reviews published on the Integrated Risk Information System (IRIS; http://www.epa.gov/iris/); the IRIS listing for elemental mercury (mercury vapor) can be found at http://www.epa.gov/iris/subst/0370.htm

As mentioned, the science upon which the US EPA based their safe or reference exposure level for elemental mercury, the kind of mercury that arises from dental amalgam, is quite dated. The most recent article on neurotoxicity cited by the U.S. EPA dates back to 1993 and the keystone paper dates to 1983. The published reference dose has not been revised since 1995. This agency has so far failed to update that reference level to reflect and include the plethora of new science on the neurotoxicity of mercury vapor that has been published since 1994. It is apparent from that literature[10] that neurological effects occur at levels of exposure much lower than believed 7 years ago.

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Mercury from amalgam crosses the placenta and contaminates the unborn fetus[11], in proportion to the number of amalgam fillings in pregnant women's teeth. Yet, no research has attempted to identify a safe dose, if one exists, for elemental mercury in an unborn child. Mercury from amalgam contaminates breast milk[12], in proportion to the number of amalgam fillings in nursing mothers' teeth, and amalgam fillings may be placed into the teeth of children as young as 3 years old[13]. Young children are a population group who's central nervous system is still developing and in whom neurological toxins such as mercury are more harmful than in adults. Again, however, we don't know what effects this exposure might be causing.

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[13] Richardson, 1995 (Addendum 1); Richardson and Allan, 1996 (Addendum 2)

Several countries, including Canada[14], Sweden[15], Norway[16], Germany and Austria[17] have now taken or initiated steps to reduce or eliminate the use of amalgam as a dental restorative material. Canada has identified an obligation of informed consent and made a series of recommendations regarding in whom amalgam should NOT be used. The identified groups include pregnant women, children, and persons with kidney diseases, among others. In Sweden, with a national socialized dental health care program, the placement of amalgam fillings is no longer funded.

The Superfund program in the United States does not permit as much mercury exposure to residents near those sites as is currently permitted in the United States from the use of amalgam as a dental restorative material[18] (Figure 1). Dental amalgam is a hazardous waste and landfill sites contaminated with waste mercury amalgam have been listed as Superfund sites[19]. Yet its placement directly into the human body is still permitted, if not promoted[20].

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[14] Health Canada's recommendations concerning population groups in which amalgam use should be avoided is attached as Addendum 3 and may be found at: http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/publicat/dental_position_e.html

[15] Forssell, J., E. Gustafsson and H. Parkman. 2001. Global assessment of mercury and its compounds: Contribution from Sweden. Submission to the United Nations Environment Programme Global Assessment of Mercury and its Compounds. Dated August 24, 2001. http://www.chem.unep.ch/mercury/gov-sub/sub28gov.pdf

[16] Norwegian Directorate for Health and Social Services (NDHSS). 2002. The Norwegian Directorate for Health and Social Services encourages dentists to use an alternative to amalgam. Press release, dated July 11, 2002 (http://www.shdir.no/index.db2?id=1522). Norwegian Directorate for Health and Social Welfare. July, 2002. Directive for the Use of Dental Restorative Materials (in Norway): Draft for public comment. Information to dental health personnel about the use of dental materials for restoring single teeth. See http://www.shdir.no/index.db2?id=1430 for the complete directive (in Norwegian)

[17] U.S. Public Health Service (USPHS). 1997. *Dental Amalgam and Alternative Restorative Materials: An Update Report to the Environmental Health Policy Committee.* U.S. Department of Health and Human Services, Working Group on Dental Amalgam. http://www.health.gov/environment/amalgam2/National.html

[18] Exposure to mercury from a Superfund site can not exceed what the U.S. EPA has determined to be the Reference ('safe') Dose or Reference Concentration. Average amalgam-related mercury exposure exceeds that reference level with 12 or more average amalgam fillings in an adult (see Figure 1) and with more than 3 average fillings in a young child. However, larger-than-average fillings will result in greater than average exposures leading to a lower number of fillings to reach the reference dose. 5 or more fillings in an adult, and more than 1 filling in a toddler, will result in exceeding the reference dose developed by Richardson (1995).

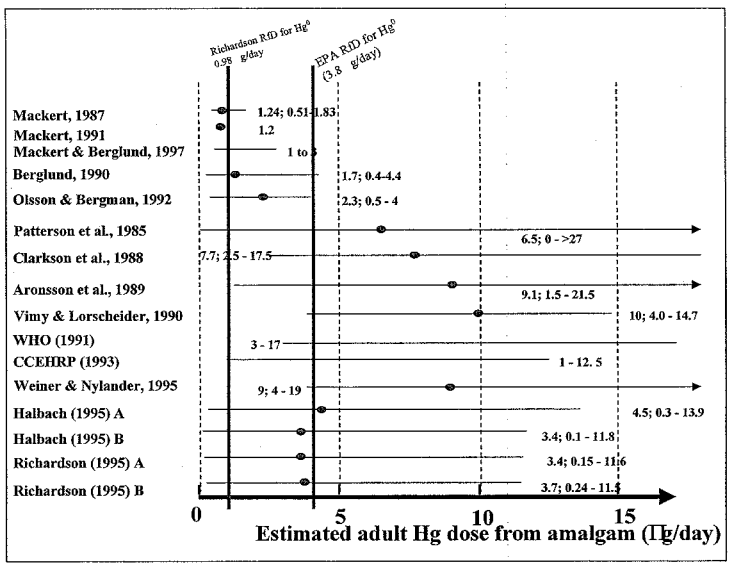
[19] For example, see Parris Island Marine Corps Recruit Depot NPL Site (http://www.epa.gov/superfund/sites/npl/nar1443.htm)

[20] Social dental health care programs for the poor and other disadvantaged groups will only fund the placement of amalgam in most cases

In both the US and Canada, efforts are now underway to force major industries, particularly coal-fired electrical generators, to spend hundreds of millions or perhaps billions of dollars to reduce or eliminate mercury emissions. The reduction of mercury emissions to the environment is a worthwhile cause worthy of your support. However, the reductions in mercury emissions that will result from those massive expenditures will do little to reduce mercury exposure in the general population; not as long as dental amalgam is still in use. Industrial emission reductions will reduce mercury levels in the atmosphere and, with time, in the environment in general, but exposures in the general population will change only marginally, if at all, since most do not eat fish from mercury impacted lakes and rivers, and their main source of exposure has been planted directly in their teeth.

If the desired goal is to reduce mercury exposure in the United States population, then massive action on minor contributors to that exposure will be ineffective. Dental amalgam use must be reduced or eliminated if a significant reduction in mercury exposure in the US population is to be achieved.

Figure 1. Published estimates of human mercury vapour exposure due to the presence of dental amalgam fillings. Estimates offered by supporters of the continued use of dental amalgam (Mackert, 1987, 1991; Berglund, 1990, Olsson and Bergman, 1992; Mackert and Berglund, 1997) are significantly out of step with all other researchers on this issue, including the Committee to Coordinate Environmental Health and Related Programs (CCEHRP) of the U.S. Public Health Service. EPA's Reference ('safe') Concentration for elemental mercury of 0.3 g/m^3 converted to equivalent absorbed dose of 3.8 g/day based on daily (24 hour) adult inhalation rate of 16 m^3/day (Allan and Richardson, 1996), and an inhalation absorption factor of 80% for elemental mercury (WHO, 1991). Amalgam-related mercury exposure exceeds the EPA's reference level in a large proportion of the population. However, elemental mercury exposures arising from Superfund Sites would not be permitted to exceed that reference level.



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Mr. BURTON. Thank you, Dr. Richardson.

Dr. Fischer, how are you?

Mr. FISCHER. Great. How are you?

Mr. BURTON. You are recognized.

Mr. FISCHER. Good morning, Mr. Chairman, members of the committee, and guests. My name is Rich Fischer. I am a dentist. I have been practicing for 30 years. Over 20 years ago, based on information available at that time, I made an ethical decision to stop using mercury in my practice. Dental amalgam, or silver mercury fillings, whatever you would like to call them, contribute more mercury to the body burden in humans than all other sources, including dietary and vaccines put together. These fillings contain 50 percent mercury, which is more neurotoxic than lead, cadmium, or even arsenic.

To put this in perspective, the amount of mercury contained in one average size filling exceeds the U.S. EPA standard for human exposure for over 100 years. Put in other terms, it takes only one-half gram of mercury, the amount in one filling, to contaminate all fish in a 10-acre lake.

Mercury vapor escapes from dental amalgam fillings and is readily absorbed into the body. It accumulates in all body tissues and has been shown to cause pathophysiology, which means abnormal changes in the way our organs function. Furthermore, in the case of pregnant women with mercury fillings, the mercury readily passes from her bloodstream through the placental barrier and accumulates in the developing fetus. Mercury from dental amalgam has also been shown to concentrate in mother's milk, providing not only a prenatal, but a perinatal and a postnatal exposure for the developing child whose immune system and central nervous system are exquisitely vulnerable to this poison.

Scrap amalgam mercury, that unused portion of the filling material remaining after the filling is made, must by law be handled as a toxic waste disposal hazard. It cannot be thrown in the trash, buried in the ground, or incinerated. Yet, some will justify storing this same mixture in people's mouths just inches from the brain stem and declare it harmless. That just does not make sense to me.

Governments of six other countries, including Canada, Germany, and the United Kingdom, have placed restrictions and/or issued advisories against the use of mercury in dental fillings, particularly in children and pregnant women.

In addition to the direct exposure to humans from dental fillings, there exists a secondary route of exposure from dental offices. Published research shows that between 14 percent and 75 percent of the mercury found in municipal waste waters originate from dental offices. This poison finds its way into our rivers and oceans where it contaminates fish as well as the environment.

There is not scientific debate over the following facts regarding mercury from dental fillings:

One, mercury is more toxic than lead, cadmium, or even arsenic.

Two, mercury escapes from dental amalgam fillings continuously as a vapor.

Three, some 74 to 100 percent of inhaled mercury vapor is absorbed into the human body.

Four, inhaled mercury vapor from dental fillings accumulates in the body to levels which cause pathophysiology.

I would like to direct your attention to the graph, please. The graph represents data on mercury intake for the unborn fetus and newborn. On the left here, this is the fetus, this is the first 9 months of life for the newborn, and this is the second 9 months. I have broken this data down into those three equal time periods.

Again, these data are taken directly from published studies by mercury toxicologists, not from dentists publishing in dental journals, in the World Health Organization. The intake data again is divided into three intervals of 9 months each. The red indicates mercury intake into the fetus and the child from dietary sources. The black represents intake into the fetus from the mother's fillings. The blue represents mercury intake to the child from vaccines. And the green represents the EPA upper limit of exposure for adults. We have no standard for children or fetuses.

Any toxicologist will tell you that the larger and the earlier the absorbed dose of a poison the greater the degree of damage. The FDA has very wisely been looking at this tuna fish, swordfish, shark situation and advising pregnant women not to be eating those fish because of the dietary intake. I submit that the big one has gotten away. They have not dealt with the issue of mercury from amalgam, which is the earliest and the largest insult to the child.

Also in my testimony there is a list of bibliography which show that there are a number of human and animal studies published in peer reviewed journals demonstrating the transfer of mercury from amalgam fillings of pregnant females into the brains of unborn babies. There are no studies that contradict those findings.

You have heard a lot of science already this morning. I would tell you that this issue is really not that complicated. The Environmental Protection Agency says that amalgam is a toxic waste disposal hazard before we put it into the mouth, it is a toxic waste disposal hazard after we take it out of the mouth, and it does not take a genius to figure out what it is in the mouth. Thank you.

[The prepared statement of Mr. Fischer follows:]

TESTIMONY BEFORE THE COMMITTEE ON GOVERNMENT REFORM U.S. HOUSE OF REPRESENTATIVES

NOVEMBER 14, 2002

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November 14, 2002

Dental amalgam ("silver") fillings contribute more mercury to the body burden in humans than all other sources (dietary, air water, vaccines, *etc.*) combined.[1,2,3] These fillings contain 50% mercury - which is more neurotoxic than lead, cadmium, or even arsenic.

To put this in perspective, the amount of mercury contained in one average size filling exceeds the U.S. E.P.A. standard for human exposure for over 100 years. Put in other terms, it takes only ½ gram of mercury (the amount in one filling) to contaminate all fish in a 10 acre lake.[4]

Mercury vapor escapes from dental amalgam fillings and is readily absorbed into the body. It accumulates in all body tissues and has been shown to cause pathophysiology. Many studies have confirmed this. Furthermore, in the case of pregnant women with amalgam fillings, the mercury readily passes from her bloodstream through the placental barrier and accumulates to even higher levels in the developing fetus' organs than it does in the mother's. Mercury from dental amalgam has also been shown to concentrate in mother's milk, providing not only a prenatal, but a perinatal and a postnatal exposure[5] for the developing child, whose immune system and central nervous system are exquisitely vulnerable to this poison.

Scrap amalgam mercury, that unused portion of the filling material remaining after the filling is placed into a tooth, must by law be handled as a toxic waste disposal hazard.[6] It cannot be thrown in the trash, buried in the ground or incinerated. It must be stored in an air-tight vessel until properly disposed of. Yet some will justify storing this same mixture in peoples' mouths just inches from the brainstem and declare it harmless!

Governments of other countries (Canada, Germany, Sweden, France, Norway and the United Kingdom) have placed restrictions and/or issued advisories against the use of mercury in dental fillings - particularly in children and pregnant women.

In addition to the direct mercury exposure to humans from dental fillings, there exists a significant secondary route of exposure from dental offices. Published research shows that between 14% and 75% of the mercury found in municipal waste waters originate from dental offices. Mercury in this form ultimately finds its way into our rivers, lakes, bays and oceans where it undergoes a bioconversion by bacteria into methyl mercury - the form which commonly contaminates fish and shellfish. In this form, when eaten, 90-100% of the mercury is absorbed. It was this compound which caused the tragedy in Japan's Minimata Bay in the 1970's when hundreds of people were poisoned and many died from eating mercury contaminated fish.

In conclusion, there is no scientific debate over the following facts regarding mercury from dental fillings:

1. Mercury is more toxic than lead, cadmium or even arsenic
2. Mercury escapes from dental amalgam fillings continuously as a vapor
3. 74-100% of inhaled mercury vapor is absorbed into the human body
4. Inhaled mercury vapor from dental fillings accumulates in the body to levels which cause pathophysiology

Respectfully submitted,

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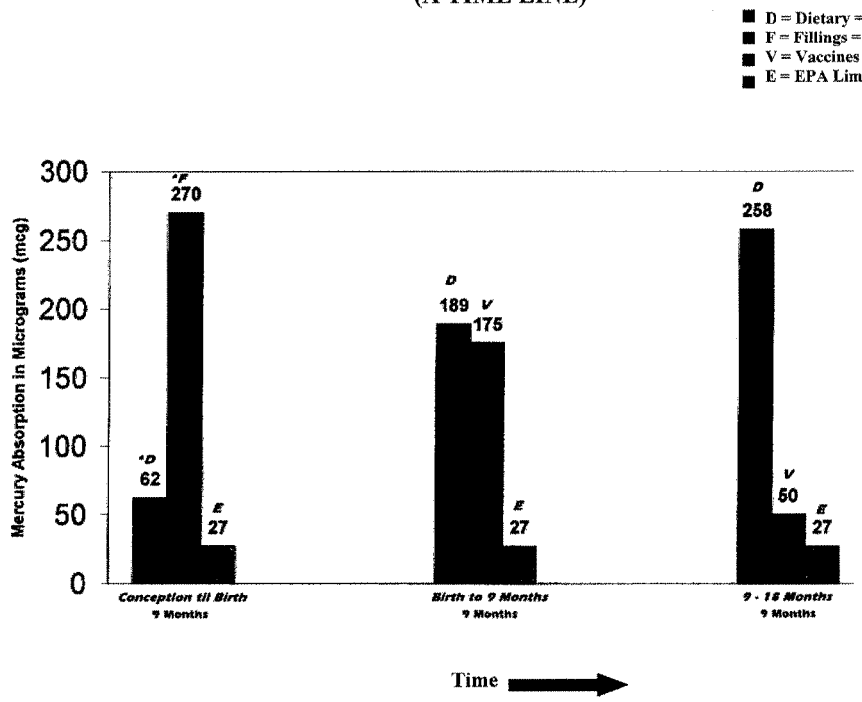
AVERAGE FETAL/INFANT ABSORBED DOSES OF MERCURY
(A TIME LINE)



*Contributed from Mothers Absorbed Doses Transferred to Fetus via Placenta

Mercury/Amalgam Mercury: Maternal-Fetal Transfer/Mothers' Milk/Effects

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Mr. BURTON. Thank you, Dr. Fischer.

Dr. Mackert.

Dr. MACKERT. Mr. Chairman and members of the committee, my name is Rod Mackert. I am a dentist, I hold a Ph.D. in material science, and I am a professor of dental materials at the Medical College of Georgia School of Dentistry, and a member of the ADA Council on Scientific Affairs. I speak on behalf of the more than 140,000 members of the ADA, the voice of more than 70 percent of the Nation's dentists. I am grateful for this opportunity to discuss dental amalgam, which increasingly is a subject of controversy, the discussion often marked by half-truths and misinformation.

I want to begin by stating categorically that dental amalgam is a safe and effective treatment option for dental decay. I also want to clarify the ADA's role. It is not our intention to advocate one restorative material over another. We are here to attest to the safety of dental amalgam. Our purpose is also to help dentists and patients understand all of the appropriate treatment options that are available to fill cavities, to provide that scientific basis for professional choice of safe materials, and to defend the rights of dentists and their patients to make informed choices among those safe options. And the vast majority of American dentists support us in that purpose.

The ADA wants dentists and patients to understand dental treatment. I call your attention to the chart on restorative materials that is in the materials that we have provided, which the ADA prepared to help dentists understand the various restorative options. Amalgam is, by far, the most thoroughly researched and tested restorative material among all those that we dentists use. That is why we oppose any legislative or regulatory action to limit its continued appropriate use.

One of the principal difficulties in designing a study on low-dose neurological effects of any substance is identifying an appropriate control group. To be valid, such studies must compare apples to apples. In this light, a particularly important study population is that of the Swedish Adoption Twins Study of Aging, or SATSA, conducted by the Karolinska Institute which awards the Nobel Prize, which evaluated twins reared apart and control twins reared together. A total of 587 subjects with mean age of 66 years were studied. The authors concluded, "This study does not indicate any negative effects from dental amalgam on physical or mental health or memory functions in the general population over 50 years of age."

A 1998 multi-center study by Amelcart and colleagues examined 4,787 patients to determine whether there is a difference in symptoms between patients with and without amalgam fillings. They concluded, "Based on the present results, the first question of the study, whether patients with amalgam fillings differ from patients without amalgam fillings in regard to clinical symptoms, has to be answered with a clear no. Additionally, there was no quantitatively assessable relationship between the presence or intensity of special symptoms and the number of amalgam surfaces."

Many other human studies have investigated the possible relationship between dental amalgam and Alzheimer's disease, mul-

tiple sclerosis, adverse pregnancy outcomes, reduced immune competence, impaired kidney function, or other adverse health effects and they have found none. This is not to say that we consider the book closed. Significant research about dental amalgam is ongoing, most notably two major studies supported by the National Institute of Dental and Craniofacial Research which you will hear about from the next panel. We enthusiastically support these efforts and any other legitimate research that deepens our understanding of the science behind dental practice.

Simply put, mercury and dental amalgam are very different substances and using the terms interchangeably is misleading. When mercury is mixed with other metals such as silver, copper, and tin it forms inter-metallic compounds that behave completely differently from liquid mercury. The ADA is not alone in its position that dental amalgam is safe and effective. The National Institutes of Health, the U.S. Public Health Service, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the World Health Organization, among others, have independently reached the same conclusion.

The Alzheimer's Association, the National Multiple Sclerosis Society, and the American Academy of Pediatrics all have explicitly stated that there is no scientific evidence linking dental amalgam with any known disease or syndrome that these groups track. These organizations exist to understand these diseases and to advocate for those who suffer with them. They would not put their reputations and the safety of their members on the line if they did not agree with the majority of the scientific community that dental amalgam is safe.

Dentists use amalgam because it is durable and easy to handle, and therefore particularly useful for large fillings in back teeth on which the bite pressure is greatest. It is especially valuable for treating children and some disabled patients who have difficulty keeping still because it can be placed quickly and does not require a perfectly dry environment. Any dentist who has placed a good filling in a moving 3 year-old can tell you how important this is.

It should go without saying that if we doubted the safety of amalgam, its qualities, durability, ease of use, and cost-effectiveness would not matter. But this is not the case. Dental amalgam is safe. We are greatly concerned that emotionally and scientifically invalid reports about amalgam are confusing and even alarming people to the point where they will not seek necessary dental care. Postponing needed care only ensures that the problem will get worse. Mr. Chairman, amalgam fillings are no threat to patients. The real danger is untreated dental disease. Amalgam is an excellent material, albeit only one of many, in our fight against dental disease. We urge you to consider only valid, scientific information and take no action that would rob us and our patients of this valuable safe and effective therapy.

[The prepared statement of Mr. Mackert follows:]

STATEMENT

BY THE

AMERICAN DENTAL ASSOCIATION

TO THE

GOVERNMENT REFORM COMMITTEE

UNITED STATES

HOUSE OF REPRESENTATIVES

ON

"MERCURY IN DENTAL AMALGAMS:

AN EXAMINATION OF THE SCIENCE"

THURSDAY, NOVEMBER 14, 2002

Washington Office: 1111 14th Street NW Washington DC 20005 (202) 898-2400

Mr. Chairman and members of the Committee, thank you on behalf of the American Dental Association (ADA) for inviting us to testify today. The ADA is very pleased to speak to the safety and efficacy of dental amalgam and the Association's position that *every* dental patient should have an opportunity to make an informed choice about his or her dental treatment options.

If the Association believed that dental amalgam posed a threat to the health of dental patients, we would advise our members to stop using it. But the best and latest available scientific evidence indicates that it is safe. Banning amalgam would deprive patients and dentists of an essential treatment option that is clinically and scientifically substantiated to be safe and effective.

The ultimate decision about what filling materials to use is best determined by the patient in consultation with the dentist. Toward that end, the ADA has developed a chart that compares restorative dental materials. (See attachment #1) The chart provides easily understood comparative information on thirteen distinct factors, including durability, clinical considerations, leakage and recurrent decay, and resistance to wear and fracture. This information sheet has been widely circulated through ADA publications and is on our website.

Rep. Diane Watson (D-Calif.) in April introduced H.R. 4163, the Mercury in Dental Filling Disclosure and Prohibition Act, which would ban the use of dental amalgam by 2007. Congresswoman Watson's attempt to ban dental amalgam because of concern for patient safety flies in the face of accepted scientific information about the safety of dental amalgam.

Dental Amalgam Offers a Safe, Cost-Effective Treatment Option

It should be clearly understood at the outset that dental amalgam and mercury are not the same thing, and their characteristics and properties are not interchangeable. Chlorine is a toxic gas, but when combined with sodium, a toxic metal, table salt is the resulting product. No one compares the proprieties of table salt to either chlorine or sodium. Similarly, when mercury is combined with other metals to make dental amalgam, it is safe for use in accepted dental applications.

Dental amalgam has been used for more than 150 years. After all that time, and considering the billions of amalgams that have been placed, we would expect to see some epidemiological evidence if there were any ill effects on patient health. Instead, we have fewer than 100 cases of documented localized allergic reaction.

Thousands of dentists and their staffs work with dental amalgam every day, with no demonstrated ill effects on their health. Dentists are exposed daily to a number of materials, often at dosage levels and durations much higher and longer than a patient, so it is likely that any adverse outcomes would be manifested first in the dentist. Again, we simply have not seen them in the case of amalgam.

The ADA has funded many studies looking at potential occupational hazards facing dentists, including mercury from amalgam. The American Dental Association Health Foundation (ADAHF) has compiled the largest repository of data on the occupational health of dentists from data gathered at the annual ADAHF Health Screening Program. Research has been done on the mean urinary mercury levels of dentists from 1975-83 and again from 1984-2001 (Chou H-N, in press; Naleway CA, 1985). The research shows that dentist urinary mercury levels are well below established limits for occupational exposure. Dentist urinary mercury levels have fallen from 1975, until they now approach those of the general population. This is largely due to better mercury hygiene methods prompted by the ADA, such as the use of precapsulated amalgam. ADA investigators have looked at a possible correlation between kidney dysfunction and urinary mercury levels (Naleway CA, 1991). None was found.

ADA scientific investigators have examined whether enteric bacteria might have the ability to convert inhaled or ingested mercury to more toxic organic (methyl) mercurials. They hypothesized that, if bioconversion did occur, then occupationally exposed dentists would show higher levels of organic mercury in blood than non-dentists. Their research showed no significant difference in organic mercury levels. Higher blood organic mercury levels did not correlate with the number of amalgams in an individual's mouth, nor did it correlate with the number of amalgams placed or removed by the dentists. However, organic mercury did correlate well with the frequency of seafood consumed. This study concluded that bioconversion of mercury from amalgam in an occupationally exposed group did not occur at a detectable level (Chang S-B 1992, 1990, 1988, 1987; Siew C, 1987).

Of course, if amalgam presented a health hazard, no cost considerations would warrant its continued use, and the ADA would be the first to advise its members of the risks. However, the major U.S. and international scientific and health bodies, including the National Institutes of Health, the U.S. Public Health Service, the Food and Drug Administration, the Centers for Disease Control and Prevention and the World Health Organization, among others, have all stated that dental amalgam is a safe restorative material. In fact, dental amalgam is the most thoroughly researched and tested restorative material among all those in use.

Indeed, the Alzheimer's Association, the Autism Society of America, the National Multiple Sclerosis Society and the American Academy of Pediatrics all have explicitly stated that there is no scientific evidence linking dental amalgam with any known disease or syndrome that those groups track. These organizations, which devote their entire efforts to understanding the diseases they represent, surely would not make such statements without confidence that they are true.

Not only is dental amalgam safe, it remains a valuable restorative option for dentists and their patients because it is so effective. Banning dental amalgam would have a dramatic effect on oral health care. At present, there is no direct restorative material that works as well as amalgam for certain types of fillings. Amalgam, unlike other direct restorative materials, tolerates moisture during placement. That is important for fillings in places that are difficult to keep dry, like below the gum line. Amalgam is also still the strongest,

most durable direct restorative material for large, load-bearing restorations on the posterior teeth. Certain indirect restorative materials, like gold and porcelain, may also be suitable for these situations. But they are considerably more expensive because of the material and because they require at least two office visits and laboratory services to complete. The U.S. Public Health Service, at its website, addresses the economic impact of banning amalgam: "[A] total conversion from dental amalgam to alternative materials would cause a significant increase in U.S. health care costs."

In fact, many patients choose dental amalgam because while safe, it is less expensive than the alternatives. Dental amalgam is approximately 25 to 30 percent *less* expensive on average than the next least expensive restorative material, composite resin, according to the ADA Survey Center's 1999 *Survey of Dental Fees*. Cost is a major consideration for most individuals seeking dental care because, unlike medical insurance, a good deal of patients' own money is used to pay for dental services. The demand for dental services is significantly responsive to changes in dental fees – it's intuitive, the higher the fees, the lower the demand. As a consequence, fewer people are likely to seek needed dental treatment in a timely fashion as the cost of care rises, or if a safe, less costly material were not allowed for use.

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U.S. Federal Agencies and International Organizations Conclude that Dental Amalgam is Safe

As questions have arisen about the safety of dental amalgam related to its mercury content, they have been investigated by responsible bodies and answered to the satisfaction of the major U.S. and international scientific and health organizations. From 1991 to 1992, the U.S. Public Health Service (PHS) performed a comprehensive risk assessment of dental amalgam. In 1993, the PHS issued a report on its findings and concluded that dental amalgam did not have any adverse health effects other than a few reported cases of allergic reaction due to individual sensitivity rather than the amalgam itself. Specifically, a Risk Assessment Subcommittee of the PHS, comprised of 34 senior level experts from the fields of health promotion and disease prevention, dentistry, dental materials, toxicology, and biostatistics, reviewed nearly 120 publications that reported the results of studies on levels of exposure to mercury. The Risk Assessment Subcommittee found that available data showed that there were no health hazards identified in non-occupationally exposed persons.

A companion PHS subcommittee, the Benefits Assessment Subcommittee, reviewed the benefits of dental amalgam products. It concluded that dental amalgam, which had been used successfully to treat millions of individuals, was an effective restorative material. The subcommittee also stated that dental amalgam products had reasonable clinical serviceability, wide potential applications, ease of manipulation, and relatively low cost.

The conclusions reached in the 1993 PHS Report were reaffirmed by the PHS in both 1995 and 1997. The 1997 PHS Report included information from two PHS-sponsored

workshops on mercury and amalgam safety. Both workshops concluded that scientific evidence did not link mercury vapor exposure, at typical levels associated with dental amalgam restorations, with an unacceptable or significant health risk to the general population.

Moreover, in response to several citizen petitions filed in 1993 requesting that FDA take various actions regarding dental amalgam and mercury – including banning dental mercury – the FDA convened a group of experts to assess the extensive scientific publications submitted by the petitioners seeking to demonstrate that amalgam was unsafe. The publications cited by the petitioners were grouped by study type (i.e., general toxicology, neurotoxicology, immunotoxicology, epidemiology, dental/clinical materials) and disseminated to scientific specialists and dental professionals recruited from various PHS agencies. The government reviewers focused on five major areas of concern: (1) adequate controls; (2) methodological flaws; (3) mercury exposure measurements; (4) relevance of the article to dental amalgam safety assessment; and (5) fetal mercury exposure.

Ultimately, none of the experts who reviewed the petitioners' data concluded that dental amalgam restorations caused adverse health effects to patients. The experts involved in this review, like those authoring the 1993, 1995, and 1997 PHS Reports, were familiar with the characteristics of both free mercury and dental amalgam. Free mercury, like other heavy metals, can be toxic, depending on the dose level. Dental amalgam does not share the same toxicity characteristics of mercury. These experts concluded that there is no evidence in the medical or dental literature to suggest that individuals with dental amalgam restorations will experience adverse health effects from these restorations.

In addition, the FDA has evaluated a number of reports from international authorities that both assessed the available body of scientific literature as well as reviewed the opinions of leading researchers and renowned experts in the fields of oral health, toxicology, medicine, and other related disciplines. Expert groups from Sweden, New Zealand, Canada, and the European Commission all concluded that the minimal exposure to mercury from dental amalgams does not have an adverse effect on patients' health, with the exception of isolated cases of allergic reactions noted above.

Likewise, a report generated from a nine-country information exchange concluded that no systemic toxic effects have been shown to be related to dental amalgams. Also, several studies included in a comprehensive report published by the World Health Organization concluded that there is no direct evidence of an adverse effect on patients' general health from dental amalgam.

Issued in late 1997, the FDI World Dental Federation and the World Health Organization consensus statement on dental amalgam stated, "*No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations.*" The document also states that, aside from rare instances of local side effects of allergic reactions, "*the small amount of mercury released from amalgam restorations, especially*

during placement and removal, has not been shown to cause any ... adverse health effects."

In its 1997 Annual Report, the FDA conducted an extensive literature search on dental amalgam. The findings of the Office of Science and Technology are included here:

> *In response to three citizen's petitions, the Working Group on Dental Amalgam, a group under the PHS Environmental Health Policy Committee, was charged with evaluating 175 citations related to the potential adverse effects of dental amalgam mercury. OST scientists organized the review literature in order to determine if the science cited by the petitioners, in whole, or part, shed any new light on the safety of dental amalgam and past risk assessments performed by PHS and others. The citations represented an assortment of literature, including peer-reviewed publications, non-refereed publications, untranslated foreign documents, print media articles, and letters to the editor.*
>
> *Therefore, OST scientists first performed a triage of the citations in order to focus its evaluation on these studies that met a set of criteria established by the review group. This process resulted in 57 articles, which were reviewed by scientific experts from FDA, CDC, and NIH representing disciplines of general toxicology, neurotoxicology, immunotoxicology, epidemiology, dental materials, and clinical dentistry. These experts commented on the strengths and weaknesses of each paper, the appropriateness of methodologies, control groups and statistics, and whether the conclusions were supported by the data.*
>
> *The conclusions drawn by these experts were overwhelmingly unanimous. None of the reviewers suggested that any study under review would indicate that individuals with dental amalgam restorations would experience adverse health effects. When the citations were considered in the aggregate, the data did not imply to the reviewers that adverse human health effects would occur as a result of exposure to dental amalgam.*

And, finally, critics of dental amalgam have often cited the Agency for Toxic Substances and Disease Registry's (ATSDR) 1999 Report titled "Toxicological Profile for Mercury" as evidence the federal government believes dental amalgam is dangerous. Specifically, opponents of dental amalgam incorrectly claim that this report concludes that mercury vapors released from amalgam pose a major health risk for the developing brains of children.

The 1999 ATSDR Report reviewed a wide spectrum of literature in this area; being included in this review does not mean that the reviewers agreed with the study's conclusions. The broad scope of the 1999 ATSDR Report includes a subsection entitled "More on Health Effects and Dental Amalgam" to specifically address the state of the science with regard to dental amalgam. This section clearly concludes and states that "*[a] number of government sponsored scientific reviews of the literature on the health effects associated with the use of dental amalgam have concluded that the data do not*

demonstrate a health hazard for the large majority of individuals exposed to mercury vapor at levels commonly encountered from dental amalgam."

Additional Studies Support the Safety and Efficacy of Dental Amalgam

There have been numerous peer reviewed scientific studies concerning the safety of dental amalgam. These studies disprove any link between dental amalgam and various medical conditions. We have listed some of them below:

- Mackert JR, Berglund A. "Mercury exposure from dental amalgam fillings: absorbed dose and the potential for adverse health effects" Crit Rev Oral Biol Med 1997; 8:410-436.

The researchers conducted a critical review of the scientific literature on mercury exposure from dental amalgam and examined the question whether adverse health effects are attributable to amalgam-derived mercury. Taking into consideration the release rate of such mercury vapor from amalgam and various parameters that influence the absorption of mercury vapor, their analysis of the literature showed that the daily absorbed doses of mercury from amalgam restorations is quite low: from $1 - 2\ \mu g$ for inhaled mercury and less than $1.5\ \mu g$ for ingested mercury.
Conclusions: These low levels are unlikely to constitute a health hazard.

- Dahl J. E., Sundby J, Hensten-Pettersen A, Jacobsen N. " Dental workplace exposure and effect on fertility" Scand J. Work Environ Health 1999 Jun; 25(3): 285-90.

The study groups consisted of 558 female dental surgeons (1/3 of whom placed more than 50 fillings a week) and 450 high school teachers (control) that had given birth in Norway to at least 1 living child. The study comprised data from a total of 1408 pregnancies. The effects of practicing dentistry and of the given workplace exposure on fertility were analyzed with the discrete proportional hazard regression method.
Conclusions: Occupational exposures had no clear adverse effects on fertility among the female dental surgeons studied.

- Schuurs A. H. " Reproductive toxicity of occupational mercury. A review of the literature" J. Dent 1999; 27(4): 249-56.

This paper provides insight into the potential reproductive effects on handling dental silver amalgam. Both animals and case reports and epidemiological studies were reviewed.
Conclusions: The studies conclude that there are no adverse effects to reproductive function from exposure to mercury in the dental office. Consequently, given the even lower exposure to mercury from dental amalgam, the patient is at even less risk than dental staff.

- Saxe S.R., Wekstein M.W. et al. " Alzheimer's disease, dental amalgam and mercury", JADA 1999 Feb; 130(2): 191-9

This study consisted of 68 human subjects with diagnosed Alzheimer's disease and 33 control subjects without Alzheimer's to determine mercury levels in multiple brain regions at autopsy and to ascertain the subjects' dental amalgam status and history.
Conclusions: Mercury in dental amalgam restorations is not a neurotoxic factor in the pathogenesis of this disease. The authors found that brain mercury levels are not associated with dental amalgam, either from existing amalgam restorations or according to subjects' dental amalgam restoration history. Furthermore, dental amalgam restorations, regardless of number, occlusal surface area or time, do not relate to brain mercury levels.

- Ahlqwist M., Bengtsson C. et al, " Serum mercury concentration in relation to survival, symptoms, and diseases: results from the prospective population study of women in Gotherburg, Sweden". Acta Odontol Scand 1999 June; 57(3): 168-74

This prospective population study of women in Gothenburg, Sweden was started in 1968-69 and comprised of 1462 women aged 38-60 years at baseline. Follow-up studies were conducted in 1974-75, 1980-81 and 1992-93.
Conclusions: No statistically significant correlation was observed between dental amalgam and the incidence of diabetes, myocardial infarction, stroke, or cancer. No association was established between disease and mercury on a population basis in middle-aged and older women.

- Wahl M.J. "Amalgam – resurrection and redemption. Part 1: The clinical mythology of anti-amalgam". Quintessence International 2001 32(7), 525-535

A literature search revealed that the vast majority of amalgam restorations do not cause fractured cusps or have recurrent caries. Most amalgam restorations have been shown to last longer than resin composite restorations. The use of dental amalgam has not been banned in any country in the European Union. According to the latest scientific information available, dental amalgam is a remarkably durable restorative material.
Conclusions: Although its appearance is unaesthetic, its clinical performance and effectiveness are unsurpassed by those of resin composite.

- Wahl M.J. "Amalgam – Resurrection and redemption. Part 2: the medical mythology of anti-amalgam". Quintessence International 2001 32(3), 696-710

Literature review indicated that amalgam restorations release infinitesimally small quantities of mercury but not enough to cause systemic health problems. Mercury from dental amalgam restorations cannot be linked to kidney damage, Alzheimer's disease, multiple sclerosis, other central nervous system diseases including ' amalgam disease', mental disorders, damage to the immune system, increases in antibiotic resistance, or harmful reproductive effects.

Conclusions: This review of the latest literature concludes that dental amalgam is a safe and effective restorative material.

Research Continues

Research on dental amalgam is ongoing. The National Institute of Dental and Craniofacial Research (NIDCR) is currently supporting two large clinical trials on any effects on the health of dental amalgam and they should provide additional evidence to support scientific answers to many of the questions raised about this material. Studies underway for several years each in Portugal and the northeastern United States involve direct neurophysiological measures, as well as behavioral and cognitive functional assessments. In addition, the trials are monitoring the effects, if any, of amalgam on immune function, antibiotic resistance and renal function.

Results of the studies are expected to be released sometime in 2006, yet H.R. 4163 proposes to eliminate amalgam by January 1, 2007. Results thus far from these studies have not raised any alarms that would cause the studies to be limited or discontinued, as would be required if any adverse response were recognized.

The ADA believes we owe it to our patients to practice dentistry based on good science and not act precipitously based on flawed or incomplete science. This approach has provided Americans with quality oral health care that is second to none in the world. The ADA is committed to making sure that our patients benefit from improvements in dental practice that will come from sound science.

Conclusion

The ADA and its members are committed to placing patients' health first and to following the guidance of sound science in preventing and treating disease. We also are committed to providing patients with scientifically accurate information and fostering open communication between patients and their dentists about all appropriate treatment options – leaving it to the *patient,* in consultation with the dentist, to make the final treatment decision. We are greatly concerned that emotional and scientifically invalid reports claiming that amalgam is responsible for a variety of diseases are confusing and alarming some people to the point where they may not seek care. The real danger to patients is untreated dental disease. Amalgam is one of the excellent tools available in our fight against dental disease. We urge you to consider only valid, scientific information and not take any action that would deprive our patients of a repeatedly proven safe and effective dental restorative material.

Comparison of Indirect Restorative Dental Materials

Factors	All-Porcelain (ceramic)	Porcelain Fused To Metal	Gold Alloys (high noble)	Base Metal Alloys (non-noble)
General Description	Porcelain, ceramic or glass-like fillings and crowns.	Porcelain is fused to an underlying metal structure to provide strength to a filling, crown or bridge.	Alloy of gold, copper and other metals resulting in a strong, effective filling, crown or bridge.	Alloys of non-noble metals with silver appearance resulting in high strength crowns and bridges.
Principal Uses	Inlays, onlays, crowns and aesthetic veneers.	Crowns and fixed bridges.	Inlays, onlays, crowns and fixed bridges.	Crowns, fixed bridges and partial dentures.
Leakage and Recurrent Decay	Sealing ability depends on materials, underlying tooth structure and procedure used for placement.	The commonly used methods used for placement provide a good seal against leakage. The incidence of recurrent decay is similar to other restorative procedures.		
Durability	Brittle material, may fracture under heavy biting loads. Strength depends greatly on quality of bond to underlying tooth structure.	Very strong and durable.	High corrosion resistance prevents tarnishing; high strength and toughness resist fracture and wear.	
Cavity Preparation Considerations	Because strength depends on adequate porcelain thickness, it requires more aggressive tooth reduction during preparation.	Including both porcelain and metal creates a stronger restoration than porcelain alone; moderately aggressive tooth reduction is required.	The relative high strength of metals in thin sections requires the least amount of healthy tooth structure removal.	
Clinical Considerations	These are multiple step procedures requiring highly accurate clinical and laboratory processing. Most restorations require multiple appointments and laboratory fabrication.			
Resistance to Wear	Highly resistant to wear, but porcelain can rapidly wear opposing teeth if its surface becomes rough.	Highly resistant to wear, but porcelain can rapidly wear opposing teeth if its surface becomes rough.	Resistant to wear and gentle to opposing teeth.	
Resistance to Fracture	Prone to fracture when placed under tension or on impact.	Porcelain is prone to impact fracture; the metal has high strength.	Highly resistant to fracture.	
Biocompatibility	Well tolerated.	Well tolerated, but some patients may show allergenic sensitivity to base metals.	Well tolerated.	Well tolerated, but some patients may show allergenic sensitivity to base metals.
Post-Placement Sensitivity	Sensitivity, if present, is usually not material specific.			
	Low thermal conductivity reduces the likelihood of discomfort from hot and cold.	High thermal conductivity may result in early post-placement discomfort from hot and cold.		
Esthetics	Color and translucency mimic natural tooth appearance.	Porcelain can mimic natural tooth appearance, but metal limits translucency.	Metal colors do not mimic natural teeth.	
Relative Cost to Patient	Higher; requires at least two office visits and laboratory services.	Higher; requires at least two office visits and laboratory services.		
Average Number of Visits to Complete	Minimum of two; matching esthetics of teeth may require more visits.	Minimum of two; matching esthetics of teeth may require more visits.	Minimum of two.	

Comparison of Direct Restorative Dental Materials

Factors	Amalgam	Composites Direct and Indirect	Glass Ionomers	Resin Ionomers
General Description	A mixture of mercury and silver alloy powder that forms a hard solid metal filling. Self-hardening at mouth temperature.	A mixture of submicron glass filler and acrylic resin that forms a solid tooth-colored restoration. Self- or light-hardening at mouth temperature.	Self-hardening mixture of fluoride containing glass powder and organic acid that forms a solid tooth-colored restoration able to release fluoride.	Self- or light-hardening mixture of sub-micron glass filler with fluoride containing glass powder and acrylic resin that forms a solid tooth-colored restoration able to release fluoride.
Principal Uses	Dental fillings and heavily loaded back tooth restorations.	Esthetic dental fillings and veneers.	Small nonload-bearing fillings, cavity liners and cements for crowns and bridges.	
Leakage and Recurrent Decay	Leakage is moderate, but recurrent decay is no more prevalent than other materials.	Leakage low when properly bonded to underlying tooth; recurrent decay depends on maintenance of the tooth-material bond.	Leakage is generally low; recurrent decay is comparable to other direct materials, fluoride release may be beneficial for patients at high risk for decay.	Leakage is low when properly bonded to the underlying tooth; recurrent decay is comparable to other direct materials, fluoride release may be beneficial for patients at high risk for decay.
Overall Durability	Good to excellent in large load-bearing restorations.	Good in small-to-moderate size restorations.	Moderate to good in nonload-bearing restorations; poor in load-bearing.	
Cavity Preparation Considerations	Requires removal of tooth structure for adequate retention and thickness of the filling.	Adhesive bonding permits removing less tooth structure.		
Clinical Considerations	Tolerant to a wide range of clinical placement conditions, moderately tolerant to the presence of moisture during placement.	Must be placed in a well-controlled field of operation; very little tolerance to presence of moisture during placement.		
Resistance to Wear	Highly resistant to wear. Brittle, subject to chipping on filling edges, but good bulk strength in larger high-load restorations.	Moderately resistant, but less so than amalgam.	High wear when placed on chewing surfaces.	
Resistance to Fracture	Brittle, subject to chipping on filling edges, but good bulk strength in larger high-load restorations.	Moderate resistance to fracture in high-load restorations.	Low resistance to fracture.	Low to moderate resistance to fracture.
Biocompatibility	Well-tolerated with rare occurrences of allergenic response			
Post-Placement Sensitivity	Early sensitivity to hot and cold possible.	Occurrence of sensitivity highly dependent on ability to adequately bond the restoration to the underlying tooth.	Low	Occurrence of sensitivity highly dependent on ability to adequately bond the restoration to the underlying tooth.
Esthetics	Silver or gray metallic color does not mimic tooth color.	Mimics natural tooth color and translucency, but can be subject to staining and discoloration over time.	Mimics natural tooth color, but lacks natural translucency of enamel.	
Relative Cost to Patient	Generally lower; actual cost of fillings depends on size.	Moderate; actual cost of fillings depends on size and technique.		
Average Number of Visits to Complete	One	One for direct fillings; 2+ for indirect inlays, veneers and crowns.	One	One

Note: The information in this chart is provided to help dentists discuss the attributes of commonly used dental restorative materials with their patients. The chart is a simple overview of the subject based on the current dental literature. It is not intended to be comprehensive. The attributes of a particular restorative material will vary from case to case depending on a number of factors.

A SELECTED *BIBLIOGRAPHY* ON AMALGAM SAFETY

The following bibliography is based on the current areas of amalgam controversy and the staff of toxicology considered them to be significant milestones in the evolution of continuing debate on the safety of amalgam.

Background: According to Paracelsus, an eminent Swiss alchemist and physician of the 16th century, " [A]all substances are poisons: there is none which is not a poison. The right dose differentiates a poison and remedy."

Before 1979, it was assumed that amalgam, once placed in prepared dental cavities, remained inert and stable. This perception was first disputed after the publication of a 1979 Lancet paper by Gay et al. (Gay DD, Cox RD, Reinhardt JW 1979. "Chewing releases mercury from fillings," Lancet I (8123): 985-986). Later using a Jerome Gold Film Mercury Vapor Analyzer (JGFMVA), Svare et al. were able to detect minute amounts of mercury vapor released from hardened dental amalgam. The JGFMVA registers changes in the electrical resistance of a gold film that occur when mercury is adsorbed, and automatically transforms these changes into an amount of mercury. Within the apparatus, this amount is divided by the programmed value of the sampling volume, and the results are given as a concentration (mg Hg/cubic meter) on the display. According to the manufacturer, these instruments are designed to analyze mercury vapor in the workplace environment and to locate mercury spills. The following investigators further confirmed Gay's findings in subsequent years: Svare et al. 1981. "The effect of dental amalgams on mercury levels in expired air." J Dent Res 60:1668-1671; Abraham JE et al. 1984. "The effect of dental amalgam restorations on blood mercury levels." J Dent Res 63(1): 71-73. The questions that then arose included the following: 1) how to quantitate the amount of mercury vapor release from amalgam?; and 2) what potential adverse biological effects would this released mercury vapor have on humans?

I. Release of Mercury Vapor from Dental Amalgam

Vimy and Lorscheider were the first to perform systematic intra-oral mercury vapor measurements to estimate the daily intake of mercury from amalgam fillings. Two of their major publications remain controversial even today.

- Vimy MJ, Lorscheider FL (1985), "Intra-oral air mercury released from dental amalgam," J Dent Res. 64:1069-1071.

- Vimy MJ, Lorscheider FL (1985), "Serial measurements of intra-oral air mercury: estimation of daily dose from dental amalgam." J Dent Res 64:1072-1075.

In these two papers, Vimy and Lorscheider estimated that the daily exposure to mercury from dental amalgam is 48 ug, which approaches the limit established by OSHA for inhalation of mercury vapor in a working environment. The methodology used by Vimy and Lorscheider in these two papers has been severely criticized by other investigators, including Mackert, JR (1987). "Factors affecting estimation of dental amalgam mercury

exposure from measurements of mercury vapor levels in intra-oral and expired air." J Dent Res 66:1775-1780; Olsson S, Bergman M (1987). Letter to the editor. J Dent Res 66:1288-1289; Berglund et al (1988). "Determination of the rate of release of intra-oral mercury vapor from amalgam." J Dent Res. 67:1235-1242; Clarkson TW et al. (1988). "The prediction of intake of mercury vapor from amalgams" in *Biological monitoring of toxic metals.* Clarkson TW et al. New York: Plenum Press. pp. 247-264.

Olsson and Bergman have evaluated the study using a comprehensive inspiratory-expiratory air-volume analysis, and concluded that the mercury release was 16 times less than that claimed by Vimy and Lorscheider. Other investigators have since confirmed this discrepancy (Bjorkman and Lind in 1992; Skare and Engqvist in 1994). In another publication, Berglund (Berglund, A 1990, "Estimation by a 24-hour study of the daily dose of intra-oral vapor inhaled after release from dental amalgam." J Dent Res. 69:1646-1651) reported that the estimated average daily dose of mercury vapor inhaled from amalgam restoration was 1.7 ug, i.e. about 1% of the average daily amount obtained by a person exposed for 40 hours per week to an environment where the WHO threshold limit value (50 ug Hg/cubic meter air) is attained. The major error committed by Vimy and Lorscheider is their methodology. The use of intra-oral mercury vapor measurements to estimate daily uptake must take into account the differences between the collection volumes and flow rate of the measuring instrument, and the inspiratory volume and the flow rate of air through the mouth during inhalation of a single breath. Their failure to account for these differences resulted in a substantial overestimation of the absorbed dose.

II. Biotransformation of inorganic mercury into toxic organic mercury

- Heintze U, Edwardsson S, Derand T, and Birkhed D. "Methylation of mercury from dental amalgam and mercuric chloride by oral streptococci in vitro." Scand J Dent Res 1983; 91:150-2.

The capacity of the oral bacteria Streptococcus mitior, S. mutans and S. sanguis to methylate mercury was investigated in vitro. Mercuric chloride and pulverized dental amalgam in distilled water, respectively, were used as sources of mercury. Methylmercury was found in the bacterial cells of all three tested strains. The results indicate that organic mercury compounds may be formed in the oral cavity.

This study, however, is relatively old and has never been duplicated by other laboratories since its publication. In discussions with the authors many years ago, the impression was given that the oral bacteria used in the study were developed in laboratory culture and were mercury-resistant strains unlike what were naturally occurring in the oral cavity of the patient. This study, nevertheless, has been frequently cited by others to support the concept that the mercury vapor released from dental amalgam has the potential to be biotransformed into more toxic organic mercury (methylmercury) species and resulting in major adverse biological reactions in humans. This study was highly preliminary and conducted in vitro in a bacterial culture system in laboratories.

In vivo biotransformation of inorganic mercury into organic mercury has not been demonstrated in occupationally exposed dentists (Chang, SF, Siew C, and Gruninger SE, "Factors affecting blood mercury concentrations in practicing dentists." J Dent Res. 1992; 71(1): 66-74). Blood from volunteer dentists participating in the Health Screening Program (HSP) at the American Dental Association (ADA) Annual Sessions was collected from venipuncture and analyzed by cold-vapor atomic-absorption spectrophotometry for total, inorganic and organic mercury. The authors concluded that there is no detectable biotransformation of inorganic mercury to organic mercury in vivo. However, the concentration of blood organomercury was positively correlated with the frequency of fish consumption. Accidental mercury spills in the dental operatory may contribute most to the concentration of inorganic blood mercury in the blood of dentists.

- J. Leistevuo, T. Leistevuo, H. Helenius, L. Pyy, M. Osterblad, P. Huovinen and J. Tenovuo. "Dental amalgam fillings and the amount of organic mercury in human saliva" Caries Research 2001; 35:163-166.

Investigators took paraffin-stimulated saliva from 187 human subjects and measured both the organic as well as inorganic mercury with a cold-vapor atomic absorption spectrometry. They divided the subjects into amalgam (A), no lifetime exposure to amalgam (NA), and amalgams removed (NAR) groups. The percentages of the study subjects, whose fish eating frequency was <1 per week, were 2.3, 4.7 and 7.1 %, respectively.

The authors concluded that the amount of organic and inorganic mercury concentrations in saliva were significantly higher in subjects with amalgams than in NA and NAR individuals. Organic Hg in saliva is linearly related to inorganic Hg implying that all organic mercury came from mercury derived from amalgam. There is correlation between inorganic and organic mercury with the number of amalgam surfaces in the group with dental amalgams. Therefore, the authors concluded that amalgam fillings might be the continuous source of organic mercury. Since organic mercury is known to be more toxic than inorganic mercury, they speculated that inorganic mercury derived from dental amalgam was biotransformed into organic mercury in vivo.

Although this study is provocative, the investigators could have selected the study subjects more uniformly. There is a major discrepancy in age:

Group A: mean age 48; range 15-83
Group NA: mean age 24; range 18-65
Group NAR: mean age 50; range 18-65

Question: Do all subjects receive same type of amalgam products? Amalgams placed 40-50 years ago are not the same as those placed most recently. The number of amalgam fillings in Group A is huge, and the mean number of amalgam surfaces is 22; range 2-51. Data on the number of amalgam fillings removed in the NAR group were not provided.

Saliva sampling time varied. Although the studied subjects did not eat or brush teeth for one hour prior to saliva sampling, subjects contributing saliva at 7:30 am had most likely fasted overnight, while those contributing saliva later in the day, most likely had lunch or breakfast. Diurnal variation and diet may assert an influence on the composition of saliva.

Methodology details were very sketchy and many questions remain to be answered. The sensitivity provided by the investigators is one nmol/L, which is equivalent to 0.2 ng/mL. Is this sensitivity achievable under the experimental conditions? Authors did not explain the "zero" values in the Hg range. The investigators used stimulated whole saliva, which is a mixture of secretion from three pairs of different glands, and all of them are richly perfused by blood. Whole saliva is full of cell debris and proteins. Mercury extraction from this type of sample is quite complicated. The authors provide little information on the method and its reliability or reproducibility e.g. standard curve, percentage of recovery etc.

Salivary organic mercury observed most likely was derived from blood of the studied subjects. It is unlikely that methylation of mercury occurred in the oral cavity during the short transition time for paraffin-stimulation. Organic mercury, if formed, would rapidly traverse tissue membranes and enter the circulatory system. Thus it seems very unlikely that organic mercury would accumulate to be flushed out of the oral cavity with saliva. Blood organic and inorganic concentrations levels were not provided in the paper to verify their observation. These data are contradicted in another study published in the JDR 71(1): 166-74, 1992. "Factors affecting blood mercury concentrations in practicing dentists". This study indicated that both dentist and non-dentist controls without amalgam (zero) all have an organic mercury level around 4 ng/mL (20 nmol/L). Even in dentists with at least 12 amalgams (maximum mercury exposure), the blood organic mercury level remained at about 4 ng/mL, concluding that in vivo bioconversion of elemental mercury to organic forms did not occur at a detectable level. On the contrary the Leistevuo study indicated that the concentration of organic mercury in saliva is at least 5 times higher in the amalgam group (A) than both the control groups.

Biological Implications. If the concentration of organic mercury is converted to ng/mL (ppb) from nmol/L, the concentration of organic mercury from the group (A) comes out to be 2.8 ng/ml (ppb). This level is substantially below the MRL (minimal risk levels) set by the U.S. Agency for Toxic Substances and disease Registry (ATSDR) at 0.3 ug/kg/day or 300 ng/kg/day.

III. Central Nervous System

- Ngim CH, Foo SC, Boey KW, Jeyaratnam J, "Chronic neurobehavioural effects of elemental mercury in dentists." Br J Ind Med 1992 Nov; 49(11): 782-90.

Neurobehavioural tests were performed by 98 dentists (mean age 32) exposed to elemental mercury vapor and 54 controls (mean age 34) with no history of occupational exposure to mercury. The dentists were exposed to an average personal air concentration time weighted average (TWA) of 0.014 me/cubic meter for a mean period of 5.5 years,

and had a mean blood mercury concentration of 9.8 micrograms/L. In neurobehavioural tests measuring motor speed (finger tapping), visual scanning (trail making), visuomotor coordination and concentration (digit symbol), verbal memory (digit span, logical memory delayed recall), visual memory (visual reproduction, immediate and delayed recall), and visuomotor coordination speed (bender-gestalt time), the performance of the dentists was significantly worse in these tests. In trail making, digit span, logical memory delayed recall, visual reproduction delayed recall, and bender-gestalt time test scores were more than 10% poorer. In each of the tests in which significant differences were found in the block design time, the performance decreased as the exposed dose increased. These results raise the question as to whether the current threshold limit value of 0.050 mg/cubic meter (TWA) provides adequate protection against adverse effects of mercury. This study has been used extensively by advocacy groups opposing the use of amalgam to lower the TWA to the point of amalgam's elimination from use.

The Ngim et al. study was rejected by ATSDR (1994) in the establishment for exposure limits (Minimal Risk Level, MRL) for mercury because of methodological and reporting deficiencies. Among the deficiencies cited by the ATSDR were: 1) exposure status of the subjects was known to the investigators during testing; 2) mercury levels were not reported for controls; 3) methods used to correct for confounders (especially the common use in this population of traditional medicine containing mercury in Singapore) were not reported; 4) the study involved the method in which exposure to mercury was estimated rather than calculated as an actual measurement. The authors measured the dentists' exposure on a single work day and used this measurement as an estimate of exposure; and 5) the dentists in the Ngim et al. study typically worked 10 hours per day, six days per week. It is unlikely that staff members of the group who served as controls had comparatively demanding work schedules. This difference in work schedules may explain the aggression score exhibited by dentists, since they were a self-selected group that likely would have garnered higher aggression scores even prior to entering dental school.

- Echeverria D, Heyer NJ, Bittner AC, Woods JS, Rohlman D and Anger K. "Behavioural effects of exposure to Hg^0 from dental amalgam." 2002, Society of Toxicology annual meeting (Nashville), abstract #1023.

This study claims that chronic exposure to low levels of mercury cause significant alterations of CNS function. The authors found a mean urinary mercury level of 2.51 ± 3.01 μg/L in 2,835 dental professionals. From a subpopulation of 1,488 eligible subjects, 200 dentists (3.08 ± 2.00 μg/L) and 200 assistants (1.96 ± 1.82 μg/L) were chosen for a battery of 16 behavioral tests repeated 6 months later. The criteria for eligible subjects were not defined. The authors found significant neurological (CNS) impairment in 11 tests and no impairment in 5 tests. Ten of the eleven tests showed about the same level of impairment significance (beta 0.11-0.20). The most pronounced impairment was in mood (beta 0.38). However, mood was determined by the subject's own very subjective assessment and not by a more objective, independent test. When judging the validity of results, one must consider the ability of the study to detect changes. In this study the higher the beta, the more likely that a change in CNS effects will be detected. A beta of

1.0 is certainty to detect a change, while a beta of 0 is no probability of detecting a change. Therefore, this study shows very low probability of being able to detect a change in CNS effects, and probably has no practical significance. That is, one is not likely to experience noticeable CNS impairment in everyday activities from chronic exposure to 1-5 μg/L of urinary mercury. Finally, the most important criticism of this study is its lack of a non-dental, no amalgam control group for comparison. The authors acknowledge that the general population has a 3-9 μg/L urinary mercury level. Their dental population is at the low end of the general population range. Since the level of CNS impairment was found to be extremely low in the dental group, might not the same result have been found in a non-dentist control group?

- Bittner AC, Jr, Echeverria D, Woods JS, Aposhian HV, Naleway C, Martin MD, Mahurin RK, Heyer NJ, Cianciola M. "Behavioral effects of low-level exposure to mercury among dental professional: cross-study evaluation of psychomotor effects." Neurotoxicol Teratology. 1998 Jul-Aug; 20 (4): 429-39.

A cross-study design was used to evaluate the sensitivities of five psychomotor tasks previously used to assess preclinical (subclinical) effects of low-level mercury (urinary > or = 55 ug/L). This study by Bittner et al pooled dental professional subject populations from six studies (including the one previously reported in 1995) over the last six years. The five psychomotor tests were the Intentional Hand Steadiness Test (IHST); Finger Tapping: The One-Hole Test; NES Simple Reaction Time (SRT); and Hand Tremor. Multivariate analyses were conducted following the hierarchical analysis of multiple response (HAMR) approach. Taken as a whole, the results of this study support the following conclusions and recommendations: 1) the Intentional Hand Steadiness Test (IHST) factor summary score is very highly related (B =0.42, p > ten to the six) to the long-transformed urinary mercury at low levels (>55 ug/L) and holds occupational relevance for dental professionals; 2) Use of dental professionals or another similarly homogeneous group is recommended for future studies where low-level mercury exposure and threshold effects are of concern; and 3) Statistical methodologies are recommended for use in future studies for condensation of multiple scores into summary scores with enhanced reliabilities, computation of these reliabilities, and using these to derive correction for attenuation relationship with environmental exposure levels.

The subjects involved in these two studies were highly selective (urinary mercury greater than 55 ug/L) and the study subjects' past history of mercury exposure was unknown to the investigators. Peak exposure in the past may play an important role in the neuropsychological deficits observed in these subjects Albers et al. (Albers JW. Kallenbach LR et al., "Neurological abnormalities associated with remote occupational elemental mercury exposure," Ann Neurol 24:651-659) in 1988 demonstrated that the number of peak exposure events may be actually responsible for the neurological damage that is revealed by neurobehavioral tests (i.e. the number of peak exposure events have been shown to be a better predictor of neurological effects associated with exposure to mercury than mean or cumulative Hg exposure levels). Furthermore, the average urinary mercury level in practicing dentists participating in the ADA's annual Health Screening Program is currently at 3-5 ug/L, which is close to the general population. This most

likely resulted from efforts in mercury hygiene education, as well as the persistent use of pre-encapsulated amalgam preparations. The data presented in these two papers may not be applicable to patients with amalgams. A recent study reported by a group of investigators at the School of Public Health, Columbia University (Factor-Litvak PR, Hasseloren G, Jacobs DM et al. "Mercury-containing amalgam and neuropsychological function in health adults." Journal of Dent Res 80;special issue (absts. 1619 and 1791), January 2001. In this study, the investigators examined whether the low levels of mercury derived from amalgam were associated with subtle neuropsychological deficits in a population of healthy, employed adults (age 30-49). This cross-sectional epidemiologic study recruited 550 men and women for a study of dental health and general well being. Data from a modified oral examination, laboratory assays, structured questionnaire and neuropsychological test battery were used in this analysis. The authors concluded that no statistically significant associations were found for any exposure measure or any of the outcomes. These results do not provide evidence that low-level mercury exposure, derived from dental restorations, is associated with neuropsychological function in healthy, employed adults in this age group.

- Pendergrass JC, Haley BE, Vimy MJ, Winfield SA and Lorscheider FL, "Mercury vapor inhalation inhibits binding of GTP to tubulin to rat brain: similarity to a molecular lesion in Alzheimer diseased brain." Neurotoxicology 1997; 18(2): 315-24.

Hg^{++} interacts with brain tubulin and disassembles microtubules that maintain neurite structure. Since it is well known that Hg vapor is continuously released from "silver" amalgam tooth fillings and absorbed into the brain, the rats were exposed to mercury vapor 4 hours/day for 0, 2, 7, 14 and 28 days at 250 or 300 micrograms Hg/cubic meter air, concentrations present in the mouth air of some humans with many amalgam fillings. The average rat brain mercury concentrations increased significantly (11-47 fold) with duration of mercury vapor exposure. By 14-day mercury exposure, photoaffinity labeling on the beta-subunit of the tubulin dimmer with [alpha 32P] 8N3 GTP in brain homogenates was decreased 41-74%, upon analysis of SDS-PAGE autoradiograms. The identical neurochemical lesion of similar or greater magnitude is evident in Alzheimer brain homogenates from 80% of patients, when compared to human age-matched neurological controls. Since the rate of tubulin polymerization is dependent upon binding of GTP to tubulin dimmers, the authors conclude that chronic inhalation of low-level mercury vapor can inhibit polymerization of brain tubulin essential for formation of microtubules.

The authors have frequently used this paper to imply that mercury vapor causes Alzheimer's disease in humans. The rat model used by the investigators appears to be interesting, but the concentration of mercury vapor (250-300 ug/m^3 air) used by the investigators was 5-6 times higher than the OSHA and NIOSH threshold limit values of 50 ug/m^3. This is not a realistic or simulated level of mercury exposure for patients with dental amalgams. In a series of studies published by Fung et al. (Fung YK, Meade AG, Rack EP, Blotchy AJ et al. "Determination of blood mercury concentrations in Alzheimer's patients." J Toxicol Clin Toxicol 1995; 33(3): 243-7; Fung YK, Meade AG,

Rack EP et al. "Mercury determination in nursing home patients with Alzheimer's disease." Gen Dent 1996 Jan-Feb; 44(1): 74-8 and Fund YK, Meade AG, Rack EP and Blotcky AJ. "Brain mercury in neurodegenerative disorders." J Toxicol Clin Toxicol 1997; 35(1): 49-54. Fung et al. conducted these studies to determine the concentrations of mercury in seven different brain regions from patients histologically confirmed with Alzheimer's disease, as compared to control subjects without known central nervous system and renal disorders. Brain mercury concentrations in all deceased subjects can be derived from amalgam restorations, diet, and the working environment. Based on their studies, the investigators concluded that there is no significant difference in blood and brain mercury concentrations between Alzheimer patients and aged-matched control patients, thus demonstrating that mercury derived from dental amalgam is not considered a significant factor in the pathogenesis of Alzheimer neurological disorder.

In a similar study conducted by Saxe SR, et al. (Saxe SR, Wekstein MW et al. Alzheimer's disease, dental amalgam and mercury. JADA 1999, Feb; 130(2): 191-9. This study consisted of 68 human subjects with diagnosed Alzheimer's disease and 33 control subjects without Alzheimer's to determine mercury levels in multiple brain regions at autopsy, and to ascertain the subjects' dental amalgam status and history. The investigators concluded that mercury in dental amalgam restorations does not appear to be a neurotoxic factor in the pathogenesis of this disease. Furthermore, the authors found that brain mercury levels are not associated with dental amalgam, either from existing amalgam restorations or according to the subjects' dental amalgam restoration histories. Furthermore, dental amalgam restorations, regardless of number, occlusal surface area or time, do not relate to brain mercury level.

- Leong, CC, Syed, NI, and Lorscheider, FL. "Retrograde degeneration of neurite membrane structural integrity and formation of neurofibrillary tangles at nerve growth cones following in vitro exposure to mercury." NeuroReports 12(4): 733-73 2001.

The authors claimed that exposure of snail neuron cells, in the culture system of the laboratory, to mercury chloride salt caused the formation of neurofibrillary tangles (NFTs), which is one of the hallmark pathological findings in the autopsy brain samples of patients that died from Alzheimer's disease. In addition to NFTs, such abnormalities as amyloid plaques and the hyperphosphorylation of Tau protein have also been found in post-mortem brain tissues obtained from Alzheimer patients. With time-lapsed microscopic pictures, the authors claimed these morphological changes are direct evidence that mercury is an etiological factor for Alzheimer's disease in humans. The major criticism with this paper is that the study only provides morphological data. Also, the mercury chloride concentration (20.1 ug/L) used in the study is at least five times high than data reported by other investigators on patients with amalgam restorations. This contradicts the claim made by the authors that the mercury dose employed in the study has clinical relevance in humans. It is well documented and commonly known that manganese (Mn); lead (Pb) and cadmium (Cd) are neurotoxins. Yet, in this study, these authors showed no adverse effects. The purity of $HgCl_2$ salt, as well as other metal salts, were not known or provided in their study. Various grades of chemicals may contain

many impurities, which may bias the experimental observation. A cause-and-effect relationship needs to be established on the sprouting assay of the neurite outgrowth study. A dose-response is needed to establish this relationship. This study has not been independently verified in other laboratories. Finally, this study simply showed that the treatment of mercury chloride caused disruption of the membrane structure and reduction of linear growth rate of neuritis of cultured snail neurons. The authors' finding that mercury from amalgam restorations "as a potential etiological factor for Alzheimer's disease" is not supported by this study. Despite these deficiencies, the authors insisted that they have found the smoking gun they have been looking for to identify mercury as an etiological agent for Alzheimer's disease.

IV. Renal System

- Boyd ND, Benediktsson H, Vimy MJ, Hooper DE, Lorscheider FL 1992, "Mercury from dental 'silver' tooth fillings impairs sheep kidney function." Am J Physio. 199 Oct; 261(4Pt2): R1010-4.

In humans, mercury vapor is released from "silver" amalgam fillings that contains 50% mercury by weight. These studies show that when 12 show fillings are placed in sheep teeth, the kidneys will concentrate amalgam mercury at levels ranging from 5 to 10 micrograms Hg/g renal tissue 4-20 weeks after placement. Twelve occlusal fillings were placed in each of six adult female sheep under general anesthesia, using standard dental procedures, and glass ionomer occlusal fillings (12) were inserted in two control sheep. At several days before dental surgery, and at 30 and 60 days after placement of fillings, renal function was evaluated by plasma clearance of inulin and by plasma and urine electrolytes, urea, and proteins. An average plasma inulin clearance rate of 69.5 ± 7.2 ml/min before amalgam placement was reduced to 32.3 +/-8.1 ml/min by 30 days and remained low at 27.9± 8.7 ml/min after 60 days. Inulin clearance did not change in controls. After amalgam placement urine concentration of albumin decreased from 93.0 ± 20.5 to 30.1 ± 15.3 mg/L and urine sodium concentration increased steadily from 24.8 ± 7.7 to 82.2 ± 20.3 mmol/L at 60 days. Based on these parameters, the authors concluded that sheep kidney function is impaired by the placement of dental amalgams.

In 1992, Lorscheider's study was severely criticized by Malvin et al. (" Mercury from dental 'silver' tooth fillings – letter. Am J Physiol 262 R 716-717). Malvin, a well-known renal physiologist from the University of Michigan School of Medicine, indicated that the evidence provided by Boyd et al. did not demonstrate nephrotoxicity as a result of the placement of dental amalgam. Furthermore, the data presented in the paper is incompatible with the conclusion. The only result in the paper that seems to support the conclusion is the 60% decrease in the glomerular filtration rate (GFR) of sheep that received 12 amalgam fillings. Malvin et al. even cast doubt on the validity of the GFR data. The authors pointed out errors in the inulin clearance technique used to measure the GFR, noting that "the clearance methods are so poorly described that they are not possible to understand." The authors also stated that critical data necessary to interpret the results are not presented. They further point out that the data are not even self-

consistent, and conclude that the evidence for a reduced GFR was based on faulty and poorly described inulin clearance methods and contradicted by the urea data. They conclude their criticism by pointing out other data in the paper that are inconsistent with mercury nephrotoxicity, and by noting the lack of appropriate controls.

Three human studies, published later, further rejected the link between dental amalgam and renal dysfunction. First, in 1995, Herrstrom et al. published "Dental amalgam, low-dose exposure to mercury, and urinary proteins in young Swedish men" (Arch Environ Hlth 50:103-107). In this paper, the authors conclude that no significant relationship was found between any of the proteins (e.g. albumin, alpha-microglobulin, kappa and lambda light chains, and N-acetyl-beta-D-glucosaminidase) and amalgam or urinary mercury. Furthermore, the authors concluded that the study's results did not suggest that amalgam fillings cause kidney dysfunction in humans.

The second study was reported by Sandborgh-Englund et al. in 1996 ("No evidence of renal toxicity from amalgam fillings." Am J Physiol 271:R941-945). The aim of this study was to determine whether signs of renal toxicity could be observed in humans exposed to inorganic mercury from amalgam fillings in conjunctions with dental treatment. In ten patients, all amalgam restorations were removed during one single treatment session. One week before and 60 days after removal, the glomerular filtration rate (GFR) was determined by the Cr(51)-EDTA clearance techniques. Blood and urine samples were collected for analysis of mercury, creatinine, Beta(2) microglobulin, N-acetyl-beta-glucosaminidase (NAG), and albumin one week before and 1,2 and 60 days after amalgam removal. The plasma mercury concentration increased significantly 1 day after removal. Sixty days later, significantly lower mercury levels were found in blood, plasma, and urine. The GFR values were similar before and after mercury exposure (mean 94 and 94 mL/min per 1.73 meter square, respectively) No detectable effects occurred on excretion of NAG, Beta(2)-microglobulin, or albumin. It is concluded that no signs of renal toxicity could be found in conjunction with mercury released from amalgam fillings. One additional study was conducted at the Health Screening Program, held annually at the American Dental Association's Annual Meeting (Naleway C, Chou, HN, Muller T, Dabney J, Roxe D, and Siddiqui F. "On-site screening for urinary Hg concentrations and correlation with glomerular and renal tubular function." J Public Health Dentistry 51(1), 12-17, 1991). At the ADA 1985-1986 Annual Sessions, an on-site screening for mercury was conducted to identify dentists having elevated urinary mercury concentrations. The data generated from this study were used to examine the relationship between elevated urinary mercury exposure and kidney dysfunction. Kidney dysfunction was assessed by measurement of serum and urine beta 2 microglobulin concentrations, serum creatinine, and creatinine clearance. The mean values found for urinary mercury were 5.8 micrograms Hg/L and 7.6 micrograms Hg/L for 1985 and 1986, respectively. Urinary mercury concentrations for this population were found to fall within the range of not detected to 115 micrograms Hg/L Of the total number of participants assayed in 1985 and 1986, roughly 10% of the sample exhibited elevated mercury concentrations above 20 micrograms Hg/L. An analysis for the clinical markers indicated no clear relationship between elevated urinary mercury concentrations and kidney dysfunction.

V. Immunology System

- Eggleston DW, "Effect of dental amalgam and nickel alloys on T-lymphocytes: Preliminary report." J of Prosthetic Dentistry, 1984; 51 (5): 617-623.

- Hultman P, Johansson U, Turley SJ et al. "Adverse immunological effects and autoimmunity induced by dental amalgam and alloy in mice." 1994; 8(14): 1183-90.

In 1984, Eggleston suggested that dental amalgam could adversely affect the quantity of T-lymphocytes. His study was extremely preliminary and consisted of a total of two patients. The study consisted of no proper control group. Nevertheless, this study was cited in many later studies to support the reduced immunocompetence of patients with dental amalgams. The findings of Eggleton's study are difficult to interpret because no information was provided as to the method of counting cells, the determination of T lymphocytes as a percentage of the total lymphocytes, or the intra-subjects' variability through repeating testing. The results were expressed only in percentages, giving no indication of the total number of cells in each subject.

In 1994, Hultman et al. implanted 8-100 mg silver amalgam or silver alloy, for 10 weeks or 6 months, in the peritoneal cavity of female SJL/N mice. The authors claimed that chronic hyperimmunoglobinemia, serum IgG auto-antibodies targeting the nucleolar protein fibrilarin, and systemic immune-complex deposits developed in a time- and dose-dependent manner after implantation of the amalgam or alloy. Furthermore, splenocytes from mice implanted with amalgam or alloy showed an increased expression of class II molecules. The functional capacity of splenic T and B cells was also affected in a dose-dependent way. The authors hypothesize that, under appropriate conditions of genetic susceptibility and adequate body burden, heavy metal (Hg and silver) exposure from dental amalgam may contribute to immunological aberrations, which could lead to overt autoimmunity.

Both Eggleston's and Hultman's studies were challenged by later studies outlined below.

Eggleston's study was completely challenged by JR Mackert's 1991 published study (Mackert JR Jr., Leffell MS, Wagner DA, and Powell BJ. "Lymphocyte level in subjects with and without amalgam restorations." JADA 1991; 122(3): 49-53). This study was well designed and composed of adequate study subjects with vigorous statistical analysis. The claim that mercury from dental amalgam produces "reduced immunocompetence" was examined by measuring the levels of three populations of lymphocytes on 37 subjects (21 with amalgam restorations and 16 without). The results of Mackert's study show no indication that amalgam restorations affect the human immune system, nor do they support the "reduced immunocompetence" claim.

Eggleston's study was further challenged by a newer study published by Loftenius A et al. (Loftenius A., Sandborgh-Egnlund G., and Ekstrand J, "Acute exposure to mercury from amalgam: no short-time effect on the peripheral blood lymphocytes in health individuals: J Toxicol Environ Health A 1998; 54(7): 547-60). This study was performed to evaluate if an acute low-dose mercury exposure, achieved by total amalgam removal in ten healthy individuals, would affect the immunocompetent cells in human blood when the mercury level in blood and plasma was increasing. Induction of lymphocyte proliferation, measured as spontaneous de novo DNA synthesis, and total T cells, CD4+ T cells, CD8+T cells, and B cells, were studied prior to and 7, 31, and 48 hours after amalgam removal. In addition, the levels of interleukin-6 and C-reactive protein in serum/plasma were measured. No significant influence on the peripheral blood lymphocytes or interleukin-6 or C-reactive protein could be detected.

Hultman's study was later challenged by Langworth in a human study. Langworth's paper, "Minor effects of low exposure to inorganic mercury on the human immune system," was published in Scand J Work Environ Health 1993; 19(6): 405-13. In this study, the influence of exposure to inorganic mercury on the immune system was examined in 36 workers, who were occupationally exposed to mercury vapor, and a control group without known mercury exposure. Concentrations of mercury in blood and urine and some parameters (e.g. white blood cell differential counts, serum immunoglobulins and autoantibodies, and in vitro production of cytokines interleukin 1(IL-1), and tumor necrosis factor alpha) judged to affect immune system were determined. The authors concluded that virtually all of the immunologic parameters were within normal ranges and did not differ significantly between the two groups. Only a few individuals known to be sensitive to amalgam demonstrated minor reduction of the in vitro production of both tumor necrosis factor alpha and IL-1. No significant correlations were noted between different mercury exposure estimates and the immunologic parameters.

VI. Antibiotic Resistance

- Summers AO, Wireman J, Vimy MJ, Lorscheider FL, Marshall B, Levy SB, Bennett S. and Billard L, " Mercury released from dental 'silver' fillings provokes an increase in mercury- and antibiotic-resistant bacteria in oral and intestinal flora of primates" Antimicrob. Agents Chemother. 1993 Apr; 37(8):1730-1

- Lorscheider FL, Vimy MJ, Summers AO and Zwiers H., "The dental amalgam mercury controversy—inorganic mercury and the CNS; genetic linkage of mercury and antibiotic resistances in intestinal bacterial". Toxicology 1995, 97 (1-3): 19-22

Resistances to mercury and to several antibiotics were examined in the oral and intestinal flora of six adult monkeys prior to the installation of amalgam fillings, during the time they were in place, and after replacement of the amalgam fillings with glass ionomer fillings (in four of the monkeys). The monkeys were fed an antibiotic-free diet, and fecal mercury concentrations were monitored. There was a statistically significant increase in

the incidence of mercury-resistant bacteria during the 5 weeks following installation of the amalgam fillings and during the 5 weeks immediately following their replacement with glass ionomer fillings. These peaks in incidence of mercury-resistant bacteria correlated with peaks of Hg elimination (as high as 1 mM in the feces) immediately following amalgam placement and immediately after replacement of the amalgam fillings. Representative mercury-resistant isolates of three selected bacterial families e.g. oral streptococci, members of the family enterobacteriaceae, and enterococci, were also resistant to one or more antibiotics, including ampicillin, tetracycline, streptomycin, kanamycine, and chloramphenicol. While such mercury- and antibiotic-resistant isolates among the staphylococci, the enterococci, and members of the family enterobacteriaceae have been described; this paper represents the first report of mercury resistance in the oral streptococci. Many of the enterobacterial strains were able to transfer mercury and antibiotic resistances together to laboratory bacterial recipients, suggesting that the loci for these resistances are genetically linked. The findings by these authors indicate that mercury released from amalgam fillings can cause an enrichment of mercury resistant plasmids in the normal bacterial flora of primates. Many of these plasmids also carry antibiotic resistant, implicating the exposure to mercury from dental amalgams in an increased incidence of multiple antibiotic resistant plasmids in the normal flora of nonmedicated subjects.

The second study by Lorscheider et al (1995) basically summarizes two previously published papers by Haley et al (**see III CNS section above**) on a rat model indicating the ADP-ribosylation of tubulin and actin brain proteins is markedly inhibited as a result of mercury vapor exposure, and that mercury can thus alter a neurochemical reaction involved with maintaining neuron membrane structure and also the paper published by Summers immediate mentioned above. Lorscheider et al., however, extended Summers observation in the monkey study and indicated that mercury, specifically from amalgam, will enrich the intestinal flora with Hg-resistant bacterial species which in turn also are resistant to antibiotics.

The above two studies were disputed in two publications from the Antimicrobial Research Laboratory, National Public Health Institute, Finland (Osterblad M., Leistevuo J et al. " Antimicrobial and mercury resistance in aerobic gram-negative bacilli in fecal flora among persons with and without dental amalgam fillings." Antimicrob. Agents Chemotherapy. 1995 Nov; 39(11): 2499-502; and Leistevuo, J., Jarvinen, H. et al., "Resistance to mercury and antimicrobial agents in ***Streptococcus mutans*** isolates from human subjects in relation to exposure to dental amalgam fillings". Antimicrobial Agents and Chemotherapy, Feb. 2000, p. 456-457). The first paper was intended to test the common perception – whether antimicrobial resistance widespread can be accounted through the selection pressure caused by the use of antibiotics alone. The model chosen by these investigators to test the validity of this hypothesis: that a high mercury content in feces might select for mercury-resistant bacteria and thus for antimicrobial resistance linked to mercury resistance. Three subject groups with different exposures to dental amalgam fillings were compared. None of the subjects had taken antimicrobial agents during the three preceding months or longer. The group exposed to amalgam had 13 times more mercury in feces than the group that had never been exposed to amalgam and

the group whose amalgam fillings had been removed. The authors concluded that the amount of mercury in feces derived from amalgam was not selective for any resistance factors in aerobic gram-negative bacteria, but antimicrobial resistance was widespread even among healthy subjects with no recent exposure to antibiotics. Leistevuo et al reported in second paper that resistance to cefuroxime, penicillin, tetracycline, and mercury was demonstrated for 839 ***Streptococcus mutans*** isolates from 209 human study subjects. The Minimum Inhibitory Concentration (MIC) of these antibiotics did not differ for isolates from one dental amalgam group and control groups: one without dental amalgam and a group whose members had their amalgam fillings removed.

Furthermore, in a letter to the editor of the Antimicrobial Agents and Chemotherapy by one of our former Science Division staff (Dr. Brian Shearer) questioning the validity of the conclusions drawn by Summers in her paper quoted above, Dr. Summers responded to Dr. Shearer's criticism professionally and competently and insisted that the conclusions in her paper are both valid and defensible.

Mr. BURTON. Thank you, Doctor.

Mr. Stoute.

Mr. STOUTE. Mr. Chairman and members of the committee, thank you on behalf of the National Dental Association for this opportunity to participate in today's hearings. My name is Gregory Allen Stoute, and I am currently serving as president of the National Dental Association. In addition, I am the Chief of Dental Health Services for Harvard University in Cambridge, Massachusetts, I hold a Master's of Public Health degree, and also serve as a dental public health resident at Boston University Goldman School of Dental Medicine, and serve as a Lieutenant Colonel in the Medical Corps of the U.S. Army Reserves. I have practiced dentistry for 26 years.

The NDA represents more than 7,000 African-American dentists, both in the United States and abroad. Since 1913 the association has been dedicated to improving the health of the underserved and promoting safety, prevention, quality, and equity in oral health as well as general health. We are deeply committed to educating the consumer and helping the public make informed choices based on sound science.

Dental amalgam has been used as a restorative material in dentistry for over 150 years. In fact, the Food and Drug Administration stated that there is "more significant human experience with dental amalgam than any other restorative material." The National Institutes of Health, the Centers for Disease Control and Prevention, the U.S. Public Health Service, and the World Health Organization have all said that dental amalgam is a safe restorative material.

I will simply state for the record that the NDA supports the conclusions of these organizations that we trust and believe amalgam is a safe and effective restorative material. This belief underlies our position. Dentistry is a profession built on sound science and the NDA and our members are proud to be a part of that tradition. Because we are firm in that belief, we will continue to advocate vigorously for its continued availability as a treatment option.

All dental patients deserve the right to choose the most appropriate course of treatment. Eliminating dental amalgam as a restorative option precludes a dentist from offering his or her patients what may be the best choice from a clinical perspective. Dental amalgams are generally the preferred material for large fillings in back teeth or in very deep fillings or fillings under the gum line. Alternatives are often less effective and clinically contra indicated in these situations. The NDA believes that all dental patients should be provided with a full range of appropriate treatment options. Decisions on the most appropriate course of oral health treatment are best made by the dentist, in consultation with the patient, prior to treatment.

Dental caries, or tooth decay, are the most common chronic childhood disease, five times more common than asthma and seven times more common than hay fever. Epidemiological evidence demonstrates that dental disease rates and dental needs are highest in low-income and special needs populations—those who qualify for Medicaid and the State Children's Health Insurance Program [CHIP].

Access to quality dental care for all children, but especially poor children, is a vital element of overall health care and development. Unfortunately, children eligible for Medicaid and CHIP are three to five times more likely to have untreated tooth decay and those programs provide the only access to oral health care for a large proportion of the economically disadvantaged. Very often these children have well-advanced dental disease. About 20 million children are now covered under the Early and Periodic Screening, Diagnosis and Treatment program in Medicaid. Nevertheless, only 20 percent to 30 percent of Medicaid-eligible children see a dentist annually and an unknown but much smaller percentage receives comprehensive care. CHIP extends dental benefits to millions more children, but the law provides no mandate for dental services.

The NDA is concerned that the movement to eliminate amalgam will create unwarranted public anxiety, increase disparities, eliminate access, and eliminate viable treatment options. We believe strongly that all Americans are entitled to quality dental care and we believe that these populations who have always received the least care deserve to have all the dental care options available to them. We feel that eliminating these options will place Americans who are already disenfranchised at an ever greater disadvantage.

The NDA believes that all publicly and privately funded dental plans should be required to provide reimbursement for all appropriate restorative materials. Many public and private sector dental plans pay only for the most cost efficient restorative material. The NDA believes that the patients and their doctors should have the option to discuss and select the most appropriate course of treatment. These discussions would include the type of materials to be used and the services to be rendered, as well as other considerations such as cost, durability, and aesthetics.

The NDA, along with the National Medical Association, opposes eliminating dental amalgam as an option for dental patients because we believe this would decrease access and increase disparities.

By the way, I have spoken directly with Kweisi Mfume, the president and CEO of the NAACP, and he states that, "following delegate vote at our annual convention, our association does not formally adopt any resolution unless it is approved by the national board of directors, which has not met as of yet."

Also from their health division and the health committee, it states that they both felt that this resolution was premature because "the science is still not available yet to confirm the need to support the Watson-Burton bill to phaseout all mercury in dentistry within the next 5 years." And likewise, getting the State legislators to develop similar legislation is too soon for that as well. Thank you very much.

[The prepared statement of Mr. Stoute follows:]

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STATEMENT

BY THE

NATIONAL DENTAL ASSOCIATION

TO THE

HOUSE GOVERNMENT REFORM COMMITTEE

ON

"MERCURY IN DENTAL AMALGAMS:

AN EXAMINATION OF THE SCIENCE"

Thursday, November 14, 2002

Mr. Chairman and members of the committee, thank you on behalf of the National Dental Association (NDA) for this opportunity to participate in today's hearing. My name is Gregory Allen Stoute, D.M.D., M.P.H. and I currently am serving as president of the NDA. In addition, I am Chief of Dental Health Services for the University Health Services at Harvard University in Cambridge, Massachusetts.

The NDA represents more than 7,000 African-American dentists, both in the United States and abroad. Since 1913 the Association has been dedicated to improving the health of the underserved and promoting safety, prevention, quality and equity in oral health as well as general health. We are deeply committed to educating the consumer and helping the public make informed choices based on sound science.

Dental amalgam has been used as a restorative material in dentistry of over 150 years. In fact, the Food and Drug Administration stated that there is "more significant human experience with dental amalgam than any other restorative material." The National Institutes of Health, the Centers for Disease Control and Prevention, the U.S. Public Health Service and the World Health Organization have all said that dental amalgam is a safe restorative material.

Dentistry is a profession built on sound science and the NDA and our members are proud to be a part of this tradition. Others testifying before this committee will address the issue of amalgam safety and the science that backs that up. I will simply state for the record that the NDA supports the conclusions of the organizations listed above and believes amalgam is a safe and effective restorative material; this belief underlies our positions. Because we are firm in that belief, we will continue to advocate vigorously for its continued availability as a treatment option.

All dental patients deserve the right to choose the most appropriate course of treatment. Eliminating dental amalgam as a restorative option precludes a dentist from offering his or her patients what may be the best choice from a clinical perspective. Dental amalgams are generally the preferred material for large fillings in back teeth or in very deep fillings or fillings under the gum line. Alternatives are often less effective in these situations. The NDA believes that *all* dental patients should be provided the full range of appropriate treatment options. Decisions on the most appropriate course of oral health treatment are best made by the dentist, in consultation with the patient, prior to treatment.

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Access to quality dental care for all children, but especially poor children, is a vital element of overall health care and development. Unfortunately, children eligible for Medicaid and SCHIP are three to five times more likely to have untreated tooth decay and those programs provide the only access to oral health care for a large proportion of

the economically disadvantaged. Very often these children have well-advanced dental disease. About 20 million children are covered under the Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) program in Medicaid. Nevertheless, only 20 percent to 30 percent of Medicaid-eligible children see a dentist annually and an unknown, but much smaller, percentage receives comprehensive care. SCHIP extends dental benefits to millions more children, but the law provides no mandate for dental services.

The NDA is concerned that the movement to eliminate amalgams will create unwarranted public anxiety, increase disparities, eliminate access and eliminate viable treatment options. We believe strongly that all Americans are entitled to quality dental care and we believe that those populations that have always received the least care deserve to have all of the dental care options available to them. We feel that eliminating these options will place Americans who are already disenfranchised at an even greater disadvantage. The NDA believes that all publicly and privately funded dental plans should be required to provide reimbursement for all appropriate restorative materials.

Many public and private sector dental plans pay only for the most cost efficient restorative material. The NDA believes that the patients and their doctor should have the option to discuss and select the most appropriate course of treatment. These discussions would include the type of materials to be used and services to be rendered, as well as other considerations such as, cost, durability and aesthetics.

Summary

The NDA opposes eliminating dental amalgam as an option for dental patients because we feel that this would decrease access and increase disparities.

Mr. BURTON. Thank you. And I am sorry that I introduced you as Mr. Stoute. I understand that you are Dr. Stoute as well. So thank you.

Mr. Bender.

Mr. BENDER. Thank you, Mr. Chairman, members of the committee. My name is Michael Bender and I am the director of the Mercury Policy Project, an advocacy organization focused on reducing exposure in emissions from mercury. While there has been considerable debate about the health effects of mercury fillings, little attention has been focused thus far nationally on dental mercury releases to the environment and their subsequent impacts. Yet there is ample evidence from multiple government agencies that U.S. dental mercury uses and releases is an environmental concern that in turn presents health risks.

Due to human activities over the last century, mercury levels have increased in the environment three-to fivefold and are responsible for between 50 to 70 percent of the total mercury loadings. The most recent data from the Centers for Disease Control indicate that 8 percent of women of reproductive age in the United States have blood mercury levels that pose a risk to the developing fetus.

In June 2002, the Mercury Policy Project co-released a report highlighting the pathways by which dental mercury is released to the environment. Our study found that U.S. dentists are among the top mercury users, on average consuming well over 30 tons of mercury per year, and are the single largest polluter of mercury to the Nation's wastewater. And while most human activities for mercury, and their releases, have declined by 80 percent or more since the 1980's, this has not been the case with the U.S. dental sector.

Approximately 70 to 100 million amalgams are placed in Americans each year by dentists, and 70 percent of these are replacement fillings. Extracted amalgam materials are either rinsed down the drain, usually to a municipal wastewater treatment system where the heavy metal builds up in the sewage sludge, or deposited in biomedical containers that are incinerated or placed in trash disposed in landfills or incinerators. When amalgam waste or mercury-laden sludge is incinerated, the mercury is instantaneously released to the air, contributing to both the regional and global mercury pollution. There is no debate on this point.

Studies by EPA and numerous municipalities document that most wastewater treatment plans have high levels of mercury with significant contributions from dental clinics. Moreover, conditions within some dental unit holding tanks are perhaps favorable for promoting methylation of mercury. Recently the Association of Metropolitan Sewerage Agencies evaluated seven major municipal wastewater treatment plants to determine and quantify sources of mercury coming into facilities. At all plants dental uses were identified as "by far" the greatest contributors to the mercury load, accounting on average for 40 percent of the load, more than three times the next largest source. Yet wastewater treatment plants are not designed to reduce mercury loadings to the environment. Consequently, all mercury either settles in the sewage sludge or passes through the system to be discharged directly into a waterway.

However, there are cost-effective solutions readily available today to significantly reduce dental mercury releases through employ-

ment of best management practices and installation and, I emphasize, proper maintenance of amalgam separators at dental clinics. Several States, including Vermont and New Hampshire, are currently working with their State dental associations to foster this approach. Furthermore, the American Dental Association has demonstrated a proactive approach through review of twelve amalgam separators currently available in the United States today, finding that all exceeded testing standards and that several of the units tested exhibited removal efficiencies in excess of 99 percent.

Our June 2002 report describes successes throughout the United States and in many countries who have worked cooperatively with their dental sector in promoting installation of amalgam separators. A case in point is Canada which has recently developed nationwide standards to reduce dental mercury pollution. In response, the city of Toronto, Canada, has substantially reduced dental mercury releases over the last year solely through the installation of amalgam separators and employment of best management practices by 1,000 of Toronto's dental practices. Data from Toronto indicate that the total average monthly mass of mercury in the sludge has been reduced on average by 50 to 60 percent, and that is just over the last several months.

In a second example, a 2001 study conducted cooperatively between the Minnesota Dental Association and the Metropolitan Council Environmental Services quantified sludge mercury reductions at two wastewater treatment plants before and after amalgam separators were installed in dental clinics. The study found significant reductions of mercury loadings from dental clinics of between 29 to 44 percent at the two wastewater treatment plants.

In sum, employment of best management practices and installation of amalgam separators would divert significant quantities of mercury from ending up in the sludge at U.S. wastewater treatment plants and reduce disposal into landfills and incinerators and reduce environmental releases and the subsequent risk to humans from this dangerous toxin. Unfortunately, at this time less than 1 percent of dentists nationwide have installed amalgam separators. Based on conservative estimates, the costs for U.S. dental clinics to achieve these results would average approximately $600 per year. What we are talking about is perhaps one to five visits from dental patients would cover the cost for the entire year. This is clearly a cost-effective solution to a serious environmental problem. Thank you, Mr. Chair.

[The prepared statement of Mr. Bender follows:]

Testimony to the US Government Operations Committee on its November 14, 2002 Hearing on "Mercury in Dental Amalgam: An Examination of the Science."
By Michael T. Bender, Mercury Policy Project, http://mercurypolicy.org

Mr. Chair, members of the Committee, thank you for the opportunity to provide testimony on the important topic of mercury in dental amalgam. While there has been considerable debate about the health effects of mercury fillings, little attention has been focused thus far nationally on dental mercury releases to the environment and their subsequent impacts. Yet there is ample evidence from multiple government agencies that US dental mercury uses and releases are both a health and environmental concern.

Anthropogenic mercury uses and releases from all sources—including the dental sector—is a local, national and, increasingly, an international concern[1]. Due to human activities over the past century, mercury levels have increased in the environment 3-to-5 fold and are responsible for 50-to-70 percent of the total mercury loadings[2]. Mercury is a persistent, bioaccumulative toxin that poses a risk to human health, wildlife and the environment. In humans, mercury is a potent neurotoxin that can affect the brain, spinal cord, kidneys and liver. Like lead before it, the more we learn about the risks posed by releases—even in minute quantities—of this dangerous toxin into the environment, the more concerned we are. The most recent data from the Centers for Disease Control indicate that one in 8 women of reproductive age in the US have blood mercury levels that pose a risk to the developing fetus[3]. In 2001, the Food and Drug Administration issued new advisories warning pregnant women and children not to eat certain seafood[4], and 41 states now have fish consumption advisories for mercury-contaminated fish[5].

In June 2002, the Mercury Policy Project co-released a report with Health Care Without Harm and several other national and state organizations[6], highlighting the pathways by which dental mercury is released to the environment. Our review of the literature, government studies and expert interviews found that US dentists are among the top mercury users—on average consuming well over 30 tons of mercury per year[7]—and are the single largest polluter of mercury to the Nation's wastewater[8]. And while most other anthropogenic mercury uses—and their releases—have declined by 80 percent or more since the 1980's, this has not been the case with the US dental sector[9].

Approximately 70 to 100 million amalgams are placed in Americans each year, and 70 percent of these are replacement fillings, according to the American Dental Association. Extracted amalgam materials are either rinsed down the drain—usually to a municipal wastewater treatment system where the heavy metal builds up in the sewage sludge—or deposited in biomedical waste containers destined for medical waste incineration or autoclaves, or placed in trash disposed in municipal waste landfills or incinerators. When amalgam waste or mercury-laden sludge is incinerated, the mercury is instantaneously released to the air, contributing to both the regional and global mercury pool.

Studies by EPA and numerous municipalities[10] document that most wastewater treatment plants have high levels of mercury with significant contributions from dental clinics. Moreover, conditions within some dental unit holding tanks are perhaps favorable for

promoting methylation of mercury[11]. Recently, the Association of Metropolitan Sewerage Agencies evaluated seven major municipal wastewater treatment plants to determine and quantify sources of mercury coming into facilities. At all plants, dental uses were identified as "by far" the greatest contributors to the mercury-load, accounting, on average, 40 percent of the load, more than three times the next largest source[12].

Yet municipal wastewater treatment plants are not designed to reduce mercury loadings to the environment. Consequently, all mercury in the influent wastewater remains unattentuated in treatment plants, and either settles in the sludge (which is either land applied or incinerated) or passes through the system to be discharged into a waterway. After releases from dental offices, human wastes are the next greatest contributor of dental mercury to wastewater[13]. In addition, amalgam fillings are responsible for additional airborne releases through cremation.[14]

However, there are cost effective solutions readily available today to significantly reduce dental mercury releases through employment of best management practices and installation and proper maintenance of amalgam separators at dental clinics. Several states, including Vermont[15] and New Hampshire[16], are currently working with their state dental associations to foster this approach. Furthermore, the American Dental Association has demonstrated a proactive approach through review of the 12 amalgam separators currently available in the US today, finding that all exceeded testing standards and that several of the units tested exhibited removal efficiencies in excess of 99%[17].

Our June 2002 report describes successes throughout the US and in many countries who have worked cooperatively with their dental industries in promoting installation of amalgam separators. A case in point is the City of Toronto, Canada where a substantial reduction in dental mercury releases has occurred over the last year solely through installation of amalgam separators and employment of best management practices by 1000 of Toronto's dental practices. Data from the Toronto Sewer District indicate that the total average monthly mass of mercury in the sludge has been reduced, on average, by 50 to 60 percent[18]. In a second example, a 2001 study conducted cooperatively between the Minnesota Dental Association and Metropolitan Council Environmental Services quantified sludge mercury reductions in Hastings and Cottage Grove, Minnesota before and after amalgam separators were installed in dental clinics. The study found significant reductions of mercury loadings from dental clinics of between 29 and 44 percent at the two wastewater treatment plants[19].

In sum, employment of best management practices and installation of amalgam separators would divert significant quantities of mercury from ending up in the sludge at US wastewater treatment plants and reduce disposal into landfills and incinerators. Based on conservative estimates, the costs for US dental clinics to achieve these results would average approximately $600 dollars per year[20]. This is clearly a cost effective solution to a serious environmental problem.

Thank you.

[1] See the United Nations Environment Program's *Global Mercury Assessment Report* at: http://www.chem.unep.ch/mercury.
[2] Environmental Protection Agency (US), *Mercury Study Report to Congress.* Washington: EPA.1997.
[3] The Centers for Disease Control and Prevention concludes that 8% "of women have mercury levels within one-tenth of potentially hazardous levels (58 ppb) indicating a narrow margin of safety for some of those women and supporting efforts to reduce methylmercury exposure." The level is a benchmark dose level, derived in Faroes Island study. EPA used this level to calculate their reference dose, and the agency applies a 10-fold uncertainty factor (that results in a blood level of 58/10 + 5.8 ppb) to derive a RfD from there. EPA says that there may be harm to from exposure to mercury above the RfD. In its findings, CDC does not discuss population variability, uncertainties, etc., in the level at which harm could occur. However, if one assumes that anyone exposed above the EPA's RfD is at risk, then based on the CDC's latest data, 8% of the women of childbearing age in the US have blood mercury levels that put their newborns at risk. This is because 8% of women have blood mercury levels within a factor of 10 (= the EPA uncertainty factor of the effects level.
[4] FDA Consumer Advisory, *"An important message,"* Jan. 2001.
[5] See http://www.epa.gov/ost/fish.
[6] Bender, M., *"Dentist the Menace? The Uncontrolled Release of Dental Mercury."* June 2002. This report was co-release nationally and was also released in New England by the Mercury Policy Project, Health Care Without Harm, Sierra Club, Clean Water Action, Natural Resources Council of Maine, Toxics Action Center and the Northeast Office of the National Wildlife Federation. See: http://www.mercurypolicy.org/new/documents/DentistTheMenace.pdf.
[7] US Bureau of Mines, US Geological Survey, 1990-2000.
[8] Association of Metropolitan Sewerage Agencies, *"MercurySource Control and Pollution Prevention Program Evalution,"* prepared by Larry Walker Associates, March 2002.
[9] US Bureau of Mines, US Geological Survey, 1980-2000.
[10] Arenholt-Bindslev, S.; Larsen, A.H., *"Mercury Levels in Waste Water from Dental Clinics,"* Water, Air, Soil Pollution, 86 (1-4):93-9. Association of Metropolitan Sewerage Agencies, *"Evaluation of Domestic Sources of Mercury/Household Mercury Poses National Clean Water Compliance Concerns,"* 1996; http://www.amsa-cleanwater.org/pubs/mercury/mercury.cfm.
[11] M.E. Stone, M.E. Cohen, S.Z. Schade, J.C. Kuehbe, *"Methylmercury Content of Waste Water,"* US Naval Dental Research Institute, see: http://www.dentalmercury.com/publication.html.
[12] Association of Metropolitan Sewerage Agencies, *"MercurySource Control and Pollution Prevention Program Evalution,"* prepared by Larry Walker Associates, March 2002.
[13] Association of Metropolitan Sewerage Agencies, *"MercurySource Control and Pollution Prevention Program Evalution,"* prepared by Larry Walker Associates, March 2002.
[14] Environmental Protection Agency (US), *Mercury Study Report to Congress.* Washington: EPA.1997.
[15] Best Management Practices have been developed for use by dentists in Vermont, Minnesota, Massachusetts, New York, Indiana, Florida and Oregon.
[16] See New Hampshire House Bill 1251, as adopted into law. at:http://www.gen.court.state.nh.us/2002/HB1251.html.
[17] Fan,P.L., Batchu,H.,Chou,H-N., Gasparac,W., Sandrik,J. Meyer,D.M., *"Laboratory Evalution of Amalgam Separators"* The Journal of the American Dental Association, May, 2002. See: http://www.ada.org/prof/pubs/daily/0205/0508jada.html.
[18] Personal communication between Michael Bender and Martin P. Shaw, P. Eng., Senior Engineer, Industrial Waste and Stormwater Quality, Toronto Water & Wastewater Services, Nov 13 2002.
[19] Anderson,C.T., *"Community-Wide Dental Mercury Study,"* presented at the Water Environment Federation's (WEFTEC) 75th annual technical and educational conference, September 28-October 2,2002 in Chicago, IL.
[20] "Evaluation of Amalgam Removal Equipment and Dental Clinic Loadings to the Sanitary Sewer," Metropolitan Council Environmental Services and Minnesota Dental Association, December 2001.

Mr. BURTON. Thank you very much.

Let me start the questioning by asking a question of Dr. Mackert. I think you indicated that, and I cannot remember exactly what you said, but you indicated there is no risk with amalgams in the mouth. Why is it, as Dr. Fischer said, it is a toxic substance before you put it in the mouth and it is a toxic substance after you take it out of the mouth, but it is not a toxic substance while it is in your mouth?

Dr. MACKERT. Well when amalgam is first mixed, for several minutes after that it contains liquid mercury. The mercury reacts with the silver and tin and other elements in the metal powder and forms inter-metallic compounds which have completely different properties than liquid mercury. So immediately before it does contain liquid mercury and that is why it would be a hazard at that point.

Mr. BURTON. And it is soft when you are putting it into the mouth?

Dr. MACKERT. That is correct.

Mr. BURTON. It still does have liquid mercury in it.

Dr. MACKERT. That is correct.

Mr. BURTON. So when you are putting it in the mouth it is toxic?

Dr. MACKERT. Well, it releases some mercury vapor.

Mr. BURTON. So when you are putting it in the tooth there is a release of mercury vapor that the patient would be subject to?

Dr. MACKERT. A small amount of vapor. And this has been studied, how much is released when it is placed, and the amount is small.

Mr. BURTON. You are saying when it gets hard in the mouth it is safe?

Dr. MACKERT. Yes.

Mr. BURTON. OK. Now after the dentist takes it out of the mouth it is still hard.

Dr. MACKERT. Correct.

Mr. BURTON. So why is it toxic now?

Dr. MACKERT. It is not toxic at that point.

Mr. BURTON. Well we just heard from Mr. Bender here that one of the largest contributing factors in the toxicity of wastewater treatment plants is the mercury, and that is something that has been said all over the world. So if it is not toxic when you take it out of the mouth, why is it toxic when it gets into the wastewater treatment plant?

Dr. MACKERT. Well it is not toxic when it gets to the wastewater treatment plant. The way that these are analyzed is to digest such materials in nitric acid and you dissolve the mercury in nitric acid or other harsh chemicals and measure the amount of mercury and you just have a number there on your analysis that is mercury. That does not mean that the mercury that is in amalgam is available to be absorbed into the water or dissolved into the water.

Mr. BURTON. I think we have a difference of opinion. So let me ask you another question. If you have mercury in your teeth, does it wear down over time?

Dr. MACKERT. Yes, it does.

Mr. BURTON. So when it wears down as you are chewing, where does it go?

Dr. MACKERT. The particles of amalgam are swallowed usually and the absorption even of liquid mercury in the gut is very small, people have estimated 0.01 percent as the amount of mercury that is absorbed if you swallow liquid mercury in your gut.

Mr. BURTON. But the point is it does flake off over time and it does go into your system, this mercury.

Dr. MACKERT. Well, not through swallowing. The amount of swallowing—we have estimated this, Dr. Anders Berglund of the University of Umea—the dissolution in swallowing is about 1 microgram per day, and this is in comparison to 5 to 6 micrograms per day that we absorb from our food and other sources, not amalgam. So it is a small contribution.

Mr. BURTON. What about the mercury vapors?

Dr. MACKERT. Mercury vapor is emitted, and this has been known since about 1979. Prior to 1979, the instruments that were available for measuring could not detect mercury vapor coming off of amalgam fillings after they had set.

Mr. BURTON. What does the vapor do when it goes into the mouth?

Dr. MACKERT. The amount of mercury vapor that escapes from the fillings when a person is breathing in through the mouth is absorbed and contributes to the total daily dose. From several different ways of examining how much that is, it is between 1 and 3 micrograms per day. I know Dr. Richardson showed a chart of all these, but I have a paper from Dr. Clarkson, who he mentioned as being acknowledged by both sides of this issue as an international expert on mercury, and I just want to point out what he said in a paper he published this year, entitled "The Three Modern Faces of Mercury." He pointed out the amount of mercury that is released, he said, "As discussed below, these are far below"—talking about the amount that is released from fillings—"these are far below toxic levels." So here is the world's expert on mercury.

Mr. BURTON. OK. Let me ask you this question. I have been told, and I am not a scientist, but I have been told that mercury in the brain has a cumulative effect, it builds up. In other words, if you get a little bit in, it is hard for you to chelate it out of your brain because of the fatty tissue in the brain. So even though the amount of mercury vapor you are talking about might be very low, if you ingest that, even part of it over a period of time, would it not have a cumulative effective which could have a dilatory effect on the brain?

Dr. MACKERT. Scientists have measured about how much mercury that is inhaled is partitioned, what we called partitioned in the brain, and that is about 7 percent of the total that is inhaled. That mercury has a half-time, which means over half of it will decrease, it will decrease to half its amount in about 21 days. This has been measured by Dr. Clarkson's laboratory and others. So all the mercury that is absorbed is not retained. It is fairly rapidly excreted actually, I mean 21 days. There is another compartment that indicates a very small amount, which it is difficult to pin down exactly how much, but a small amount does accumulate. Dr. Clarkson and others have pointed out that this is because it forms compounds with the element selenium which he and others believe that this is a biologically inactive form, it is very insoluble——

Mr. BURTON. Well that is what he believes.

Dr. MACKERT. Well he's the expert in the world on mercury.

Mr. BURTON. We have got a bunch of experts here.

Dr. MACKERT. Not of the calibre of Dr. Clarkson. In the area of mercury, I do not think any of these people here would claim to be on a calibre of Dr. Clarkson. We can ask them if they think they are and they know more about mercury toxicity than Dr. Clarkson does.

Mr. BURTON. Well, we'll hear from them. I will let my colleague here ask a bunch of questions in just a moment.

Dr. Stoute, one of the things that you said was that dentists should provide a full range of options.

Mr. STOUTE. Correct.

Mr. BURTON. Why would it be wrong for all patients to know that there is some concern and a divergence of opinion about amalgams? In other words, if I go into your office and you are going to put a filling in my mouth, what would be wrong with you telling me that there is a divergence of opinion about whether or not the mercury in an amalgam is a problem and say that I think it is safe, but there is this divergence of opinion and there are other alternatives you can use, like a composite, and it is going to cost more, but I think you ought to know that. What would be wrong with that?

Mr. STOUTE. I do not see anything wrong with that.

Mr. BURTON. Do you do that in your practice?

Mr. STOUTE. Yes, we do. We offer options based on——

Mr. BURTON. Do you tell them about the divergence of opinion and whether or not mercury does cause a problem in the mouth?

Mr. STOUTE. In most aspects, I would say in all aspects of dentistry we do that. Some people have concern about x-rays and we inform them about x-rays.

Mr. BURTON. So you do that?

Mr. STOUTE. Yes.

Mr. BURTON. Well I would say that would be great if all dentists did it so we would all know those things.

I saw you shaking your head and I am going to let you respond to some of the things he said, and then I am going to let Dr. Norwood ask some questions.

Mr. RICHARDSON. In regards to what happens to mercury when it is absorbed into the body, the half-life in the blood is approximately 45 to 60 days, not 21 days. The half-life in the brain is on the order of 30 years, not 21 days. It accumulates there. There have been studies done on cadavers and, in fact, the concentration of the mercury in the brain correlates with the number of amalgam fillings in the teeth of those cadavers, as it does in numerous other tissues of the body. And, yes, it does accumulate in the brain, it does get locked in. Once it crosses the blood-brain barrier it is converted to a different form by binding with sulfhydryl groups, not with selenium, and once in that form it cannot cross back across that blood-brain barrier and be taken out of the brain. So that is why there is the prolonged 25 to 30 year half-life for concentrations in the brain.

Mr. BURTON. Anybody else have any other comments real quickly before we go to Dr. Norwood?

Mr. HALEY. Yes. I have the highest respect for Dr. Clarkson, but I would say that if you read Dr. Clarkson's papers, he totally ignores synergistic toxicities. What we presented here today is you cannot tell what level of mercury is toxic unless you know a lot of things about the person, the concentration of lead they are exposed to, cadmium, and certain other things. The potentiation of toxicity is dramatic, and I do not think Dr. Clarkson would disagree with me that what we have shown with the effect of mercury on the neurons is a very significant find and that it really lowers the level of mercury that would be considered safe for young infants to be exposed to.

Mr. BURTON. OK. Dr. Fischer.

Mr. FISCHER. Thank you, Mr. Chairman. I would have one question to my colleague. When he says that the amount of mercury vapor coming off the fillings is very small, I would like to know what units "very small" would be, if we can get an idea of units, and at what level would it be of concern.

Mr. BURTON. OK. Dr. Mackert.

Dr. MACKERT. There have been a number of different assessments of the amount of mercury vapor that comes off of fillings. I believe looking at all the available literature, and I am familiar with all of the studies that Dr. Richardson showed on his slide, but in evaluating these, 1 to 3 micrograms a day for a person with an average number of fillings is the amount that would be absorbed. And this compares with 5 to 6 micrograms per day that people would absorb from other sources, including seafood.

In terms of what would be a level of concern, the World Health Organization published numbers along that line for people, the most sensitive group in the population where the first sub-clinical effects would appear, and it would take between 400 and 500 fillings, surfaces of fillings to achieve these levels with the release rates that we know.

Mr. BURTON. Dr. Norwood, I know you have some questions. I will let you take it now.

Dr. MACKERT. May I also comment on Dr. Richardson's response. Are you saying that the half-time of mercury is 30 years, the amount of mercury a person takes in, half of that takes 30 years for that to go away? Are you claiming that on the record?

Mr. RICHARDSON. I will submit to this panel a paper that documents the half-life of mercury in the brain as being on the order of 25 to 30 years.

Dr. MACKERT. All of the mercury that is absorbed, is that what you are stating for the record?

Mr. RICHARDSON. Yes.

Dr. MACKERT. You are sadly mistaken.

Mr. BURTON. If you have a position paper on that or some documentation, I would like to have it from both of you so we can look at it. OK?

Dr. Norwood.

Dr. NORWOOD. Thank you very much, Mr. Chairman. I have got so many questions I do not know where to begin.

Mr. BURTON. Well there are only two of us so I am going to let you go for a while.

Dr. NORWOOD. Thank you, sir. I want you to know that I recognize this is not my committee and I am going to mind my manners. I really would not be this nice if this were a Commerce Committee meeting. But having said that, Mr. Chairman, I was greatly and personally offended by the remarks in the opening statement from Congresswoman Watson and I would like your permission to respond to that in writing for the record rather than making a big to-do about it right here.

Mr. BURTON. Sure. Without objection, that is fine, Doctor.

Dr. NORWOOD. Dr. Haley, you are a chemist. Yes or no?

Mr. HALEY. Yes.

Dr. NORWOOD. Do you have degrees in biology?

Mr. HALEY. I did 3 years post-doctor at Yale in physiology and my major emphasis area in chemistry was in biochemistry.

Dr. NORWOOD. OK. I understand. You must be a smart guy because that is a hard subject.

Mr. HALEY. I enjoy it.

Dr. NORWOOD. Good. I see that you do. I noted, and I have no idea whether your scientific work is correct or not, and would not question it anyway at this point, but I did note that most of it was about mercury, the toxicity of mercury.

Mr. HALEY. What I talked about today, yes. Most of my work is not about mercury.

Dr. NORWOOD. What is most of your work about?

Mr. HALEY. About the structure and function of nucleotide binding proteins that regulate body functions.

Dr. NORWOOD. Thank you. I got you. [Laughter.]

But your scientific work today was about liquid mercury. And our hearing really is about amalgam, a metallic compound that varies in percent but is at least 50 percent silver. So I do not question you, I bet you are right about the toxicity of mercury. But that is not what we are here about. We are here about the possibility of considering banning a major restoration material in this Nation that will affect dental health. So we thank you for being here, mercury you may be right on, you may be right about the environment, but we need to talk I think about what we are here about, which is the amalgam filling.

It is clear to me from my work in the Commerce Committee with the EPA that there are two or three known things. No. 1, you can buy a scientific report saying anything you want to say. It just does not matter. Whatever the opinion is that you want you can get it paid for and get it done. I have seen that for 8 years in the EPA. So I do not know who is right or who is wrong about the science. I tend to think probably Dr. Clarkson is one of the world's foremost toxicologists in mercury. Do you still stand by that, Dr. Mackert?

Dr. MACKERT. Yes, I do.

Dr. NORWOOD. Do you agree with that, Dr. Haley?

Mr. HALEY. Yes, I mean he works primarily on methyl-mercury. And to say that he would understand the toxicity and medical effects of mercury any better than any other well-trained bio-chemist, I would not give him—it is the area he worked in. But it is something you teach to freshman——

Dr. NORWOOD. That is his area of specialization, like yours is whatever that long list was?

Mr. HALEY. He mainly works with methyl-mercury. Most of the research I have read from Dr. Clarkson's laboratory has been on the mercury that comes from fish, not from amalgams.

Dr. NORWOOD. So he is an expert like all of you are experts, for which nobody here dare define the word "expert?"

Mr. HALEY. Probably. But I would point out one thing. We did talk about amalgams. I get the same effect if I take an amalgam made outside the mouth or in a tooth that has been given to me by a dentist, if I drop it in water and I take that water after a period of time, and I showed that on the slides, and add that to brain tissue enzymes or neurons in culture, it is toxic. So the amalgams release mercury. And I tell you the problem here, which I would challenge you and Dr. Mackert, let's make 1,000 amalgams outside the mouth and send it to Cal Tech and Harvard and the major science institutions in the United States and let's live with how much mercury, let's determine how much mercury comes out of amalgam with no brushing, brushing 1 minute a day, and——

Dr. NORWOOD. Dr. Haley, I do not know that test has not been run. I do not know that study has not been run. Are you telling me you know of every study ever done with amalgams?

Mr. HALEY. No.

Dr. NORWOOD. Of course you do not.

Mr. HALEY. I am telling you that I have done it in my lab and I get results that totally disagree with what Dr. Mackert says.

Dr. NORWOOD. Dr. Mackert, do you want to respond to that?

Dr. MACKERT. There is a big difference in doing a study in a lab in a petri dish and doing human studies. Always the first step is you look in the laboratory study, then you look in animals, and then you look in humans. All the studies that I referenced today were in humans. If these theoretical possibilities Dr. Haley has raised were true in actual fact, then we would see them in these human studies that have been done, and we do not.

Mr. HALEY. This is not theoretical. This is absolute——

Dr. NORWOOD. Excuse me. We need to have order. It seems to me that it is hard to refute that only the EPA, who I have mentioned earlier is the one who buys the studies they want, is saying that amalgam is toxic and we cannot get the CDC or the FDA or the Public Health Service or the World Health Organization—I mean, come on, are these people—I am not asking a question just making a statement. [Laughter.]

I saw you warming up. I am going to ask you a question in just a minute. It seems to me all of these people are not in cahoots with the ADA. I do not believe they are. And this all says to us that we do not really know that you are right at all about what you are saying about the toxicity. People like me know what happens if you are wrong and you get rid of this restoration, which in many cases nothing else we have today will work. So I am just asking you to be just sort of real careful with what you are saying now.

Dr. Haley, Dr. Linder asked me to ask you a question, and I am not sure if he wanted to know this on a personal basis or just wanted to know in general. But he wants to know if there have been any studies that show a higher incidence of Alzheimer's disease in retired dentists.

Mr. HALEY. There have been no studies done.

Dr. NORWOOD. Anybody know of any?

Mr. HALEY. I do not know of a one. I do not know of a study. This is a thing that says there is no proof of amalgams being toxic or being dangerous or causing disease. There is no proof that it does not.

Dr. NORWOOD. I understand. But there is absolute proof of the damage done to the dental health of this country if you eliminate it. I can tell you about that. I know something about that.

Dr. Mackert, next year I will have been a member of the ADA, American Dental Association, for 40 years and I can guarantee you they do not gag me on anything or I would not have paid my dues. I would have just said good-bye and leave. Are you aware of any gag rules in our Code of Ethics about talking to our patients?

Dr. MACKERT. No, I am not. In fact, the ADA encourages dentists to discuss treatment options with patients. The ADA is concerned that they not misinform patients on this or any other issue and encourage patients to subscribe to treatments that are not in their best interest. They would certainly be opposed to that.

Dr. NORWOOD. Well I feel fairly certain that there are not any gag rules. And if there were, we are an ornery group, dentists are, and we would not pay them any attention anyway.

Most of us, Mr. Chairman, do talk to our patients about what their alternatives are. Most patients do not want to sit there and have me or any other practitioner respond to them on the details of what is in, for example, amalgam fillings, although none of us that I ever knew of would—you know, what the heck, if you do not want amalgam, that is OK. I used to make a lot of money using gold, probably the best restoration known to man. The only reason we do not use it all the time now is because if we did another 30 percent of Americans would not be able to go to the dentist. That is why we do not do it. That is the restoration of choice for us.

Part of our job is to treat Americans and we have to be very concerned about the cost because in dentistry, unlike medicine, thank God, we do not have the Federal Government funding everything that we do. People pay out of their own pockets. And we have to keep that in mind if we want them to be treated. And that is really what we are there for is to treat those patients. Now if you want to tell a patient they need to have all their amalgam fillings taken out so you can put in all new fillings, I would not lose, I would not do badly in that arrangement to tell you, sit down, let's take them all out and do them all over again. We are a capitalistic country; I am going to make a little profit on every one of them I take out and every one of them I put in. So it is not that we mind doing that. If that is what a patient wants us to do, let's do it, although I would question it.

Dr. Fischer, I want to ask you about that. What I know of you is you are a really nice guy, a good guy, concerned, and really believe this honestly. But let me ask if I could just yes or no questions. You talk about the danger to children from dental amalgams. Does the American Academy of Pediatrics agree with you? Just yes or no.

Mr. FISCHER. I do not know. About what?

Dr. NORWOOD. Whether dental amalgam is dangerous to children.

Mr. FISCHER. Did they say that? Is that what you are asking me?

Dr. NORWOOD. No. You believe that, don't you?

Mr. FISCHER. I believe it is dangerous to some children and to some people, yes.

Dr. NORWOOD. Does the American Academy of Pediatrics agree with you?

Mr. FISCHER. As I say, I do not know what they say about it.

Dr. NORWOOD. Well you ought to, it seems to me.

Mr. FISCHER. I am not a pediatrician.

Dr. NORWOOD. No, I know, nor a physician.

Mr. FISCHER. Right.

Dr. NORWOOD. But if you are going to tell people this material is dangerous, it should be I think of interest what the entire medical community that treats children think.

Next question. You talk about a relationship between dental amalgam and autism. Yes or no, does the Autism Association agree with your position on dental amalgam?

Mr. FISCHER. First of all, I do not tell patients it is dangerous. You asked me if that was my opinion, and it is. Do I tell that to patients? No, I do not. So let me clarify the first question.

Dr. NORWOOD. You do not tell patients that you are concerned that they should not have dental amalgam, you just do not give them the option?

Mr. FISCHER. I do not give them the option because I do not want to expose the patients, my staff, or myself to the material. So that is an option we do not give. If they want it, we refer them out for that. I do not do root canals either, we refer them out.

Dr. NORWOOD. Do you basically think then that there is a negative relationship between dental amalgam and autism, patients with autism?

Mr. FISCHER. Again, I am not a physician and I cannot make a medical diagnosis. But from the American Academy of Pediatricians, they say in one of the conclusions in this report, "Mercury in all its forms is toxic to the fetus and children."

Dr. NORWOOD. Of course, mercury. Who the hell would disagree with that. We are not talking about mercury though. I would have loved to have brought some mercury and put it out on that table and then put a big wad of amalgam and ask you to pick each of them up. Have you ever tried to pick up mercury?

Mr. FISCHER. OK.

Dr. NORWOOD. Me too. It is not easy.

Mr. FISCHER. The point being?

Dr. NORWOOD. The point I am making to you is there is a difference between mercury and amalgam.

Mr. FISCHER. Are you saying that there is no mercury in amalgam?

Dr. NORWOOD. Did I say that?

Mr. FISCHER. No, but——

Dr. NORWOOD. I sure didn't.

Mr. FISCHER. OK.

Dr. NORWOOD. Now since I am going to ask the questions, let me go to the next question. You talk about a relationship between dental amalgam and Alzheimer's disease. Does the Alzheimer Association agree with you on your position on dental amalgam?

Mr. FISCHER. I did not speak about Alzheimer's disease.

Dr. NORWOOD. Do you have a position on that?

Mr. FISCHER. No, I am not a physician or a neurologist.

Dr. NORWOOD. Did you have a position on that, Dr. Richardson?

Mr. RICHARDSON. No. It was Dr. Haley who spoke on Alzheimer's.

Dr. NORWOOD. Do you have a position on that?

Mr. HALEY. Yes. I think absolutely you can say that exposure to mercury would exacerbate the clinical condition we call Alzheimer's disease since it causes all the aberrant biochemistry and hallmarks to be produced.

Dr. NORWOOD. And does their association agree with you?

Mr. HALEY. I have never talked to them. But they are just a group of lay people. They are not scientific body. So there are a lot of committees who do not know anything about this.

Dr. NORWOOD. How do you know they are a group of lay people? Since you have never talked to them, I would like to know how you know that.

Mr. HALEY. I read their literature, I know when they are out raising money, I talk to the people at conferences that have Alzheimer's booths.

Dr. NORWOOD. Well have you ever mentioned to them, hey, guys, you ought to be on my side and be against dental amalgam, this is real bad for Alzheimer's and your association?

Mr. HALEY. Yes, I have. I sent them a letter a long time ago.

Dr. NORWOOD. And do they agree with you?

Mr. HALEY. No, they did not fund me.

Dr. NORWOOD. Thank you. Multiple sclerosis, that society does not agree either. Do you ever advise your patients, Dr. Fischer, with multiple sclerosis and other diseases that they ought to have all of their amalgam fillings removed?

Mr. FISCHER. I am glad you asked me the question because the answer is, no, I have never advised any patient to have their amalgams removed. When they come to me and ask me to do that, even if it is based on a referral from a physician, we explain the options to them—I give them the ADA materials without any references to safety but they say it is safe and it is inert. We give them that material as well as some of the scientific references and then we let them make their own choice. If they decide to get them out, we have them sign an informed consent form after we fully inform them. So, no, we do not recommend that they get them out.

Dr. NORWOOD. They said you were a good guy. But the question is if patients come in and they have a mouth full of amalgam, which you are on record very clearly thinking that is a very dangerous thing, do you advise them to remove their fillings?

Mr. FISCHER. No.

Dr. NORWOOD. That is an interesting concept. I will close, Mr. Chairman, if I may, with one last question.

Dr. Mackert, it seems that if dental amalgam were banned, frankly, the dental profession would make a lot more money because of the cost and the time that is associated with using other restorative materials, which, by the way, Medicaid patients do not all get amalgams. It was implied earlier that there was nothing else that Medicaid patients could ever get. That is just not true. It

varies State by State. But tell me why you think the ADA is fighting so hard to keep amalgam as a restorative material.

Dr. MACKERT. In a number of situations, the ADA has advocated positions that are not necessarily in the economic interests of dentists, and I think fluoride is a good example. This has been vigorously opposed by some groups but the ADA has been steadfastly behind water fluoridation even though it actually works against the economic interests of dentists. And I think this is a similar situation where there is no economic interest for the ADA or dentists or even dental manufacturers who have told me, at least one manufacturer told me they actually make a bigger profit on the resin composite materials than they do on amalgam. So they do not have any vested interest in the continued use. It is just that amalgam is one option. For example, if patients are allergic to ingredients in the resin composites and we ban amalgam, what are they going to use on those people? And people are allergic to things like hydroxy ethyl-methacrylate which is used in dental bonding agents. It is one of the most potent allergens used in dentistry. If we ban amalgam, then what are these people going to use for a filling?

Dr. NORWOOD. Mr. Chairman, people like myself who have spent their life trying to take care of patients in dental health, we are very concerned about this, and you pointed out some of it. We just do not have some alternatives in some places. We would find alternatives or we would do something different if we knew for a fact that this is harmful. What we do know is, my own personal experiences dealing and living with this and dealing with amalgam everyday, that it does not appear to be harmful to people that I am aware of. And the other part of it is that if we knew it to be harmful, we would find something else. But we cannot do that with bad science. We cannot do that with misconceptions in science that are not always right.

Dr. Mackert, do you know who out there, for example, what are the groups that are interested in banning dental amalgam? Who is out there talking about this?

Dr. MACKERT. Well, there are several groups. One is called DAMS, which I believe stands for Dental Amalgam Mercury Syndrome. Another is the IAOMT, which is International Academy of Oral Medicine and Toxicology, which was founded by Murray Vimy, a Canadian dentist in 1984, and almost the first action that group took in 1984, before most of these studies were even conducted, was to issue a press release calling for the banning of amalgam. So almost the first thing they did as an organization was to call for the banning of amalgam. So even before Vimy and Lorscheider had done their studies, they were calling for the banning of amalgam.

Dr. NORWOOD. Who is that holistic dental society?

Dr. MACKERT. I am not sure.

Mr. BURTON. Dr. Norwood, we do have one more panel and I will give you liberty to ask as many questions as you want. I would like to ask just a few more questions of this panel.

Dr. NORWOOD. You have been very kind.

Mr. BURTON. You are a good man, even though we have a little disagreement here.

Dr. Haley, what is the difference between dental mercury and a jar of pure mercury? What is the difference as far as toxicity is concerned between a dental amalgam with mercury and a jar of pure mercury?

Mr. HALEY. The mercury vapor coming off of liquid mercury and the liquid vapor coming off of amalgam fillings is the same thing. It is identical, absolutely chemically identical.

Dr. MACKERT. Could I comment on that? Are you saying that it is the same amount that comes off?

Mr. HALEY. Of course not. When you form metallic bonds in amalgam fillings and reduce the vapor pressure of the mercury and it slows the evaporation rate. But what you have is allergens that release mercury at a very low level for scores of years.

Mr. BURTON. That is the point I wanted to make. The mercury vapor does come off of the amalgam?

Mr. HALEY. Yes.

Mr. BURTON. And it does chip away over time and you do consume that, it goes into the body and is excreted through the body.

Mr. HALEY. Yes, 80 percent of the vapor that is inhaled in the body is retained by the body.

Mr. BURTON. You said 80 percent?

Mr. HALEY. Yes.

Mr. BURTON. OK. Now when it goes into the brain, I have been told by leading scientists and doctors from all over the world that the fatty tissue in the brain holds that in there more than any other part of the body, so there is an accumulation of the mercury over a period of time. Is that correct?

Mr. HALEY. The aspect is that mercury is what we call a hydrophobic gas, it would rather be in the fat. It will partition into fat tissue versus water. Mercury is not very fond of water. However, when it is in the brain it gets converted to the HG2+ and it binds to proteins.

Mr. BURTON. So it sticks around for a long time.

Mr. HALEY. The fact is that versus, say, the HG2+, which does not cross the blood-brain barrier very effectively, mercury vapor does it with a great deal of ease. Once it is inside and it is oxidized, the HG2+, then it does not come out.

Mr. BURTON. I have a couple of questions, and I do not know the answer, but I do have two questions here real quickly. One is, Dr. Norwood asked about an increase in the number of people I think that have become autistic or hurt from mercury vapors and amalgams. I do not know what the relationship is there, but I do know that we had 15 years ago 1 in 10,000 children was adjudged to be autistic. Today, according to the Food and Drug Administration, it is more than 1 in 250. We have had more than a 40fold increase. Now that could be attributed to a number of things, but we do know that mercury was in the vaccines and mercury was in the amalgams of the mother and that may be a contributing factor. We just do not know.

As far as Alzheimer's is concerned, do any of you know whether or not there has been an appreciable increase in the amount of Alzheimer's?

Mr. HALEY. Yes.

Mr. BURTON. Can you give me statistical data on that?

Mr. HALEY. I would feel uncomfortable doing that, I just know it is very significant. Every time you read a paper on Alzheimer's disease they bring up that there is something like I think 6 million, somewhere in that range, of Americans today that have it and that by 2040 it will be astronomically higher than that, I cannot remember the exact number, just that it is in the millions though.

Dr. MACKERT. Mr. Chairman.

Mr. BURTON. Yes?

Dr. MACKERT. I was just wondering if I could comment on that question.

Mr. BURTON. Sure. Sure.

Dr. MACKERT. It is interesting that the use of dental amalgam has actually declined over that same period that you mentioned on autism and resin composites have increased till this year they are more than half of the restorations placed. So, actually, if you are looking for something to track—and I am not at all suggesting composites are behind it—but you would actually see the correlation between composite and Alzheimer's and autism rather than with amalgam since amalgam use has declined.

Mr. BURTON. I did not say it was just from that source. When Dr. Norwood and I get our flu shot, there is mercury in that flu shot. A lot of people do not realize that and I do not think many of our colleagues know that.

Dr. NORWOOD. It has affected us both too, I am pretty sure.

Mr. BURTON. Yes. Sure. [Laughter.]

But the point is there have been a number of things that could be contributing factors to that and that is why I asked that question.

Is there a peer reviewed study that shows mercury fillings are safe? Is there any peer reviewed study that you know of that shows they are safe?

Dr. MACKERT. The difficulty in showing that any material is safe is that you have to do several things. You have to identify potential adverse effects, you can study, for example, multiple sclerosis or even subtle changes in enzymes, and if you look at those in a study, that is all you know is whether it causes that one thing that you have studied. And there are thousands, if not millions, of things that we could study that we could try to correlate with the presence of amalgam fillings. Many of those studies have been done but we have not looked at everything. It is not possible to do so. We do not have enough money or enough people to look at everything. But the studies that have been done so far indicate that, as the ones I have cited and others that are in our statement for the record, these do not indicate any adverse effects from amalgam.

Mr. BURTON. Let me ask you one more question, and any of you can answer this, and then we will get on with the next panel. I would like to end with a little comment. Are removed mercury fillings a hazardous waste, Dr. Mackert?

Dr. MACKERT. According to the EPA test that is done to determine whether something is a hazardous waste, this was studied, amalgam was subjected to this test and it does not qualify as an EPA hazardous waste, according to my understanding.

Mr. BURTON. Well why don't we just flush it down the drains? They do not do that anymore, do they? What does a dentist do with an amalgam when he takes it out of a person's mouth?

Dr. MACKERT. Well, I all the time get mailers and packages from these different recycling companies that offer me money for amalgam scrap and other metal scrap. So many dentists, I do not know what percentage, but many of them collect this and turn it in to have the metals——

Mr. BURTON. I am not talking about many. I am saying when dentists are taking a filling out of a tooth, are they allowed to just flush it down the toilet or down the drain?

Dr. MACKERT. There are amalgam separators, there are traps and stuff that collect various amounts of that mercury. This is not an area of my expertise. There are others here I think that might better answer that question.

Mr. BURTON. Does the ADA or any of its affiliate organizations, such as the AD Health Research Foundation, hold any patents or reap any financial benefit from mercury or amalgams?

Dr. MACKERT. Well amalgam was invented long before the ADA was even established as an organization. So, obviously, the ADA was not around when amalgam was invented. As with all different materials, the Health Foundation works on improvements of materials, including amalgam. There were two patents issued I believe in the 1980's which were never exploited, never licensed.

Mr. BURTON. So they do not make any money off of amalgams?

Dr. MACKERT. They do not. In fact, the ADA Health Foundation was the organization, an ADA scientists named Ray Bowen was the man who invented the dental composite, the white filling that is used.

Mr. BURTON. OK. OK. Let me ask Mr. Bender and Dr. Haley a question. The amalgams, after they are taken out of the mouth and disposed of, are they considered toxic by the environmentalist and the EPA?

Mr. BENDER. I am not aware of the study that Dr. Mackert refers to in terms of whether or not they pass or fail the EPA's TCLP test. What I do know is from an environmental standpoint dentists are not regulated in terms of their disposal. That is one of the major problems. What I do also know, I indicated in my testimony, that approximately less than 1 percent of dentists in the United States today have amalgam separators. In fact, talk about commissioning studies to get the answers that you are looking for, the ADA recently commissioned with a group called Environ to basically come out and say that amalgam separators were not a cost-effective approach to go.

Mr. BURTON. Dr. Haley, the amalgam, when they come out of the mouth and are flushed down the toilet and down the drain and go into the water——

Mr. HALEY. They place them in sealed containers to keep the mercury vapor, when they are sitting in the dental office, from contaminating the air and making it unsafe for people to work.

Mr. BURTON. Dentists put them in a sealed container?

Mr. HALEY. In a sealed container under a liquid solution that will bind the mercury vapor if it is released.

Mr. BURTON. Is that a common practice among dentists?

Mr. HALEY. I think so.

Mr. BURTON. Is that right?

Dr. MACKERT. That is. And the reason for that, as I mentioned earlier, is that when the amalgam is first mixed it does release mercury vapor for a short time until it completely sets. So that is why it is placed under liquid, usually a photographic fixer or other sulfur containing liquids are used.

Mr. HALEY. Research has absolutely shown that amalgams release mercury for years after they are hardened. Dr. Mackert is just flat wrong in his assessment.

There was a study when they used a material called composel and they showed that it released 43 micrograms per centimeter squared per day and it did so consistently for 2 years. Unfortunately, this was put in the mouths of Americans. And the person who published this research in Clinic Dental Research was from Singapore University, it was not the FDA or the ADA. I do not think they look at it. I had a debate with the dental department at the University of Kentucky this Tuesday and I asked them, "Do you have any devices in the school of dentistry that measures mercury in the air or in the water?" They did not have a thing.

Dentists are allowed to do things that the rest of us are not allowed to do. If I were to do experiments on mercury, I have to have it picked up as a toxic waste. Mercury coming into my department is classified as in the most toxic category of chemicals whereas the FDA dental branch classifies it as a totally safe material, as safe as a bedpan. There is a lack of common sense being applied here. And that is what I am saying. Do not believe me, do not believe him, make amalgams outside of the mouth, get a Government group to go check the amount of mercury that comes out under abrasion, under heat, and then settle this. This is not rocket science; this is simple stuff. And I know I am right and I know the amount that Dr. Mackert says comes out of amalgam fillings is wrong, because if he talks about the amount that comes out per surface area exposed, and if you look at the amount that is in the urine and you multiply that by 9, because 90 percent of the mercury comes out in the feces, you cannot even possibly account for that amount of mercury with his values.

Dr. MACKERT. Let me just comment on that study. I know Professor Chou, he is a friend of mine, who published that study. It is interesting, they only pick the one material that is not even sold in the United States, never has been sold in the United States, the composel that he mentioned, it is not a standard formulation of amalgam at all. Even in that study that he mentioned it says, so he could not be unaware of this, that it released much more mercury, in fact, 400 times more mercury into solution than any other amalgam that was studied. So why does he pick that one amalgam?

Mr. BURTON. Let me interrupt here just a second. I think this is a very interesting debate. Would the American Dental Association and your association, Dr. Stoute, be willing to perform the kind of test that he is talking about? In other words, make amalgams and put them into different kinds of conditions, send them to major scientific research laboratories around the country—I would be very happy to facilitate that—and let them come up with an answer to

this because the American people would like to know. Now if the ADA says no, I would like to know why.

Dr. MACKERT. We are willing to fund any studies or——

Mr. BURTON. Are you willing to do that? Are you willing to make the amalgams——

Dr. MACKERT. It has been done.

Mr. BURTON. It has been done?

Dr. MACKERT. Yes. The study that he mentioned talks about other amalgams and they are 400 times lower than the one that he happened to cite.

Mr. BURTON. The amalgams used here in the United States, the amalgams that are used in dentists offices all across the country——

Dr. MACKERT. The other amalgams that were in that study were used in the United States.

Mr. BURTON. Would the ADA be willing to do a study where they took amalgams, 100, 200, whatever it takes, make them, put them under different conditions, send them to the various laboratories around the country and let the American people know what the results are? Would they be willing to participate in that kind of a study?

Dr. MACKERT. We would. But again, these studies have been done. The study that he cited has that very data in it that he failed to cite.

Mr. BURTON. If you would be willing to do that, that would be—so you are speaking on behalf of the ADA that you would be willing to do that?

Dr. MACKERT. We will respond in writing to that. You know, I am a faculty member of the Medical College of Georgia, I do not work for the ADA. I cannot tell you what the ADA——

Mr. BURTON. You are representing the ADA today.

Dr. MACKERT. Yes, I am. But I do not work for the ADA.

Mr. BURTON. Who would make that decision?

Dr. MACKERT. The Council on Scientific Affairs, of which I am a member, I start my term in January.

Mr. BURTON. So you are a member of that. Would you recommend that they would do that?

Dr. MACKERT. Well, if we want to be cost-effective in our expenditures of research dollars, if something has already been done multiple times, then it is not cost-effective to do it once again. If that information is not available in the literature, we would certainly be very interested in pursuing that and funding that.

Mr. BURTON. I do not see why it would not be something that you would want to do, because it would put an awful lot of this debate to rest.

Dr. MACKERT. It would never put it to rest because—I am sorry, I keep interrupting.

Mr. BURTON. I just think it is something that would allay a lot of people's concerns and fears. Because Dr. Haley I think has said very, very clearly that the amalgams outside the mouth are toxic, they release toxic vapors.

Dr. MACKERT. But they are not toxic. Toxic means it causes demonstrable adverse health effects, and they do not. There are studies that have shown that, studies that have looked at this, thou-

sands of subjects, all the things that I mentioned, Alzheimer's disease, multiple sclerosis, adverse pregnancy outcomes. You can always think of more symptoms to look for but we have looked at the major ones people have brought up as adverse health effects, reduced immune competence, kidney function, all these studies have been done and looked at it and compared groups of people with and without amalgams and they do not find any difference.

Mr. BURTON. OK. Well you are not for doing the study then? You do not want to do it?

Dr. MACKERT. If the study has already been done and we have the data in the literature——

Mr. BURTON. Has that kind of study been done, Dr. Haley?

Mr. HALEY. Just one study he reported. When I bring up the aspect of the 43 micrograms, it is that here was an amalgam filling that was used and it was placed in the mouth of Americans and nobody tested it.

Dr. MACKERT. No, it was not.

Mr. HALEY. I have tested, and I teach a class called Mercury, Science, and Politics, and I have students measure the amount of mercury that comes out of amalgam fillings. And while it is not as high as the composel, which is extremely high, it still is very significant. And when you brush it, it goes up to 43 micrograms per centimeter squared. If you abrade the amalgam filling 30 seconds, twice a day, you get a huge increase.

Now I know high copper amalgams release more mercury than low copper amalgams. I have read all the stuff. What we have to do is talk about the specific material that is being put in people's mouths and just test it. That is the only thing I think that is needed. If you are going to use it, test it and say how much comes out just setting quiescently in a test tube in water, and then abrade it, just brush it, and say how does it respond when you brush it with say a medium bristle toothbrush, add heat to it like you are drinking coffee and see does it increase it. You have got to do these studies. And no, these studies have not been done.

Dr. MACKERT. Yes, they have.

Mr. HALEY. Where?

Dr. MACKERT. Anders Berglund, at the University of Umea in Sweden, did exactly those things. He monitored patients every 30 minutes throughout the day, including all night——

Mr. HALEY. Not in a sealed container.

Dr. MACKERT. Let me finish. He had them drink coffee and, contrary to the allegations of the anti-amalgamists, it does not cause an increase in mercury release. Many foods actually cause amalgam release to go down.

Mr. BURTON. OK. Let's end this panel. Let me just say, and I have all kinds of literature that we have studied and read, mercury is a toxic chemical, mineral. Nobody has any doubt that if mercury was lying on that table there, nobody would want to be messing with it because it is toxic. It is in amalgams. It is in some of our vaccinations. And in many people's minds, mine included, there is a substantial risk. I have had my amalgams out. I am going to get even my capped teeth, the ones that have gold over them that may have a filling in them, I am going to get those out because I just do not want the risk, even though you would not agree with me.

If there is any doubt whatsoever, it seems to me that people ought to err on the side of safety. And I think the American people need to know at least that amalgams contain 50 percent mercury. They do not know that. I did not know that and I am a fairly well-read person. I think if the American people were made aware, just made aware of the fact that the amalgams contain 50 percent mercury, knowing even a small amount of what they do about chemistry and about the biology of the human body, I think an awful lot of them would opt for another kind of filling.

It just seems to me—I understand that Dr. Norwood is going to oppose this bill, it is probably not going to go anywhere—that we need to have more hearings on this subject, and we will have more hearings. This subject will be discussed and debated and it will be illuminated. At the very least, the American people will know there is mercury in fillings and they will be able to make an informed decision on whether or not they want to have that in their mouth, just like we have been trying to illuminate the issue of whether or not there should be mercury in vaccinations for children. My grandson got nine vaccinations in 1 day. He was a wonderful boy. Two days later, 3 days later he became autistic and he is ruined in part for life. He got 47 times the amount of mercury that is tolerable in an adult in 1 day and it made a big difference I believe in his life.

So when somebody asks me should there be mercury in vaccines, I say hell no. And if somebody asks me if mercury should be in anything that goes into the human body, I am going to say I do not believe so. I am a layman, I am not a scientist, but from what we have heard at our hearings and from scientific research around the world, I do not believe it should be in there. But at the very least, I think dentists ought to inform the American people that they are half mercury, and if the American people know that, I think they will make the decision themselves.

With that, I think we ought to go to the next panel. Thank you all very much. We appreciate your comments.

We will take a 5-minute break here, if you like, and I will come right back.

[Recess.]

Mr. BURTON. The committee will reconvene.

We will now hear testimony from the second witness panel. I would appreciate those individuals coming to the table. Dr. Lawrence A. Tabak, Director, National Institute of Dental and Craniofacial Research, National Institutes of Health; and Dr. David W. Feigal, Director, Center for Devices and Radiological Health, Food and Drug Administration. I appreciate your being so patient listening to all the discussion and debate.

Would you please rise and be sworn.

[Witnesses sworn.]

Mr. BURTON. Dr. Tabak, do you have an opening statement?

Mr. TABAK. Yes, Mr. Chairman, thank you.

STATEMENTS OF LAWRENCE A. TABAK, DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD; AND DR. DAVID W. FEIGAL, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

Mr. TABAK. Thank you, Mr. Chairman, for inviting me here today to discuss NIDCR-supported research on mercury in dental amalgam, a material used to restore teeth damaged by the effects of microbial infection or trauma.

The effects of elemental mercury exposure have been studied primarily in occupational studies, where the exposure levels have been on the order of 100 to 1000 micrograms per liter of urine. Estimates of exposure from dental amalgam can range from 1.2 to approximately 20 micrograms per liter of urine, depending on the number of tooth surfaces restored and the size of the restorations.

In the early 1990's, the Assistant Secretary for Health charged the PHS Committee to Coordinate Environmental Health and Related Programs to conduct a comprehensive assessment of the benefits and risks of dental amalgam based on peer reviewed scientific literature. Their 1993 report concluded that scientific evidence does not demonstrate that exposure to mercury from dental amalgam poses a serious risk in humans. However, the Committee's Subcommittee on Risk Assessment called for additional research to address whether dental amalgam creates a significant health risk to individuals. the NIDCR responded in 1996 by launching two clinical trials designed to assess whether exposure to mercury in dental amalgam in children is associated with adverse neurological, renal, immunological, microbiological, behavioral, or cognitive effects.

These studies are comparing the possible health effects of amalgam with composite dental fillings over time. Only children who did not have any prior fillings have been included as participants in order to address the concern that any possible adverse health effects might have been caused by pre-existing dental restorations. It is expected that both trials will be completed in 2006.

One clinical trial is being conducted by a group of scientists from the University of Washington in Seattle in conjunction with a group from the University of Portugal in Lisbon. 507 children between the ages of 8 and 10 years are participating in this trial. Five primary endpoints are being monitored from baseline and at 1 year intervals: three neurobehavioral indices including combined assessments of attention, memory, and motor domains; one neurological assessment involving nerve conduction velocity; and an endpoint aimed at assessing renal function. In addition, urinary levels of mercury were assessed at baseline and are being measured at each followup exam.

A second clinical trial is being conducted by a consortium of scientists from the New England Research Institutes, or NERI, in Cambridge, Massachusetts, Forsyth Dental Clinic and Harvard University in Boston, and the University of Rochester in Rochester, New York. 534 children between the ages of 6 and 8 years requiring at least two fillings were recruited into this trial from sites in the Boston/Cambridge area and in Farmington, ME. The trial is sized to detect a three-point change in IQ over a 5-year period. Ad-

ditional tests of neuropsychological, cognitive and behavioral, and renal functioning are also being carried out.

The conduct of both trials is overseen on an annual basis by an independent Data and Safety Monitoring Board, the DSMB, consisting of experts in the fields of dental restorative materials, pediatric neurology, pediatric nephrology, neurotoxicology, cognitive and behavioral development, heavy metal/environmental toxicology, biostatistics and bioethics. The DSMB has met once a year since the inception of the trials, and meets by teleconference on an as-needed basis, to review group distributions of endpoints and to evaluate trial operations. Based on these data, the DSMB determines whether or not individuals are at increased risk, whether the trials should be ended, and whether the results should be made available to the public.

Over the course of the trials several children have shown higher than acceptable urinary mercury levels. When retested, most values have been within the acceptable range. Also, some children have shown changes in one or more of the neuropsychological endpoints that caused concern and followup clinical examination by the study teams. These changes, however, have not been limited only to children receiving amalgam and, for the most part, the problems identified seem to have existed prior to the entry into the trial. To date, no harmful untoward effects attributable to amalgam have been noted in either trial, and on each occasion the DSMB has recommended that the trials be continued.

In summary, Mr. Chairman, available scientific evidence continues to indicate that dental amalgam is a safe restorative material. Of course, I would be happy to respond to any questions you might have.

[The prepared statement of Mr. Tabak follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

Mercury in Dental Amalgams: An Examination of the Science

Statement of
Lawrence A. Tabak, D.D.S., Ph.D.Director
National Institute of Dental and Craniofacial Research, National Institutes of Health

For Release on Delivery
November 14, 2002

Mr. Chairman and Members of the Committee:

Thank you for inviting me here today to discuss our research on mercury in dental amalgam - a material used to restore teeth damaged by the effects of microbial infection or trauma.

As you know, the mission of the National Institutes of Health (NIH) is to improve the health of the American people through research and research training. As one of the 27 Institutes and Centers within the NIH, the mission of the National Institute of Dental and Craniofacial Research (NIDCR) is to support research and research training that will improve the dental, oral and craniofacial health of the American people.

Dental amalgam is a restorative material comprised of a mixture of alloy powder (containing silver, tin, copper, and other metals) and elemental or liquid mercury. Liquid mercury is the 'glue' that holds the powdered metals together. Because of its unique properties, amalgam can be shaped at room temperature to fill the cavity in a tooth in a way that prevents new bacteria from entering the remaining tooth structure. Mercury has three forms - the elemental or liquid form found in dental amalgam, thermometers and batteries; the inorganic form found as a white powder or crystal; and the organic form found in foods, water, and soil, and thimerosal. Mercury found in thimerosal in vaccines is an organic form of the metal. While elemental mercury enters the body as a vapor and is excreted mainly through the kidneys, other forms are typically ingested and eliminated via the feces.

The effects of elemental mercury exposure have been studied primarily in occupational studies,

where the exposure levels have been on the order of 100-1000 ④g / L l of urine. Estimates of exposure from dental amalgam can range from 1.2 to approximately 20 ④g / L l of urine, depending on the number of tooth surfaces restored and the size of the restorations. In the early 1990s, public concerns were articulated about the health effects of mercury vapor from amalgam restorations. The Assistant Secretary for Health charged the PHS Committee to Coordinate Environmental Health and Related Programs to conduct a comprehensive assessment of the benefits and risks of dental amalgam based on peer reviewed scientific literature. Their report, published in 1993, concluded that scientific evidence does not demonstrate that exposure to mercury from dental amalgam poses a serious risk in humans. However, the Committee's Subcommittee on Risk Assessment called for additional research to address whether dental amalgam creates a significant health risk to patients. The NIDCR responded by launching two clinical trials designed to assess whether exposure to mercury in dental amalgam, in children, is associated with adverse neurological, renal, immunological, microbiological, behavioral, or cognitive effects.

The NIDCR issued a Request for Applications in 1995 and funded two clinical trials in September 1996. These studies are comparing the possible health effects of amalgam with composite dental fillings over time. Only children who did not have any prior fillings have been included as participants in order to address the concern that any possible adverse health effects might have been caused by pre-existing dental restorations. The specific aims of the trials are to investigate:

01 Potential neurological, psychological and behavioral, renal, endocrine or other relevant organ system impairments or dysfunctions attributable to amalgam restorations;

02 The degree to which mercury concentrations in urine, blood or other relevant tissues differ in

children with and without exposure to amalgam restorations; and

03 The progression of mercury in urine, blood or other relevant tissues over time beginning with the placement of amalgam restorations.

One clinical trial is being conducted by a group of scientists from the University of Washington (UW) in Seattle in conjunction with a group from the University of Portugal in Lisbon. Five hundred and seven participants between the ages of 8 and 10 years have been drawn from the population of children attending the Casa Pia Schools in Lisbon. The following five primary endpoints are being monitored from baseline and at one year intervals: three neurobehavioral indices including combined assessments of attention, memory and motor domains; one neurological assessment involving nerve conduction velocity; and an endpoint aimed at assessing renal function. In addition, urinary levels of mercury are will being assessed at baseline and at each follow up exam. The fifth year of followup is currently underway.

A second clinical trial is being conducted by a consortium of scientists from the New England **Research Institutes (NERI) in Cambridge, Massachusetts, Forsyth Dental Clinic and Harvard University in Boston, and the University of Rochester in Rochester, New York. Five hundred and thirty-four children between the ages of 6 and 8 years requiring at least two fillings were recruited into this trial from sites in the Boston/Cambridge area and in Farmington, Maine. The trial is sized to detect a three-point change in IQ as measured by the Wechsler Intelligence Scale for Children-III (WISC-III) over a five-year period. The WISC-III is used because it provides a broad-based evaluation of major neuropsychological domains. Additional tests of neuropsychological, cognitive and behavioral functioning are being carried out. Three tests of**

renal function are also being conducted. Recruitment was completed in September 1999. The third year of followup is underway.

In addition, NIDCR is supporting two ancillary studies involving a subset of participants, respectively, in each of the trials. In one study, antibiotic resistance to oral and urinary bacteria is being assessed in a subgroup of children from the UW/Casa Pia study. The second study is examining changes in immune function in a subset of children from the NERI trial. At this point, we anticipate that the two trials will be completed by the year 2006.

The conduct of both trials is overseen on an annual basis by an independent Data and Safety Monitoring Board (DSMB) consisting of experts in the fields of dental restorative materials, pediatric neurology, pediatric nephrology, neurotoxicology, cognitive and behavioral development, heavy metal/environmental toxicology, biostatistics and bioethics. The DSMB has met once a year since the inception of the trials, and meets by teleconference on an as-needed basis, to review group distributions of endpoints such as mercury burden, neurological, neuropsychological and renal function measures, general health conditions, and oral health as reflected in the need for additional dental care. In addition, if children exhibit very high values of mercury in their urine or show extreme changes in any of the primary or secondary neurological, cognitive or behavioral endpoints, a detailed analysis of their records is conducted by the investigators. These data are presented to the DSMB who determines whether or not these individuals are at increased risk, whether the trials should be ended and whether the results should be made available to the public. Over the course of the trials several children have shown higher than acceptable urinary mercury levels. When retested,

most values have been within the acceptable range. Also, some children have shown changes in one or more of the neuropsychological endpoints that caused concern and followup clinical examination by the study teams. These changes, however, have not been limited only to children receiving amalgam and, for the most part, the problems identified seem to have existed prior to entry into the trial or were identified as not related to the dental restorative procedure.in subsequent followup, their values have returned to normal. Finally, the DSMB reviews, in detail, protocol modifications/variations, retention of participants, particularly as it might impact on the ability to draw statistically meaningful conclusions at the end of the respective studies, and general timetable information. To date there have been no harmful untoward effects attributable to amalgam noted in either trial and, on each occasion, the DSMB has recommended that the trials be continued.

In summary, available scientific evidence indicates that dental amalgam is a safe restorative material. That concludes my testimony. I would be happy to respond to any questions that you might have.

Mr. BURTON. Thank you, Dr. Tabak.

Dr. Feigal.

Dr. FEIGAL. Mr. Chairman and members of the committee, I appreciate your invitation and this opportunity to discuss the issue of dental amalgam safety.

Let me begin with a brief overview of FDA's regulatory authorities over medical devices generally and how they have been applied to dental amalgam.

The term "medical device" in the statute encompasses thousands of health products, some simple and others quite complex. Dental amalgam, as well as its components—dental mercury and the alloy with which the mercury is combined—are medical devices.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act gave FDA specific authority to regulate the safety and effectiveness of medical devices and provided a variety of mechanisms with which to do so. These included the classification of medical devices into risk categories, medical device establishment registration, quality systems manufacturing requirements, and the control of the introduction of medical devices to the market.

Devices on the market at the time of the 1976 Amendments were assigned to one of three classes of risk to patients. Class I devices, posing the lowest risk, are subject to general controls applicable to all devices. Class II devices, which pose incrementally greater risk, are subject to additional controls called "special controls" designed to address the specific risks of the type of the product. Examples of a special control that might be applied to a Class II device include conformance with mandatory performance standards and, less often, clinical studies. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and require valid scientific evidence of safety and effectiveness before they can be marketed. The Act also authorizes the agency to "reclassify" a medical device to a higher or lower regulatory class when warranted.

Amalgam has an extremely long history of use by oral health care providers, well over 100 years. Amalgam consists of roughly equal parts of mercury and amalgam alloys made from other materials such as silver, tin, and copper. Historically, mercury was regulated as a Class I device. Dental amalgam alloy was regulated as a Class II because of potential risks from variations in the chemical formulation of the alloy. The encapsulated form of the amalgam, which consists of measured proportions of amalgam alloy and dental mercury, were never separately classified. However, because the encapsulated amalgam is a combination of two classified devices, it is regulated in the higher class of its components as a Class II device.

In the early 1990's, the FDA became increasingly aware of consumer concerns about the safety of the mercury component in dental amalgam. At the direction of the Assistant Secretary for Health, the National Institutes for Health, the Center for Disease Control, and FDA conducted a comprehensive review of both the health risks and clinical effectiveness of the product.

This extensive evaluation demonstrated that the clinical benefits of dental amalgam outweighed the observable risks, specifically

mild, transient allergic reactions among a very small percentage of patients. In 1993, the Public Health Service issued a comprehensive risk assessment management plan developed with outside peer review to ensure that the NIH, CDC, and FDA collaborated to advance the state of the science, and to keep dental professionals current on the latest scientific information about dental amalgam safety, and to maintain an appropriate level of regulatory control over the product.

The PHS conducted followup reviews of the literature in 1995 and in 1997. And in 1997, FDA invited concerned groups to submit scientific studies for review to FDA by toxicology experts and other experts outside of FDA. Since 1997, we have reviewed more than an additional 170 studies which, taken together, did not change our risk profile for dental amalgam.

In addition to keeping abreast of the science here in the United States, we and our PHS colleagues have aggressively pursued information about the risks of dental amalgams from public health agencies and organizations around the world. To date, a review of the risks and benefits of dental amalgams has not changed FDA's risk-benefit assessment.

We are planning to begin another review with NIH and CDC to update the assessment of the scientific literature on the health effects of dental amalgam. Once again, this later effort will involve experts from both the Government sector and the outside scientific community and we will solicit broadly for information which we should review.

Let me speak a bit about the current regulatory status of amalgam. There has been some confusion among those interested in this issue about the regulatory status of dental amalgam and the purpose of a rule that the agency proposed last February. As explained earlier, mercury, alloy, and encapsulated amalgam are all legally marketed products. Mercury is a Class I device, amalgam alloy is a Class II device, and the combination is regulated as a Class II.

In February 2002, FDA proposed a rule to bring all amalgam products into Class II, requiring ingredient labeling and perform conformance to international standards. Disclosure of amalgam ingredients will also help dental providers to quickly diagnose and treat rare allergic reactions to amalgam components. Given the high level of interest in this proposed rule, we twice reopened the comment period, and we are now in the process of reviewing more than 750 comments submitted to the docket.

In conclusion, Mr. Chairman, FDA is committed to monitoring the scientific evidence closely relating to dental amalgam safety. We will continue to exercise our regulatory responsibilities appropriately in accordance with the best available science. And we will continue to work with the public health community to reduce the incidence of dental caries and improve the quality of oral health care.

Thank you again for this opportunity. I am happy to answer any questions you or the members of the committee may have.

[The prepared statement of Dr. Feigal follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

DAVID W. FEIGAL, M.D., M.P.H.

DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

NOVEMBER 14, 2002

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. David Feigal, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I appreciate your invitation and the opportunity to discuss the issue of dental amalgam safety. My remarks will address FDA's regulatory policy as it relates to dental amalgam.

BACKGROUND

Let me begin with a brief overview of our regulatory authorities regarding medical devices and how we exercise them in the case of dental amalgam.

As defined by Federal law, the term "medical device" encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers and imaging technologies. Dental amalgam, as well as its components – dental mercury and the alloy with which the mercury is combined – are medical devices.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) gave FDA specific authority to regulate the safety and effectiveness of medical devices. The FD&C Act prescribes a variety of mechanisms to achieve this goal. These include classification of medical devices, establishment registration, Quality Systems Requirements for manufacturing, and controls over the market introduction of medical devices.

Devices on the market at the time the 1976 Amendments were passed were assigned to one of three "classes." Devices posing the lowest risk, such as elastic bandages, were placed in Class I, subject to the "general controls" I just outlined. Class II devices, which pose incrementally greater risk and whose safety and effectiveness cannot be adequately controlled with Class I requirements, are subject to "special controls." These range from post-market surveillance studies to conformance with mandatory performance standards. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and undergo premarket evaluation, including clinical studies, before manufacturers can introduce them into commerce.

The FD&C Act also authorizes the Agency to "reclassify" a medical device to a higher or lower regulatory class as more knowledge emerges regarding product risk gained from actual use. In most cases, reclassifications result in de-regulation, or moving a device type to a lower class. Occasionally, though, new circumstances or information demonstrate that a device's risk profile has changed, warranting more rigorous regulation or placement in a higher regulatory class.

REGULATORY HISTORY OF DENTAL AMALGAM

The Classification Process

Now let me address the specific issue of dental amalgam and the evolution of our regulatory position on this product, as well as how we presently regulate dental amalgam.

Dental amalgam is a restorative material used to treat dental caries. Amalgam has an extremely long history of use; oral health care providers have utilized amalgam for well over 100 years. Evidence accumulated over the years has consistently shown amalgam to have wide applications. Dental amalgam is easy to manipulate, has reasonable clinical serviceability, and is highly durable.

Dental amalgam consists of roughly equal parts of elemental mercury (43-54 percent) and an amalgam alloy made from other metals such as silver, tin and copper, sometimes with smaller amounts of zinc, palladium or indium present. Dental amalgam alloy, both in encapsulated and free-standing form, are pre-Amendment devices. Historically, dental mercury has been regulated as a Class I device. The alloy has been regulated as a Class II product because of potential risks that could result from variations in chemical formulation related to percent composition and types of materials. The encapsulated form of amalgam, which consists of measured proportions of amalgam alloy and dental mercury that are separately sealed and sold as a single-use capsule, was never classified during the original classification process. However, because it is a combination of two classified devices, the encapsulated form is regulated in Class II given that one of its components, the alloy, is a pre-Amendments Class II device.

Early Concerns About Safety

In the early 1990s, FDA became increasingly aware of consumer concerns about the mercury component of dental amalgam and whether certain, and in many cases, non-specific health problems were attributable to mercury exposure.

At the direction of the Assistant Secretary for Health, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and FDA (as members of the Committee to Coordinate Environmental Health and Related Programs) conducted a comprehensive review of both the health risks and clinical effectiveness of the product.

This extensive evaluation demonstrated that clinical benefits of dental amalgam outweighed observable risks, including mild, transient allergic reactions among a very small percentage of the patient population. In 1993, the Public Health Service (PHS) issued a comprehensive risk management plan that had been developed with outside peer review. Its purpose was to ensure that NIH, CDC and FDA collaborated to advance the state of science, to keep dental personnel current on the latest scientific information about amalgam safety, and to maintain an appropriate level of regulatory control over the product.

It is important, Mr. Chairman, to emphasize the 1993 Public Health Service report's science-based conclusions that there was no definitive evidence linking the placement of amalgams and the onset of systemic disease. These conclusions have not changed in the intervening nine years. PHS experts conducted follow-up reviews in 1995 and again in 1997. Also in 1997, FDA toxicology experts and other experts from outside FDA performed an extensive review on more than 170 scientific studies that consumer advocacy and other concerned groups submitted at our invitation. Taken together, these reviews did not provide a basis on which to alter our risk management approach. These ongoing efforts have occurred at the same time the NIH has been actively

pursuing a highly-focused agenda of clinical and non-clinical research in this area.

In addition to keeping abreast of the science here in the United States, we and our PHS colleagues have aggressively pursued information from public health agencies and organizations around the world in order to advance our scientific understanding.

To date, as I said, scientific opinion has remained constant and has validated and reaffirmed the 1993 findings of the Public Health Service. We are planning another review in conjunction with NIH and CDC to ensure the scientific underpinning of our regulatory policies remains current. Once again, this latest effort will involve experts from both the government sector and the external scientific community.

CURRENT REGULATORY STATUS OF AMALGAM

There has been some confusion about the regulatory status of dental amalgam and the purpose of a rule that the Agency proposed last February. As I explained earlier, mercury, alloy, and encapsulated amalgam are all legally marketed products. Since 1976 and at this time, mercury is a Class I device, alloy is a Class II device, and the encapsulated combination is unclassified but regulated as a Class II device.

In February 2002, our Agency proposed a rule to bring all amalgam products into Class II and increase the Agency's regulatory oversight by requiring ingredient labeling and proposing conformance to international standards. By requiring disclosure of amalgam ingredients, the rule would help dental providers to quickly diagnose and treat rare allergic reactions arising from exposure to amalgam components. Given the high level of interest in this proposed rule, we twice reopened the comment period. We are now in the process of analyzing the more than 750 comments submitted to the docket.

CONCLUSION

Mr. Chairman, I want to reiterate that FDA is committed to monitoring closely the body of scientific evidence relating to dental amalgam safety in which NIH and others are now engaged. We will continue to exercise our regulatory responsibilities appropriately in accordance with the best available science. Finally, we will continue to work with the public health community on approaches to reduce the incidence of dental caries and optimize the quality of oral health care.

Thank you again for this opportunity. I would be pleased to respond to any questions Members of the Committee may have.

Mr. BURTON. Thank you, Dr. Feigal.

Mr. Gilman, do you have any comments you would like to make before we start the questions?

Mr. GILMAN. Thank you for conducting this hearing. I am sorry I had another engagement that delayed me from coming over. I want to recognize the importance of your decision to hold hearings on mercury levels in dental amalgams and commend your efforts in investigating medical exposures to mercury and other potentially toxic materials.

I think today's hearing is important because it deals with mercury, a highly toxic element. Unlike other toxins, mercury is unable to be filtered out or eliminated by our bodies; instead, it accumulates over time. For that reason, efforts have been made to reduce the level of exposure of the public to mercury. Mercury thermometers have been phased out, and the FDA has issued warnings that vulnerable populations such as pregnant women and young children should avoid consuming too much mercury-containing fish.

There is currently an ongoing debate of course within the dentistry community about the potential for harm from the dental amalgams which contain mercury. And while the majority of dentists use such amalgams and see no long term harm in doing so, a significant percentage are moving away from such practices.

So I look forward to being able to review all of the testimony that you are taking today, and I again commend you. I do have some questions after the panel has finished their testimony.

Mr. BURTON. Thank you, Chairman Gilman.

You said that the FDA has been following this and checking this out for a long, long time. Can I ask you a couple of questions about the history of the FDA and mercury fillings, this is from 1976 till now?

Dr. FEIGAL. Yes.

Mr. BURTON. In 1976, Congress ordered the FDA to regulate devices. In 1986, Proposition 65 passed in California, I am sure you are familiar with that. In 1987, the FDA classifies all dental fillings except encapsulated mercury amalgam. Is that correct?

Dr. FEIGAL. It was not specifically encapsulated but it was covered by the classification of its two separate components.

Mr. BURTON. Well is that a correct statement, the FDA classified all dental fillings except encapsulated mercury amalgams? Is that a correct statement?

Dr. FEIGAL. That is correct.

Mr. BURTON. OK. Why did they not classify that as well?

Dr. FEIGAL. To be honest, we do not know if it was an oversight or if it was the intent to regulate the combination product by regulating its two components, both of which were classified. There is no unclassified component in the product. But we actually have not been able to reconstruct that history.

Mr. BURTON. Citizens groups sued the FDA for failing to classify mercury amalgams in 1991 and 1993. In 1993, Public Health Service asked the FDA to classify mercury amalgams. In 1997, OSHA backed off regulating dental offices because of FDA promise to classify. In 1997, FDA writes a letter again promising to classify mercury amalgams. And from 1990 to 2002, meanwhile the FDA prohibits other mercury containing items, including disinfectants, vac-

cines, even horse medicine, there is still some in some vaccines. But did you ever classify mercury amalgam?

Dr. FEIGAL. Dental mercury is classified as Class I and the alloy has been classified as Class II, and the component is classified as a mixture of two products, one of which is Class I and the other is Class II, not separately classified. We have had petitions to change the classification, but the product has been classified for some time. I would have to get you the exact dates.

Mr. BURTON. It has been classified?

Dr. FEIGAL. Yes.

Mr. BURTON. It said that OSHA backed off in 1997 regulating dental offices because of FDA promise to classify. And it says FDA writes a letter in 1997 again promising to classify mercury amalgams. But you say it actually has not been done. You classified the components but not the mercury amalgam itself.

Dr. FEIGAL. The manufacturers of the combination product where the two are encapsulated together have been regulated since the classification of Class I and Class II as a Class II product.

Mr. BURTON. What is a Class II product again?

Dr. FEIGAL. A Class II product is a product that has specific controls. So in the case of the alloy, the amalgam alloy, there are international standard organizations, ISO standards and there are ANSI standards on the compositions of alloys, recognized standards for what those compositions can be, and they have to meet those standards.

Mr. BURTON. OK. So does that mean that Class II would be considered a toxic substance or a possible toxic substance?

Dr. FEIGAL. Well, the risk classification is not actually based on the toxicity of the compound in the absolute sense. It is based on the risk in use to the patient. And so it is not based on environmental toxicity, on toxicity to animals, it is based on whether or not it needs to have special controls in order to assure that the product will be safe and effective as used. And in this case, the control is to know what is in the alloy.

Mr. BURTON. Do you have any idea how many micrograms of mercury vapor is emitted by a filling in the day?

Dr. FEIGAL. We have reviewed the same studies that were discussed by the first panel and we have, as part of the process over the years, gone over that literature and we understand that literature presents a range of values.

Mr. BURTON. A range from where to where?

Dr. FEIGAL. I would have to followup in terms of providing that——

Mr. BURTON. We have somebody here that has a mercury amalgam. Don't you have a device that measures the micrograms in it? Can you do that for us while we are here? I would like for them to have that information while they are here. I do not know how you do that.

Mr. RICHARDSON. Someone here brought a sniffer.

Mr. BURTON. What was that?

Mr. RICHARDSON. Someone here has a mercury vapor sniffer.

Mr. BURTON. Right. If they would like to come up here and show us, we would like to have that.

Does the FDA take a position on the amount of mercury that accumulates in the brain and whether or not it is easily excreted from the brain?

Dr. FEIGAL. The toxicology of chronic implants, like alloy, are looked at through a series of standards that evaluate biomaterials. And most of the evidence that we evaluate biomaterials with come from animal data and come from special exposure studies in animals. Manufacturers are required to know the toxicology profile of their products as part of the controls that they have over their products. The risk is not assessed in terms of any absolute amount or characteristic of the toxicology, but in the context of the risk and benefits in clinical use.

Mr. BURTON. You were here for the previous panel.

Dr. FEIGAL. Yes.

Mr. BURTON. You heard some of the researchers, the scientists that testified who said that when you brush your teeth, when you chew, when you have hot coffee or a hot substance in your mouth vapors are emitted, and when you chew some of it flakes off over a period of time and goes into your body. Has there ever been a study done on cadavers, people that have had a lot of fillings in their mouths to see what the mercury content is in the brain, any studies that you know of?

Dr. FEIGAL. The studies that they cited are the same studies that we reviewed in our process of looking at the literature. How that relates to our classification is to look at the product in actual use and to look at the risk and benefit. All implants, including hip implants, jaw implants, that are made of metal have metals that leech into the body, plastic materials have volatiles, and we assess all of those exposures. It is not a question of whether or not there is an exposure. The question is whether there is adequate evidence that the exposure causes clinical——

Mr. BURTON. These other substances that you are talking about, though, steel, plastic, they are not in the same class as mercury, are they?

Dr. FEIGAL. There are problematic compounds that in very low amounts—for example, there is cadmium in the alloys of hip implants.

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

Dr. FEIGAL. My point is that we——

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

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

Mr. BURTON. Do you mean to tell me cadmium is as toxic a substance as mercury? Is that what you are saying? Come on.

Dr. FEIGAL. What I am trying to do is put it in the context of how FDA regulates products. We do not assess the environment, we do not assess the effect of pure compounds and absolute toxicity. We look at how they are used in practice.

Mr. BURTON. You do agree though that mercury vapors leech out of the tooth?

Dr. FEIGAL. Yes, we do agree with that.

Mr. BURTON. And that it is ingested into the body?

Dr. FEIGAL. Yes, we do agree.

Mr. BURTON. And it gets into the bloodstream?

Dr. FEIGAL. Yes.

Mr. BURTON. And it goes to the brain and other organs of the body?

Dr. FEIGAL. Yes, we agree with that.

Mr. BURTON. And mercury has a cumulative effect in the brain?

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

Mr. BURTON. You know, I do not understand why—many people in this country, probably the majority, do not know that there is mercury in a silver filling in their mouth, in the amalgam. Why doesn't the FDA at least, since mercury vapors do escape into the mouth and into the body, why doesn't the FDA at least make people aware of that? Why not publicize that?

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

Mr. BURTON. What about the mercury in the vaccines, the thimerosal and that sort of thing?

Dr. FEIGAL. I am afraid I will have to get followup from someone else in the agency who can comment about vaccines. That is outside my area.

Mr. BURTON. Thimerosal contains mercury that is injected into kids, and you heard me talk about that earlier.

Dr. FEIGAL. Yes.

Mr. BURTON. I think that has been pretty well publicized, hasn't it? Hasn't the FDA talked about that?

Dr. FEIGAL. Yes. But I think if you are talking about the informed consent process——

Mr. BURTON. I am not talking about informed consent. I am just talking about making people aware.

Dr. FEIGAL. I think that is a reasonable request to do that.

Mr. BURTON. Then I would make that request, that the FDA put a card or something in every dentist's office saying that the amalgams that you get from your dentist contain approximately 50 percent mercury, and then let the people make the decision themselves. I think people ought to be held accountable for their actions, but they at least ought to know what the hell they are doing. And they do not.

Did you check that out? Ladies, did you check that out? What did you find? Why don't you sit down there at the table, Doctor, and give us that. What was the amount?

Mr. RICHARDSON. They took a preformed pill-sized amalgam filling that I suspect was prepared in Dr. Haley's lab, wiped it with a napkin, and then held it to a Jerome mercury analyzer to measure the mercury content in micrograms per cubic meter. That device only measures the vapor. It does not measure particulate or other forms.

They took three measurements. The first one was 283 micrograms per cubic meter, which is over 10 times the threshold limit value for occupational exposure and some I think about 100 times higher than the U.S. EPA reference concentration. The second measurement, when it was held slightly distant from the inlet to the device, came back at 82 micrograms per cubic meter. Again, that is approximately a little more than double the threshold limit value. They then polished it again, held it to the front of the device, and got a number of 774 micrograms per cubic meter. With 25 micrograms per cubic meter being the threshold limit value for occupational exposure, that is some 5 times higher than the TLV for the air that passed over that pre-made amalgam filling.

Mr. BURTON. Doctor, come on up here. We will let you make a comment on that. I do not want the American Dental Association to feel left out.

You stick around up there. I want the FDA people to hear this because that is why we asked them to be here is so they could glean from the testimony some insights into what maybe ought to be done.

Go ahead.

Dr. MACKERT. OK. This instrument that was used is designed for measuring mercury vapor in a room where the collection volume, which is, depending on the model, 250 milliliters to 500 milliliters, the collection volume is small compared to the volume of air of the room. Again, this is a matter that has been studied extensively in the literature, particularly in Sweden by a colleague of mine named Anders Berglund at the University of Umea. This is not an appropriate use of this instrument. I hope Dr. Richardson knows that this is not an appropriate use of this instrument. To report micrograms per cubic meter and then imply that a person inhaling mercury vapor would be exposed to the levels that he described as if that person were in a room with those concentrations, are you saying that the person that would breath next to that would absorb the same amount of mercury vapor as a person in a room with 280, or whatever you just quoted, micrograms per cubic meter?

Mr. RICHARDSON. No. All I was trying to do was put into perspective the three measurements that were made by this device. Agreed, in the context of if you were trying to estimate exposure, you can in fact, and there have been studies done, use that information in combination with information on the size/shape of the oral cavity, the amount of air that is inhaled with a breath, etc., to come up with estimates of exposure.

Mr. BURTON. Let me ask the people from the FDA something. I asked the American Dental Association representative here who is going to be on their decisionmaking board if they would agree to do a study, take 100, 200, or 1,000 amalgams and split them up and send them to different scientific research laboratories, like Harvard or others, and have them tested under heat and abrasion to measure the amount of mercury that is emitted from these. Could the FDA participate or would they participate? It does not sound like to me it would be that costly. You just make the amalgams and you send them and they would do the research. It does not seem like it would take a rocket scientist to do that if you had the proper equipment.

Dr. FEIGAL. The FDA does relatively little funding of research itself. It usually relies on the Public Health Service and on the manufacturers or on other independent bodies to do the research, or on standards bodies such as the International Standards Organization or ANSI to develop standards. We would welcome the results of such studies.

Mr. BURTON. Can you not admonish somebody to do that? You guys, come on, you are the ones that put the pressure on supplements manufacturers and go in and raid them and everything else to stop them from selling their supplements. You do all kinds of stuff like that. Don't tell me you do not have enough authority to kind of push them along to make them do that. Why don't you do that?

Dr. FEIGAL. Well, believe it or not, Congress actually wrote some authorities that we have to follow the rules. And in devices, the logic would have to be that we would need that information in order for the product to be used in a way that would result in it being safe and effective. The way we have looked at the review of the literature with the Public Health Service is we have made the determination that the evidence to date still comes down in the favor that these products are safe and effective.

Mr. BURTON. Dr. Tabak can do the study. He can do the study.

Dr. FEIGAL. Yes.

Mr. BURTON. He is a scientist who works in that area. But you guys say because it does not come down on the side that you agree with that no further studies are necessary.

Dr. FEIGAL. No I did not say that.

Mr. BURTON. That is what I got from it.

Dr. FEIGAL. No. I apologize if I gave you that impression. We welcome ongoing developments in the science. We can measure mercury exposure levels, as you have heard, that we were never able to measure in the past. And when we look at that information and we say as a biomaterial is this still an acceptable biomaterial, then we look at that both with animal studies and with human studies and benchwork.

Mr. BURTON. Have you done the kind of study I was just talking about?

Dr. FEIGAL. As I understand it, you were asking to see what the kind of exposure would be. But the context that we are asked to regulate devices in, the context of risk and benefit, and so we have to look at the two as they weigh together. We would have to conclude in order to take an action that the action was necessary for the product to be used safely and effectively.

Mr. BURTON. So what kind of a scientific research project would you have to have that would give you that kind of information?

Dr. FEIGAL. I think there are many different sources. I think the ongoing development of the toxicology. Many of the questions today where there were disagreements of conflicting studies, it would be nice to get the animal work and the benchwork about what is the level of exposure, the duration of exposure. You heard that there was disagreement about the half-life of materials in different parts of the body and what the consequences of those are. We use the information from epidemiology, we use the information from studies such as the studies that Dr. Tabak described. It is a process

that is ongoing with us. So that when we feel that a risk has reached a level where changing the classification or changing the requirements by a manufacturer would make the product be used more safely or more effectively, then we take those actions. So we are constantly in the midst of that process. We just do not fund it ourselves; we look at what everybody else does.

Mr. BURTON. But you could, of course, urge this kind of a study be done.

Dr. FEIGAL. Yes, we could, and we would probably do that in the context of the Public Health Service, particularly given the number of particularly small device firms.

Mr. BURTON. Would you be willing to urge that amalgams in some quantity be tested by leading scientific laboratories to find out the amount of emissions?

Dr. FEIGAL. Yes, I would be willing to do that.

Mr. BURTON. Would you do that. OK. Very good. We finally got to where I wanted to go. [Laughter.]

Ben, do you have a question?

Mr. GILMAN. Thank you, Mr. Chairman. Dr. Feigal, elsewhere in the FDA mercury is not generally recognized to be safe, but apparently the dental device division classifies dental mercury as a Class I safe and effective device. Is that correct?

Dr. FEIGAL. That is correct.

Mr. GILMAN. Why? Is that classification likely to stand, or is it under review?

Dr. FEIGAL. We have proposed reclassifying it as a Class II device. Again, the context of the risk is risk to the patient in its use as a medical device. So it is not the same as risk from food or risk from an environmental exposure.

Mr. GILMAN. What are the differences in Class I, II, and III dental devices? What are the differences?

Dr. FEIGAL. Class I devices are devices which require general controls for medical devices, including registering and listing the product, having a quality manufacturing system which includes a mechanism of detecting adverse experiences in a reporting system and reporting them to us, it includes labeling requirements and other things, but it does not require that the product be submitted to FDA for review prior to marketing. There are a small number of Class Is but most of them are exempt from pre-marketing.

Mr. GILMAN. What about Class II?

Dr. FEIGAL. Class II, there are about 800 different Class II products. Each of those has its own set of special controls. The special controls are the controls that are necessary for the product to be used safely, in addition to the controls the Class Is have. So, for example, in the case of the alloy, there is a range of materials that are allowed in alloys, a range of amounts that have been developed by the American National Standards Institute and by the International Standards Organizations.

Mr. GILMAN. And what about Class III?

Dr. FEIGAL. Class III is a group of products that must demonstrate that they are safe and effective, and they usually are products that have no comparable product that is on the market or a product in which there is a substantial risk and the only way to demonstrate the safety and the effectiveness of the products is by

performing clinical trials, usually prior to marketing, although when a product is on the market at the time of the amendments, they do not come off the market if they are classified as Class III.

Mr. GILMAN. So an amalgam with mercury in it is no problem and that is why it is a Class I?

Dr. FEIGAL. No problem is—the Class I is the appropriate level of regulation to have a well-manufactured product that performs as intended and can be expected to be substantially equivalent in safe and effective compared to other products.

Mr. GILMAN. Do you have any reservations about the safety and effectiveness in mercury being used as part of amalgam?

Dr. FEIGAL. The misconception I think about safety in FDA is that we certify products as safe. We do not. All products have risks. The question is is the risk——

Mr. GILMAN. Does mercury have a risk?

Dr. FEIGAL. Of course it does.

Mr. GILMAN. Then why is it a Class I?

Dr. FEIGAL. It is Class I for the same reason that medical needles in shops are Class I, is it can be manufactured in a way that it will perform in the way that it is expected and will be safe and effective as its intended use. Just as some forms of mercury are medical waste, used syringes are medical waste.

Mr. GILMAN. Tell me, I understand that the waste product, the removal product is classified as a hazardous substance. Is that correct?

Dr. FEIGAL. That is nothing that FDA has anything to do with. It does not affect our risk classification at all.

Mr. GILMAN. But it has been classified that way by EPA; is that right?

Dr. FEIGAL. The vast majority of medical devices after they have had human contact are classified as hazardous materials and must be handled properly, according to the EPA.

Mr. GILMAN. If it is a hazardous material, why isn't it reclassified as a hazardous material for the dental community?

Dr. FEIGAL. The EPA classification is different than the FDA classification. The FDA risk is risk to the patient as a medical device. There are OSHA classifications on risks to health personnel, there are EPA classifications on risk to the environment. So there are things where a product will be in one classification but not in another.

Mr. GILMAN. So it can be a risk to the environment but not to the patient, is that what you are saying?

Dr. FEIGAL. Absolutely. The vast majority of medical devices waste are hazardous to the environment and must be properly handled and incinerated.

Mr. GILMAN. Doesn't that seem to be inconsistent in your mind, that it is hazardous to the environment but not to the patient?

Dr. FEIGAL. No, because it is in the context of use. A needle is hazardous to the environment but it is not hazardous to the patient. It is effective for what it is intended to do.

Mr. BURTON. Would you yield for just 1 second.

Mr. GILMAN. I am pleased to yield to the gentleman.

Mr. BURTON. You heard the dentists talk earlier at the first panel and they said mercury in the amalgam is toxic before, and

it is toxic after you take it out, so why isn't it toxic or a problem when it is in the tooth?

Dr. FEIGAL. My understanding of that discussion was that the toxicity was in terms of how EPA considered it in terms of toxicity to the environment. That is a different issue than its risk to the patient as a medical device.

Mr. BURTON. If the gentleman would yield further. That substance that is taken out of the tooth, that amalgam goes into the water supply, into the sewage system, into everything. And we know from you that we should not eat a lot of fish that contain mercury. Where do you think that mercury comes from? It does not come out of the air.

Dr. FEIGAL. The environmental issues are not the basis of the FDA risk classification.

Mr. BURTON. Do you guys ever talk to one another? I do not understand it. If mercury is a toxic substance—Ben, thank you for yielding—if mercury is a toxic substance, it is toxic before it is put in the mouth and it is toxic afterwards, you would assume that there is a modicum of risk while it is in the mouth. You had the environmentalist there a while ago talking about the horrible problem they are having with wastewater treatment plants around the country and the water system, and they are dumping huge amounts of these amalgams down the drain because there is no regulation by FDA on what to do with it. Why don't you regulate what to do with those things after the dentist takes them out of the mouth so they do not get into the ecological system?

Dr. FEIGAL. Because Congress has not given us the jurisdiction to do that and they have given the jurisdiction to the EPA and to OSHA. Another common example, for example, is the use of radioactive substances in medical devices. Those are hazardous products to the medical environment; they must be handled in specific ways before use, they must be disposed of carefully after use. But our risk classification would be to classify their risk based on their use as a medical device. OSHA, EPA, the State authorities would take care of the other things. These have been divided.

Mr. BURTON. Let me just make one more comment and then I will yield back to my colleague. You know, because of the threat to the security of America, we are combining a whole bunch of agencies into what they call Homeland Security. It sounds to me like we ought to do that with the health agencies. We ought to take EPA and the health agencies and everybody else and put them under one governing body so that you guys work together.

If there is an amalgam that is dangerous before and dangerous afterwards to the environment, and I believe it is dangerous to the person, it seems to me there would be a consistency of thought. And it does not sound like there is. You guys are saying the amalgam is not a threat to the person, at least not in your opinion right now, the merits outweigh the problems with it, and yet before and after it is a problem for the ecology and the environment. There is an inconsistency there that just alludes me.

Dr. FEIGAL. There are countries, Singapore is an example, where the EPA and the FDA functions are in the same organization. But that is not how we have been organized. Historically, actually much of the staff of EPA was drawn from FDA at the time Presi-

dent Nixon created the EPA. The functions were separated and made different.

Mr. BURTON. Ben.

Mr. GILMAN. Thank you, Mr. Chairman. Dr. Feigal, how do you explain the extraordinary variance between the amalgam's vapor release rates between the various researchers, as illustrated by Dr. Haley, Richardson, and Fischer?

Dr. FEIGAL. Again, we do not dispute the fact that there is exposure to mercury. The question is whether or not mercury as a medical device still has benefits that outweigh the risk and whether or not the product meets the standards that we look at for a biomaterial in terms of its toxicity.

Mr. GILMAN. What are the benefits of mercury usage?

Dr. FEIGAL. The benefits of dental amalgam would be a question better answered by Dr. Tabak or one of the dentists. But the question is it effective as a dental restorative device, I think that probably has not been one of the things that has been questioned.

Mr. GILMAN. Based on today's standards at the FDA, if mercury amalgams were new and were submitted for approval as a dental device using the existing published research, would it be approved?

Dr. FEIGAL. That is a very good question. I have actually thought a lot about that.

Mr. GILMAN. I am pleased to hear that.

Dr. FEIGAL. The products that are already on the market, the burden of proof is on the agency to demonstrate that the risks are high enough to take them off the market. And the standard is so high that in 27 years only one product has been banned and no product has been involuntarily withdrawn from the market because of safety concerns by FDA because of the very high standards for demonstrating the evidence that has been placed on the agency through the Food, Drug, and Cosmetic Act and the device amendments. It is not our choice, it is the way that it was set forward.

Now a new product coming onto the market would actually have to show as safe and effective before it was on the market. And if we start by saying we assume that its properties as a restorative material would be relatively easy to demonstrate, so it would meet the effectiveness standard relatively easily. So the question is if it were a new substance, what would they have to do to show it was safe. And there they would have to meet recognized international scientific standards on the toxicology of the substance, to show that, in fact, the way it was used that the toxicity was not a problem. It would not be an issue of whether there was toxicity or not, it is whether or not in the context of the use you could actually demonstrate risk. The kinds of studies that Dr. Tabak has done would be the kinds of studies that would be looked at, where you would have a very careful look at a group that was exposed and not exposed to look for clinical effects. We would also rely on animal work and on what is known about the physical properties of the materials.

But that is one of the differences. The old products, the assumption made in the device amendments was the old products were safe and new products to come onto the market only had to be shown to be substantially equivalent to a product on the market in 1976. That is the legal standard in the law. For the Class III prod-

ucts newly coming onto the market, products must show that they are safe and effective.

Mr. GILMAN. Dr. Feigal, if you were to deny the use of mercury in an amalgam for dentists, what harm would that do to the practice of medicine?

Dr. FEIGAL. We would have to actually do that based on the legal tools given to us in the statute, and the statute requires a very high demonstration of harm, not to answer the question of whether it would be a reasonable precaution. The statute would require that to ban a product we would actually have to show the damage that the product was causing in use as a medical device.

Mr. GILMAN. Do you have any evidence to either support or refute Dr. Haley's statement that, "The data regarding the specific ability of mercury to cause much of the aberrant biochemistry found in the brain and to produce many of the widely accepted diagnostic hallmarks of Alzheimer's disease is unquestionable." He said it is unquestionable. How do you respond to that?

Dr. FEIGAL. I think part of the discussion that occurred during the first panel was whether or not that was a view that was widely accepted. We looked at the balance of evidence across different scientific experts and studies and we would have to consider that an interesting hypothesis but something which is unproven. There are also concerns about the issue of aluminum in Alzheimer's disease and other types of exposures, and we need to look at all of those types of issues. But I do not think there is a scientific consensus that agrees with Dr. Haley at this point in time, would be my assessment.

Mr. GILMAN. So you disagree with Dr. Haley's findings?

Dr. FEIGAL. Looking at it in the balance of the rest of the data and research on Alzheimer's disease, I can speak for the process of looking at this, but we would probably not agree with him at this time.

Mr. GILMAN. Again, with regard to the use of mercury, in your testimony you state that amalgam as a restorative is used to treat dental caries. Is that correct?

Dr. FEIGAL. That is correct.

Mr. GILMAN. But that actually is not true, is it? You are not treating a cavity. The dentist drills out the cavity and fills in the gap with the amalgam. You do not actually treat it or cure it. You clear it out and fill in the gap. So what would be the harm in filling in the gap without mercury?

Dr. FEIGAL. There are multiple products that can be used the way that amalgam is used, and the way you describe it is a correct characterization of how it is used. The FDA standard, the standard that is in the Act for products to be on the market is not that they should be removed from the market if there is a better alternative. The standard is that they are safe and effective for use.

Mr. GILMAN. Are there better alternatives?

Dr. FEIGAL. There are alternatives with other advantages and disadvantages.

Mr. GILMAN. Are there better alternatives than using mercury in the amalgam?

Dr. FEIGAL. Perhaps you should ask Dr. Tabak.

Mr. GILMAN. Dr. Tabak.

Mr. TABAK. There are alternatives, sir, but not substitutes.

Mr. GILMAN. The question is, are there better alternatives than using mercury in amalgams?

Mr. TABAK. Currently, in some clinical conditions, no.

Mr. GILMAN. And what are those conditions?

Mr. TABAK. If you have extensive damage to the tooth, there are situations where you cannot restore it with a material such as a composite restoration, which is most often referred to as the alternative restorative material.

Mr. GILMAN. And you say there are no materials that could be utilized except a mercury amalgam?

Mr. TABAK. As was indicated in the first panel, sir, you can use a gold restoration which carries with it a very high cost.

Mr. GILMAN. But it is available?

Mr. TABAK. It is available.

Mr. GILMAN. And it is a better usage than a mercury amalgam, is that correct?

Mr. TABAK. I would not say it is better, sir. I would say that it is an alternative.

Mr. GILMAN. Is it a preferable alternative?

Mr. TABAK. I would not say it is preferable, sir. I would say it is an alternative.

Mr. GILMAN. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Chairman Gilman asked one question, Dr. Feigal, that you kind of skirted around. I want to get a more definitive answer. Based on today's standards at the FDA, if mercury amalgams were new and were submitted for approval as a dental device, using the existing published research today, would you approve it?

Dr. FEIGAL. I think we would approve it as a restorative, yes I do.

Mr. BURTON. Do you. And what class of device would you call it?

Dr. FEIGAL. It would still probably be a Class II device because most of the evidence would not have to come from clinical evidence.

Mr. BURTON. Now after you do that study I asked you about a while ago, if it shows that there is an inordinate amount of vapor leeching into the body, would you maybe reconsider?

Dr. FEIGAL. What we would have to know is what the significance was of the release of the vapor. And it comes back to the point I must not have made very clearly before, which is it is not the exposure which is at issue, it is the clinical significance of the exposure. That is what needs to be established.

Mr. BURTON. Man, I do not want to breath mercury vapors. Do you? Do you like breathing mercury vapors?

Dr. FEIGAL. I would prefer not to.

Mr. BURTON. But you put them in your mouth. And if you have an inordinate amount of mercury vapor leeching out because you brush your teeth, because you eat something, because you drink hot coffee, would that not be of concern, especially when you know it has a cumulative effect in the brain? Do you mean that does not even concern you? You are a scientist, a doctor.

Dr. FEIGAL. It is also of concern to me not to be exposed to x-rays, and yet I still——

Mr. BURTON. I am not talking about x-rays.

Dr. FEIGAL. But I still watch my television set. If we were to say why take the risk——

Mr. BURTON. But you sit further back, you do not sit right up on top of it.

Dr. FEIGAL. There is still exposure. Why should I have any exposure?

Mr. BURTON. I am talking about mercury. I am not talking about your television set.

Dr. FEIGAL. The issue is the same. We have to know at what level the exposure actually has clinical significance.

Mr. BURTON. That is what I am asking about in this study. If you find that there is an inordinate amount of exposure from the emission, do you think you might reevaluate that?

Dr. FEIGAL. If the exposure was known to be clinically significant, then we would change, yes.

Mr. BURTON. I hope you will allow our colleague that has done extensive research on this to be part of that research project that you are going to recommend.

Dr. FEIGAL. We are always happy to look at all sources of evidence.

Mr. BURTON. I am going to send you a letter after the hearing that says you said you thought you could do this and I am going to suggest that you have him as part of the research project. I would be very happy to take a look at the results next year because I am probably going to be very active in this next year as well and maybe we can talk again.

Dr. MACKERT. Mr. Chairman, I wonder if I could——

Mr. BURTON. Did you have a question? Yes, please.

Dr. MACKERT. I wonder if I could make a comment on your question about the release of materials into the body from amalgam and other materials.

Mr. BURTON. Yes.

Dr. MACKERT. I have studied dental materials for 24 or 25 years, all different materials. I work in ceramics, every material that we use in the body releases elements into the body and those are absorbed into our body. And if we look, there is gold in the tissue under my ring here. That is on the same order of magnitude as the mercury that would be in my gum tissue next to my filling.

Mr. BURTON. Toxicity?

Dr. MACKERT. Gold is a very toxic element.

Mr. BURTON. It is as toxic as mercury?

Dr. MACKERT. If the dose is the same, the toxicity is similar.

Mr. BURTON. So if I have a gold cap on my tooth and I have a mercury filling, they are both the same?

Dr. MACKERT. In terms of the effect on you? Both of them have no effect on you. But let me just ask a question of you, if I may.

Mr. BURTON. Oh, sure. If I do not know, I will just tell you.

Dr. MACKERT. I do not know what materials you had your amalgams replaced with.

Mr. BURTON. A composite. My dentist is right there.

Dr. MACKERT. Did the dentist tell you the ingredients of that composite before you put it in your mouth?

Mr. BURTON. Sure, he told me.

Dr. MACKERT. What were the ingredients?

Mr. BURTON. I do not remember. Tell him.

Dr. MACKERT. Did he tell you about the allergenicity of the hydroxy ethyl-methacrylate that is used as a bonding agent? It is one of the most potent allergens used in dentistry. Bob Erickson, who is the pride——

Mr. BURTON. And it is as toxic as mercury?

Dr. MACKERT. It is an allergin. It causes an adverse health effect. What I am saying is that if we remove materials just because they have the potential of causing adverse health effects in certain small groups of people, we will not have anything. I had a patient call me 2 weeks ago who was distressed because she wanted to have her amalgams replaced and she wanted to know even a temporary material that she could put in until she could make a decision. I told her some of the options, and she's, well, no, that has zinc in it, that has this in it. She was concerned about everything. And this is what I am concerned about as a dentist is that people become so frightened because of alarmist predictions that they cannot make a decision about——

Mr. BURTON. I have allowed you a lot of latitude because you do represent the ADA.

Dr. MACKERT. Thank you.

Mr. BURTON. So I am going to allow our people who have a contrary point to view to respond. Go ahead.

Mr. RICHARDSON. I would agree that risk assessments of dental materials are sorely needed. When I completed my work on dental amalgam, the question was raised, well, we know more about amalgam now than anything else, if we ban it do we jump out of the frying pan into the fire? And I looked around and there was not a single thing written in the published record on the risks of any other materials.

I approached the CDA. They refused to fund any work on risk assessment. I approached Health Canada and they refused to fund any work on risk assessment. The IAOMT funded my work to assess the risks posed by composite resin materials following the exact same procedures used that I applied to dental amalgam. The exposures to the components of composite resins that occur from having 25 fillings of composite resin material are hundreds to thousands of times below the U.S. EPA safe or reference doses for those materials.

I submitted that work to a dental journal for publication because it seemed to me that it would be in the interest of the dental community to know it, and, yes, it was rejected out of hand because the name Mark Richardson was attached to it. It was gobbled up by a peer reviewed journal that is dedicated to human and ecological risk assessment, a journal that is published here in the United States.

It is unfortunate that there are still no risk assessments going on on any other materials. There has not been one published on gallium, which was investigated as a possible replacement for amalgam, there has never been a risk assessment done on gold, and, in fact, gold is one of the most safe metals that you can be exposed to. Where this information comes from, I would love to see the literature, the risk assessments that appear to have been done

on these materials because they are not published anywhere. That is all I have to say.

Mr. BURTON. Just 1 second. Why has there not been risk assessments done on all these materials?

Dr. FEIGAL. There are actually assessments done on the materials, the Bead National Toxicology Standards. These are set by the International Standards Organization on Toxicology. Much of the material in manufacturing is proprietary information. It is——

Mr. BURTON. You guys are supposed to make sure that the things they put into our bodies are safe. And you are now telling me that it is proprietary, so you do not know?

Dr. FEIGAL. We review it. The fact that certain material is not released is, again, a creation of Congress.

Mr. BURTON. Well if you are comparing it, if you are finding out if there is a toxic substance in there, shouldn't that be made known to the public? Proprietary interests should not take precedence over what the public should know.

Dr. FEIGAL. We release the information which legally is not a trade secret. That is all defined by law and by statute. We release that information. It is our responsibility to review the information, and if there is not adequate information, to not release the product.

Now one of the concerns that is raised is not so much on the short acute exposure but on the long-term exposure. There is no way to actually cut short the fact that if you have got a material that has been used for 5 years, you do not know the 10-year or the thirty year effect. And that is something that we have to live with all the time with new materials. There is no way to test something for 30 years before you use a new material.

So we look at the acute effects, we look at exaggerated dosing. Most of the material done on alloys, on materials have intellectual property protections, have trade protections provided by Congress that does not protect them from showing it to us but does create the kinds of frustrations that exist in the community of saying we do not know much about these.

Mr. BURTON. There needs to be a modicum of trust between the Federal Government and the people. And if there are questions about whether or not something might or might not be harmful to an individual, proprietary rights, there has got to be some way around that. He said that these things have not been categorized or checked and you are saying, well, we look at them.

Dr. FEIGAL. We do, and we actually——

Mr. BURTON. I know, you say we look at them, but because of proprietary interest we cannot let the public know about them. You know, the problem is the trust factor. People want to know that they can trust their government. And when some things that happen in the health agencies that shows that there is a problem, they want to know, especially things they are putting into their body.

Dr. FEIGAL. That is right. I would agree with that. And I would say that the responsibility you have given us is to keep those things from being used. And one of the things that is written in the statute that could be changed, it is in the current statute, is that when we turn a company down for a request to use a certain material, that information cannot be released. It cannot be released even that they have requested it or the basis for our turning it

down. So there are certain things that are built into the current framework that I think could be addressed and say is this the way we want to do business at this point.

Mr. BURTON. If you have recommendations on things that should be changed so that the public can be better informed, let me know and I will help carry the mail for you.

Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman. I want to be clear on something you have said. You have tested these amalgams. You have made up a list of those that are bad and those that are good apparently. Is that correct?

Dr. FEIGAL. We actually do no testing ourselves at FDA, or a relatively small amount because we have a very small laboratory.

Mr. GILMAN. Who does the testing?

Dr. FEIGAL. All the testing is done by manufacturers and they do it in accordance with international standards that are set by international standards bodies. So in this case, the standards for alloys are set by the American National Standards Institute and by the International Standards Organization, ISO.

Mr. GILMAN. So there is no testing by any public agency?

Dr. FEIGAL. No, there is not, nor is there of drugs, nor is there of foods that come to market. That is not the standard. There are 500,000 different devices on the market in the United States. We approve 40 to 50 devices a day in this country.

Mr. GILMAN. What do you base your approval on?

Dr. FEIGAL. We base it on having a risk-based approach, so that the highest risk products must show safety and effectiveness with clinical trials, the medium risk——

Mr. GILMAN. But how do you know the safety and effectiveness if you are not doing the testing? Are you relying on the manufacturer?

Dr. FEIGAL. For drugs, for devices, and for biologics, we rely on the manufacturer's testing. We inspect. We have severe punishment and penalties for companies that falsify information and do not release everything to us.

Mr. GILMAN. How do you know whether it is an accurate assessment if you are not testing it?

Dr. FEIGAL. We do not retest. We do not have the tens or hundreds of billions of dollars that are spent every year by the device community testing their devices. We set the standards by which they test the medium and high risk devices, they present that data to us and we inspect the data and we inspect their facilities.

Mr. GILMAN. That is like leaving the fox in the chicken coop to do the policing.

Dr. FEIGAL. It would be if we allowed them to self-certify. But because we review their raw data, which no other country in the world does, we are the only country that goes in and inspects the raw data, it——

Mr. GILMAN. Let me ask you, Doctor. Don't you think it would be more important for the association, your agency to do the testing rather than to allow that testing to be done by the manufacturer?

Dr. FEIGAL. We would then need to have a testing facility of the same magnitude of the testing facilities of the manufacturers in aggregate. They currently spend billions of dollars doing this.

Mr. GILMAN. I am asking, do you think it would be more important for the agency to do the testing rather than the manufacturers?

Dr. FEIGAL. Quite frankly, I do not think the Government could do it as quickly as the private sector.

Mr. GILMAN. I am not talking about the expedited testing. I am talking about the importance of the agency to do the testing.

Dr. FEIGAL. In terms of doing all testing, no. We have to be able to inspect what the manufacturers are doing as they manufacture. It is not just even the issue of meeting the standards at the time of approval, it is also the standards when they are manufacturing. So if the logic was that we would have to do all of the testing, we would also have to do all of the testing of their ongoing manufacturing.

Mr. GILMAN. Would that not be more beneficial to the public?

Dr. FEIGAL. Only if we had the resources that industry has. And I testified——

Mr. GILMAN. If you had the resources, would that be more beneficial to the public for your agency to do the testing?

Dr. FEIGAL. I would seriously doubt if a single agency based in one location, funded on an annual basis in the way that Government manages to run itself could actually compete with the private sector in terms of producing quality products.

Mr. BURTON. There are advisory panels over at the FDA and the health agencies who are supposed to do what we call double blind studies and check all that stuff out before you put it into the marketplace.

Dr. FEIGAL. The advisory panels review the evidence as well. But the thing which is unique about both our relationship and the advisory panels in the world is our ability to request all the data and the raw data, and that is what gives us the ability to make sure that the studies are done properly.

Mr. BURTON. Ms. Watson.

Ms. WATSON. Thank you, Mr. Chairman. I must apologize for not being here throughout the hearing. If I become redundant, would you please let me know.

I am sorry that Dr. Mackert left the room. I wanted to be sure I heard him correctly. And so I am going to try to restate what he said and maybe you two gentlemen can confirm. I think I heard him say that there is no risk to mercury in the dental amalgam. Is that what he said?

Mr. TABAK. I cannot speak for him. I do not know.

Ms. WATSON. Did you hear him?

Mr. TABAK. I think that is what he said, yes, Ms. Watson.

Ms. WATSON. OK. Would you two gentlemen confirm that?

Mr. TABAK. There is no scientific evidence to indicate that there is a risk.

Ms. WATSON. Is that your response to his statement?

Mr. TABAK. Yes, it is. That is correct.

Ms. WATSON. OK. The word "amalgam" itself is part of the meaning of the word "amalgam with mercury," yes or no?

Mr. TABAK. Indeed it is.

Ms. WATSON. Is mercury toxic?

Mr. TABAK. Elemental mercury is toxic.

Ms. WATSON. Is mercury toxic?

Mr. TABAK. Elemental mercury is toxic.

Ms. WATSON. Would you answer my question. Is mercury toxic?

Mr. TABAK. I am trying to give you a correct answer.

Ms. WATSON. Is it yes, no.

Mr. TABAK. Yes.

Ms. WATSON. Thank you. Now is silver mercury? Does it contain mercury? Yes or no. Silver amalgam fillings, does it contain mercury?

Mr. TABAK. It does.

Ms. WATSON. Yes. Almost up to 50 percent?

Mr. TABAK. Yes.

Ms. WATSON. OK. Now you scientific people are doctors. I think, Dr. Feigal, you are an M.D.?

Dr. FEIGAL. Yes.

Ms. WATSON. To do no harm, what would you have against advising dentists to advise their patients that an amalgam with mercury is what we call silver, it is an amalgam, it is not pure silver, what would you have against it?

Dr. FEIGAL. No problem at all.

Ms. WATSON. All right. Would you advise that we then say to dentists you should inform your patients?

Dr. FEIGAL. Yes.

Ms. WATSON. OK. Now we all agree that mercury is a toxic substance. Would both of you agree?

Mr. TABAK. It depends on the level of exposure.

Ms. WATSON. Let me repeat. Regardless of the level, poison is poison.

Dr. FEIGAL. That is not true. Digitalis is an effective drug on one level and a poison on another.

Ms. WATSON. Hold on, sir. Mercury is a toxic substance. Agreed?

Dr. FEIGAL. Not in all uses, not in all settings.

Ms. WATSON. OK. I want what you just said given to me. So whoever is recording this, I want to be sure I can quote you correctly.

Now would you agree that once you have a silver filling, mercury amalgam filling, that it emits a vapor as long as it is within your mouth. Is that a true statement?

Dr. FEIGAL. Yes.

Mr. TABAK. Yes.

Ms. WATSON. All right. If we know that, why is it a medically trained person, a dentist would not want to share that with the patient. Doesn't the patient have a right to know. I, as a legislator, and my colleagues are here to protect the public and we speak for the public. Why is it that the ADA will not tell the public that mercury amalgam is harmful but they can choose to have it in their fillings. Now can you explain that to me?

Dr. FEIGAL. Well, you started by saying should patients be told that the product contains mercury, and should we admit that we know there is exposure from vapor release. I think those are appropriate things to discuss. And I think patients should be informed that the evidence on the health risk is something that is actively being studied as we speak, even in studies by the National Institutes of Health. Where it gets more difficult is asking a patient to understand what does it mean to have a small amount of mercury

release, just as it is hard for them to understand what their risk is from other low level exposures.

So I think we need to actually think about the message that we are trying to get. I think the patient should be informed. But it is similar to the question about the composites and about the effect of what is the long-term effect of having a substance like methylmethacrylate in your mouth and what is known about that. I think there does need to be a much more informed and empowered consumer and they need to be able to make the choice.

I suspect where there is a difference in where we may being agree to disagree——

Ms. WATSON. Would you yield for a minute?

Dr. FEIGAL. Sure.

Ms. WATSON. That is exactly what this bill is trying to do. We would like you, as representatives of the dental profession or researchers, or whatever, to educate. I asked in my bill of 10 years ago in the State of California for a protocol. We never got it because the panel was controlled by dentists. I was told by the dentists that they did not want to scare off their patients, and that it was cheaper to use a mercury amalgam or a dental amalgam, or silver, whatever they want to call it, than the alternative. So because it was cheaper, they did not want to inform their patients. I was appalled at that response coming from a medical professional. I am appalled with what I have heard here this afternoon. You do not want to answer my questions directly. Why do you think a patient would not listen to the doctor if a doctor had a protocol which explained what was in that silver. Why are we continuing to delude people by saying you have a silver filling in your mouth when we know we are not telling them the truth.

We had to research paint because we found that babies were chewing on the railings of their bassinets and it was very poisonous to their system. We did long-range studies, long-term studies and found out that those children were having difficulty in schools when they got to school. Asbestos, which was a certified building material, we found out it was a carcinogen, long-term studies. Why could we not do long-term studies on mercury at any trace amount, trace, I say, amount. And you just agreed that over a period of time it does seep out and has a vapor. Why would we want to delude people by not telling them. So that is what the bill does.

The other thing that I am appalled at is that you would not say we need to do the studies, we need to look at the risk, because we think that if mercury is going to be taken out of thermometers, if mercury is going to taken out of other products, that it is still all right to use it in someone's mouth. I do not understand your——

Dr. FEIGAL. The question to me was should FDA do the studies, and FDA does not do studies except for very small parts. We welcome the studies that are done, we encourage them, and we review the results.

Mr. BURTON. If the gentlelady would yield just a second. Dr. Feigal very graciously agreed earlier that he would—I think I am quoting you correctly—that you would——

Dr. FEIGAL. Urge.

Mr. BURTON. Urge. I urged you and you said you would accept the urging, or words to that effect. But he would urge some of the

outside scientific research facilities to take amalgams, maybe 100, 200, or 300, and have them checked to find out the amount of emissions of mercury vapor that is coming out over a period of time. I also urged that Dr. Haley be a part of that study because he has some expertise in the area.

Ms. WATSON. Great.

Mr. BURTON. So they have, in essence, agreed that they would work with us on that.

Ms. WATSON. Thank you. I do not want to be redundant. Let me just ask one more question. I understand that the manufacturers of products do the research, and I understand that you said you do not have the capacity comparably to do the research. Can someone respond to why the FDA has not required the manufacturers to show the health effects of what you have agreed to is the mercury vapors. Can someone respond?

Dr. FEIGAL. These were products that were on the market in 1976 when the Device Amendments were passed. And for FDA to take an action about safety, actually the burden falls to the Government, not to the manufacturer, to present the evidence that a product needs to be up-classified or an adverse action taken against it. And so this is an area where, because this is a product that was on the market, the burden of proof is on us.

Now the way we approach that is not do the studies ourselves but to review the scientific literature, most of which in this area, quite frankly, is not done by the manufacturers. One of the things to remember about the device industry is that of the 12,000 firms, half of them have five or fewer employees; 92 percent of them qualify or meet the Commerce Department's definition of a small business. And as Congress looked at how do you regulate an industry that makes so many products and makes 500,000 different products, they gave us the responsibility of doing it in a risk-based fashion, starting with the assumption that most of the things on the market were on the market because they were proven products. And there are products which have been up-classified and which we have called for the highest levels of evidence for. But as we have gone through the process of reviewing the literature, it has been very difficult for us to say we think mercury is causing Alzheimer's disease, or we think the evidence shows that mercury is causing the other kinds of things.

Ms. WATSON. Would you yield, please?

Dr. FEIGAL. Sure.

Ms. WATSON. I am not trying to tell you what the outcomes would be of your studies. But I am just wondering why you have not done them in the past. And I surely would have thought you would consult with Dr. Richardson. I just heard him here for a minute and he has done some of this risk assessment and he says that his results were not even considered. And so it seems as if there has been research and studies done, but apparently not at the scholarly or empirical level that FDA would want to be concerned with. I have difficulty understanding why the FDA has never classified mercury fillings.

That is the reason why this bill is here, do you understand that, because we had dentists dragging their feet, and they finally told me why. So we just got rid of the panel and we put people on there

that are really concerned about the public's health. And by your own admission, vapors are emitted as long as there is mercury in the amalgam. I think that would be enough to tip you off that you ought to classify, you ought to do the research, you ought to do it yourselves.

Therefore, we are going to help you out. We have a bill here, and I am thinking about amending it, Mr. Chair, to put in a required study and maybe some dollars to back it up. So as this bill moves, we are going to look at an amendment. So we are going to do your work for you. We are going to direct you. Because our first and foremost interest is protecting the health of the public. And if one person is injured by something they thought was silver and the dentist did not say it was mercury but silver, then you are deluding the public and we are not going to stand for that. So this bill is here because we are interested in the health of every single American.

I want to thank you, Mr. Chairman, for holding these hearings. I will turn it back to you.

Mr. BURTON. Thank you, Ms. Watson.

Mr. Gilman, do you have any more questions?

Mr. GILMAN. No questions.

Mr. BURTON. I know you have been here for a long time. I want to thank you very much for your patience, all of you in the first panel and the second panel. I am going to see you again to make sure I get the rest of the amalgams out of my mouth.

I want to thank John Rowe and Beth Clay for their hard work on the hearing.

With that, we stand adjourned.

[Whereupon, at 2:43 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

I

107TH CONGRESS
2D SESSION

H. R. 4163

To prohibit after 2006 the introduction into interstate commerce of mercury intended for use in a dental filling, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2002

Ms. WATSON of California (for herself and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To prohibit after 2006 the introduction into interstate commerce of mercury intended for use in a dental filling, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Mercury in Dental Filling Disclosure and Prohibition Act".

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Mercury is a highly toxic element.

(2) A dental amalgam, commonly referred to as a "silver filling", consists of 43 to 54 percent mercury.

(3) Consumers may be deceived by the use of the term "silver" to describe a dental amalgam, which contains substantially more mercury than silver.

(4) Dental amalgam may contain about ½ to ¾ of a gram of mercury, depending on the size of the filling.

(5) The mercury in a dental amalgam continually emits mercury vapors.

(6) Mercury toxicity is a retention toxicity that builds up over years of exposure.

(7) According to certain scientific studies, Health Canada, and the Agency for Toxic Substances and Disease Registry of the Public Health Service of the Department of Health and Human Services, children and pregnant women are at particular risk for exposure to mercury contained in dental amalgam.

(8) According to the Agency for Toxic Substances and Disease Registry, the mercury from amalgam goes through the placenta of pregnant women and through the breast milk of lactating

1 women, giving rise to health risks to an unborn child
2 or a baby.
3 (9) The Environmental Protection Agency con-
4 siders removed amalgam filling and extracted teeth
5 containing amalgam material to be hazardous waste.
6 (10) The use of mercury in any product being
7 put into the body is opposed by many health groups,
8 such as the American Public Health Association, the
9 California Medical Association, and Health Care
10 Without Harm.
11 (11) Consumers and parents have a right to
12 know, in advance, the risks of placing a product con-
13 taining a substantial amount of mercury in their
14 mouths or the mouths of their children.
15 (12) Alternatives to mercury-based dental fill-
16 ings exist, but many publicly and privately financed
17 health plans do not allow consumers to choose alter-
18 natives to mercury amalgam.

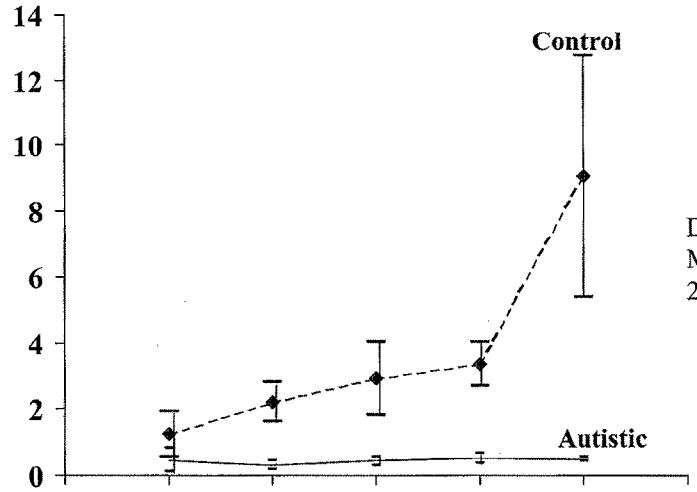
19 **SEC. 3. PROHIBITION ON INTRODUCTION OF DENTAL**
20 **AMALGAM INTO INTERSTATE COMMERCE.**

21 (a) PROHIBITION.—Section 501 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 351) is amended by
23 adding at the end the following:
24 "(j) Effective January 1, 2007, if it contains mercury
25 intended for use in a dental filling.".

1 (b) TRANSITIONAL PROVISION.—For purposes of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
3 et seq.), effective July 1, 2002, and subject to subsection
4 (a), a device that contains mercury intended for use in
5 a dental filling shall be considered to be misbranded, un-
6 less it bears a label that provides as follows: "Dental amal-
7 gam contains approximately 50 percent mercury, a highly
8 toxic element. Such product should not be administered
9 to children less than 18 years of age, pregnant women,
10 or lactating women. Such product should not be adminis-
11 tered to any consumer without a warning that the product
12 contains mercury, which is a highly toxic element, and
13 therefore poses health risks.".

○

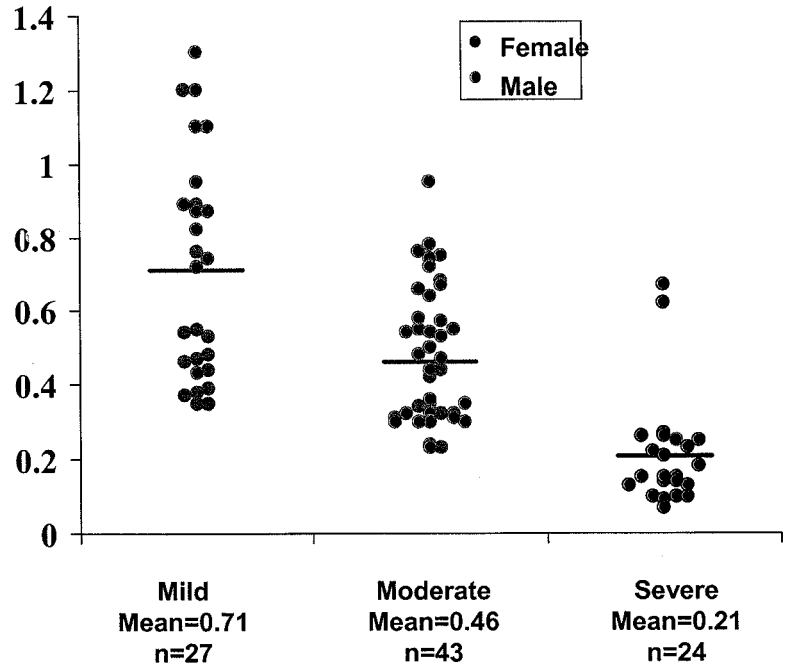
MERCURY BIRTH HAIR LEVELS VS. AMALGAM FILLINGS IN AUTISTIC AND CONTROL GROUPS



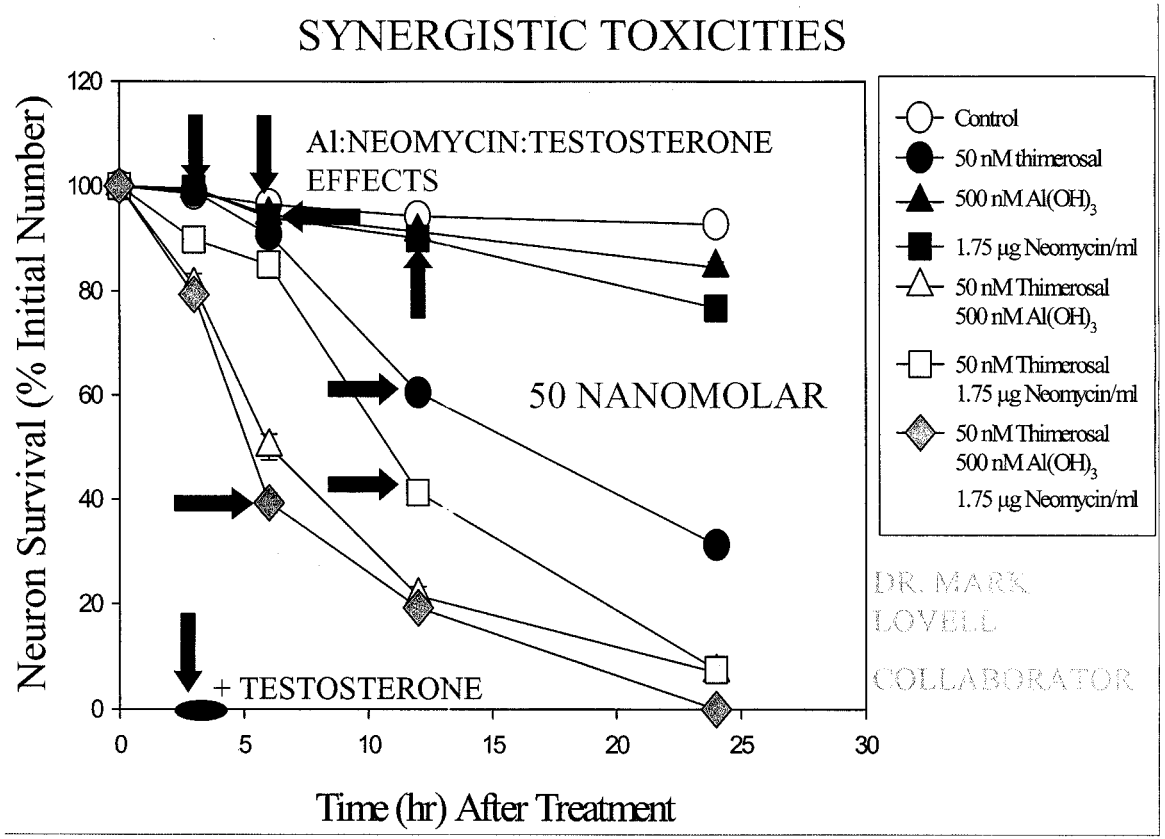
Number of amalgams:	0-3	4-5	6-7	8-9	≥10
Control: autistic ratio:	2.64	6.93	6.70	6.32	17.91
N:	15	22	29	30	43

Data from A. Holmes, M. Blaxill & B. Haley, 2002

BIRTH-HAIR MERCURY BY SEVERITY OF AUTISM



Data from Amy Holmes, Mark Blaxill & Boyd Haley


SYNERGISTIC TOXICITIES
Neuron Survival (% Initial Number)
Time (hr) After Treatment
Al:NEOMYCIN:TESTOSTERONE EFFECTS
50 NANOMOLAR
+ TESTOSTERONE
Control
50 nM thimerosal
500 nM Al(OH)3
1.75 µg Neomycin/ml
50 nM Thimerosal 500 nM Al(OH)3
50 nM Thimerosal 1.75 µg Neomycin/ml
50 nM Thimerosal 500 nM Al(OH)3 1.75 µg Neomycin/ml
DR. MARK LOVELL
COLLABORATOR

ELEVATED MERCURY IN IDIOPATHIC DILATED CARDIOMYOPATHY (IDCM).

WHERE DOES IT COME FROM?

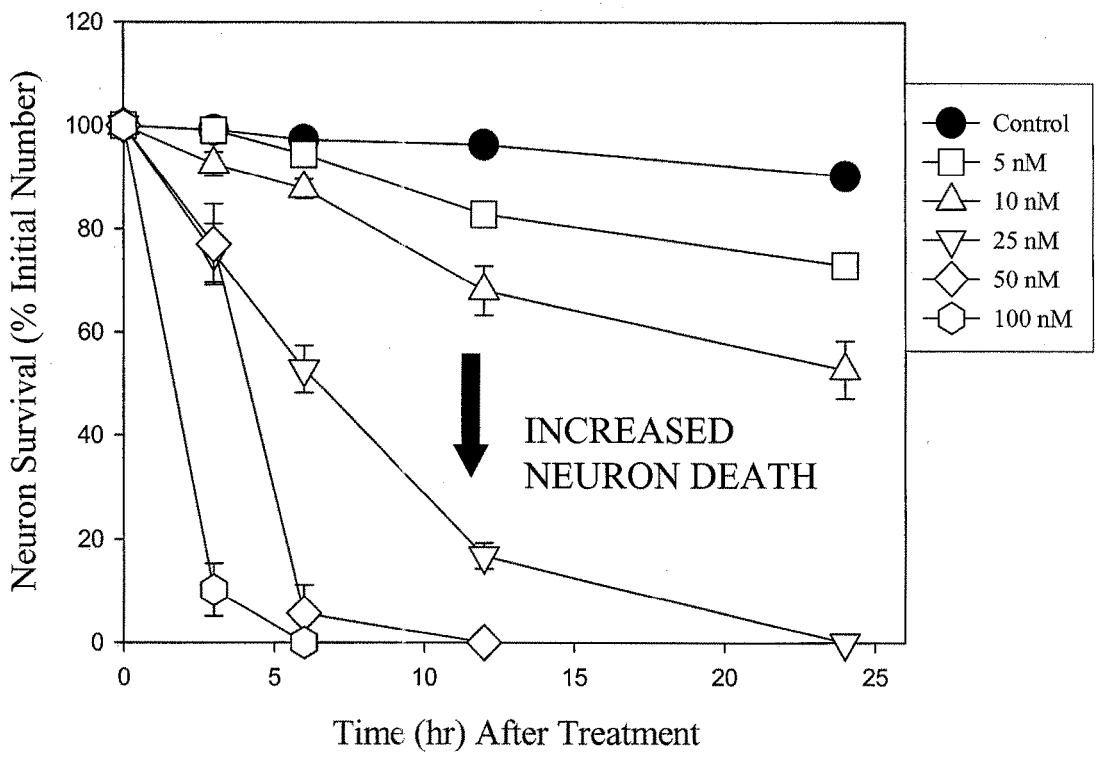
LEVELS ng/g	Hg	Sb
Controls	8.0	1.5
IDCM	178,400	19.260

Frustaci et al., J. of American College of Cardiology, 33, (6) 1578, 1999.

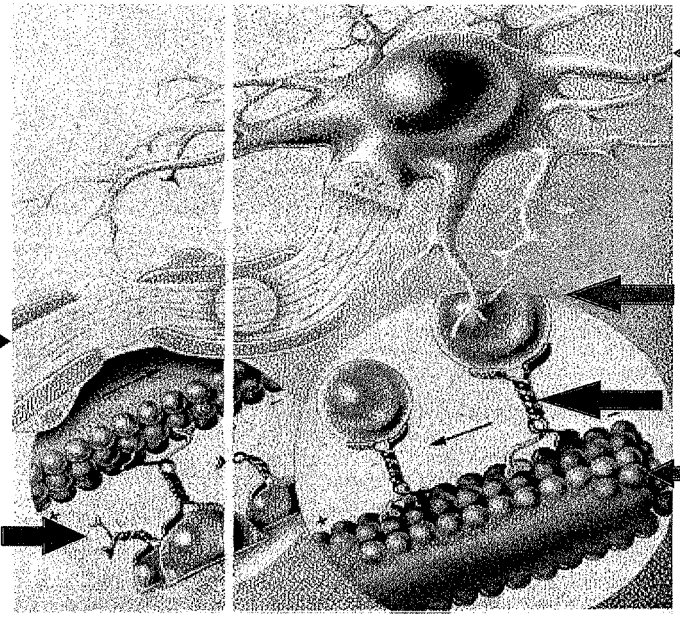
Controls were patients with valvular or ischemic heart disease.

Question is 'where does this mercury come from?' Athletic youth die of IDCM.

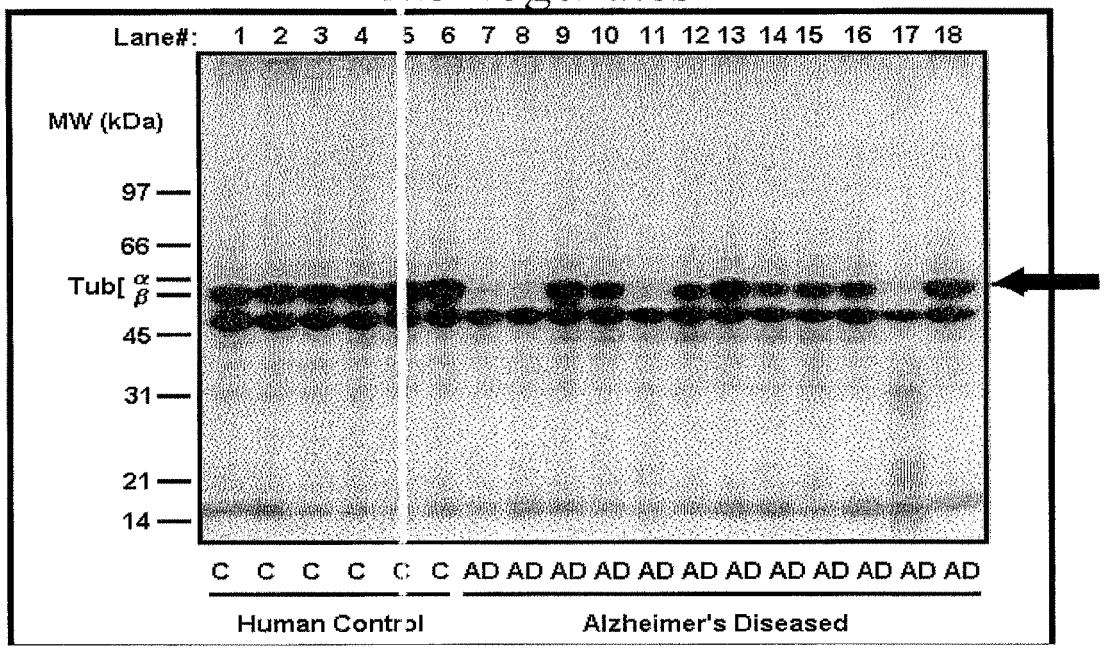
Response of Primary Hippocampal Neurons to Mercury Chloride



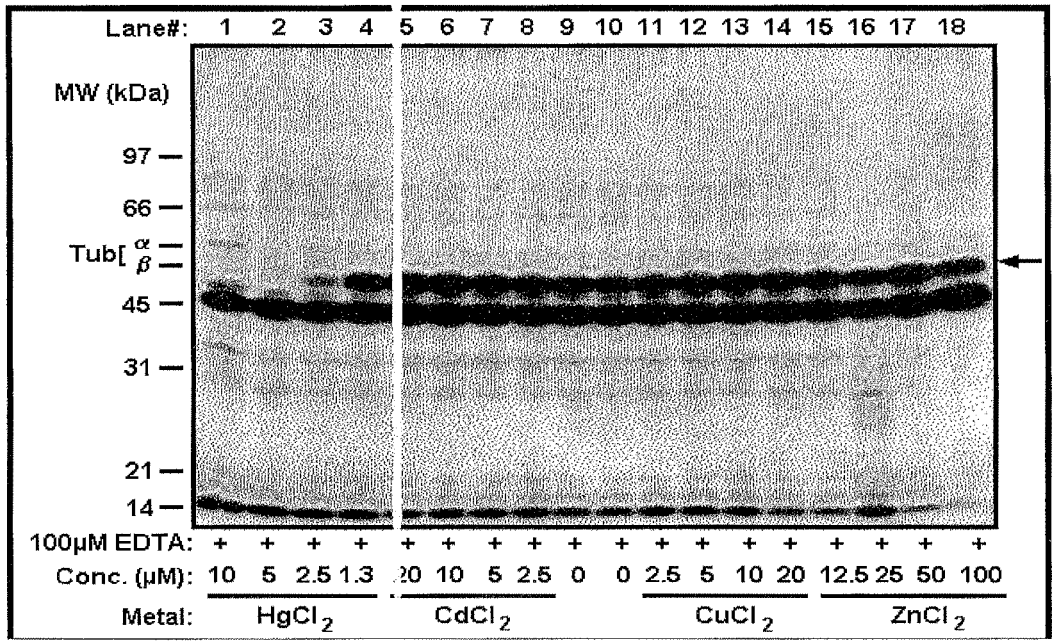
Axonal Transport - A Process Essential for the Survival of Neurons



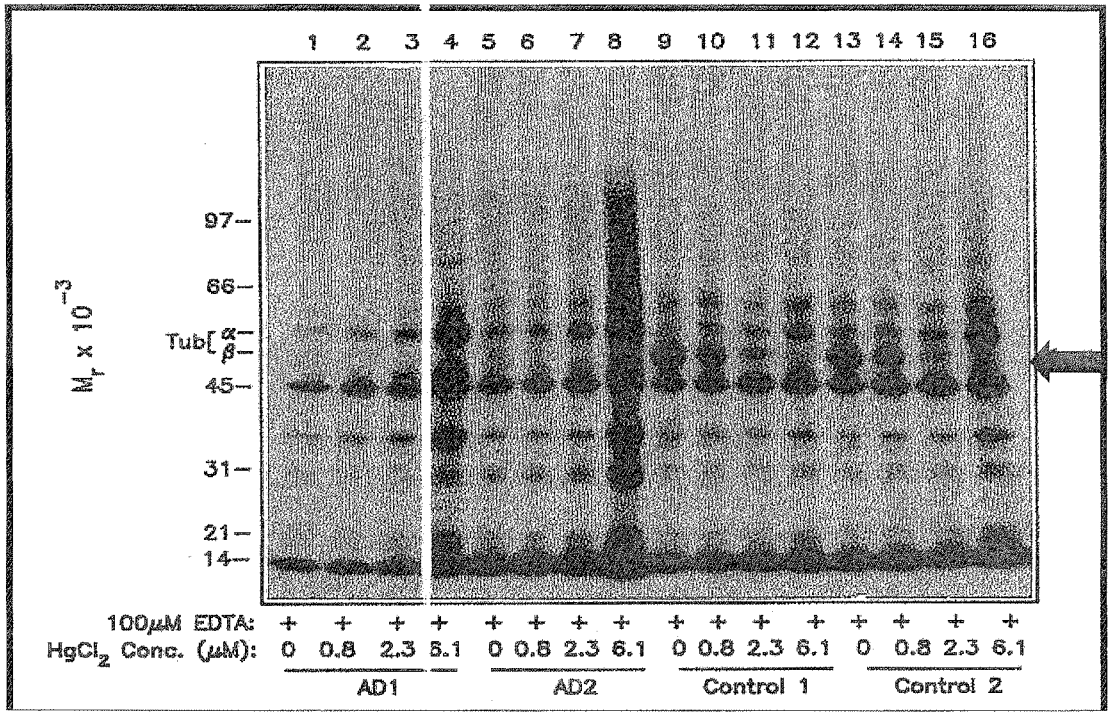
Autoradiogram of [^{32}P]8N$_3$GTP Photolabeled Control & AD Brain Hippocampus Homogenates



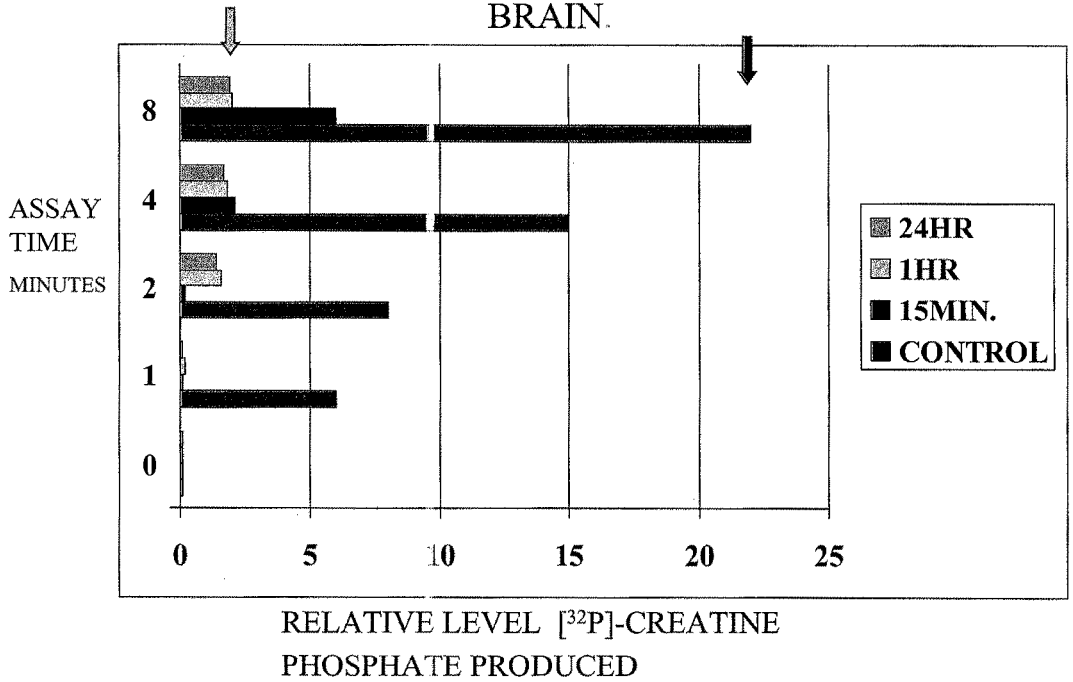
EDTA Prevents Cd, Cu & Zn But Not Hg Inhibition of [^{32}P]8N$_3$GTP Photolabeling of Brain ß-Tubulin



HgEDTA Induces Aberrant [^{32}P]8N$_3$GTP-



INHIBITION OF CREATINE KINASE (CK) BY DEIONIZED WATER EXPOSED TO AGED AMALGAM . CK IS 97% INHIBITED IN ALZHEIMER'S DISEASED BRAIN.



MERCURY AND ALZHEIMER'S DISEASE

- Exposure of neuroblastoma cells to 10^{-9} molar mercury increases Tau phosphorylation and secretion of beta-amyloid. Both of these events occur in Alzheimer's diseased brain. Amyloid plaque formation is the "diagnostic hallmark" of Alzheimer's disease. Olivieri et al. J. Neurochemistry, 74, 231, 2000.
- Exposure of cultured neurons to 10^{-7} to 10^{-10} molar mercury rapidly causes the stripping of tubulin from the neurofibrils forming the neurite processes leading to the formation of neurofibillary tangles, a "diagnostic hallmark" of Alzheimer's disease. Leong et al. NeuroReports 12(4), 733, 2001. SEE http://movies.commons.ucalgary.ca/mercury
- The Hg concentrations used in these experiments are roughly 100-fold less than is found in aged adult brains.

The New York Times
nytimes.com

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November 14, 2002

Mercury Dental Fillings Said Safe

FOR YOUR INFORMATION

By THE ASSOCIATED PRESS

Filed at 5:39 p.m. ET

WASHINGTON (AP) -- The government still considers mercury-containing dental fillings safe and is awaiting results from two major studies of children's cavities that may settle lingering public doubts.

Amalgam fillings, sometimes called silver fillings, are made of a mixture of mercury and other metals, and have been used by dentists for over 100 years.

Critics argue that mercury may leach from those fillings and cause brain disorders such as autism. Some families of autistic children have sued dentists, and legislation introduced in Congress last spring seeks to ban the fillings by 2007.

Repeated reviews from federal health officials have found no proof the fillings are dangerous, officials from the Food and Drug Administration and National Institutes of Health told a congressional committee Thursday.

More evidence may come in 2006, when two major studies comparing the health of more than 1,000 children given either amalgam fillings or a mercury-free kind are to end, said NIH dental chief Lawrence Tabak.

The studies, funded by NIH in 1996, are measuring levels of mercury in the children's bodies, and giving them IQ tests and other brain assessments.

Special oversight boards review the children's medical records every year, and ``to date there have been no harmful untoward effects attributable to amalgam noted in either trial," Tabak told the House Government Reform Committee.

Mercury is a toxic metal that can be absorbed from different sources, such by eating fish from polluted waters. Indeed, the FDA warns pregnant women and young children to avoid certain fish species that contain high mercury levels.

Why, wondered the committee chairman, Rep. Dan Burton, R-Ind., is the FDA is worried about one type of mercury and not another.

``Mercury is mercury," said Burton, a comment echoed by other mercury critics at the hearing. ``Shouldn't we exercise abundance of caution and hasten the use of those (mercury-free) alternatives?"

The American Dental Association argued that the mercury in fillings is a different form of the metal that is safe to use, and that amalgam fillings are both cheaper than other types and the best option for

certain cavities.

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The Wall Street Journal
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Friday, November 15, 2002

U.S. May Assume Liability for Smallpox Vaccine

By Sarah Lueck

WASHINGTON -- Moving to protect physicians and medical facilities that would carry out a federal smallpox-vaccination campaign, the Senate is poised to consider making the government responsible for any harmful side effects.

The legislation, part of a bill that would create a Homeland Security Department in the federal government, essentially shifts liability that might be faced by physicians, hospitals and other facilities to the federal government. Many health-care providers had said they wouldn't be willing to administer the vaccine without such protections, which the House of Representatives approved Wednesday.

The smallpox vaccine is riskier than most other vaccines, causing one to two deaths per million people who receive it and many more serious reactions. The Bush administration is considering whether to offer the vaccine to health-care workers and eventually the public, due to concerns about a possible attack using smallpox. The government has shielded smallpox-vaccine makers from liability, through its contracts to buy the vaccine.

"The threat of lawsuits mustn't be a barrier to protecting the American people," said Sen. Bill Frist, a Tennessee Republican.

The provision would extend the Federal Tort Claims Act protections to any person or facility that provides the vaccine. People who have been harmed by the vaccine would be eligible for compensation for injuries, but generally not for punitive damages. Sen. Frist's office didn't have an estimate of how much the government might have to pay in damages.

Democrats, meanwhile, are angered over a separate, last-minute provision passed by the House to protect pharmaceutical companies from vaccine-related liability. Under the measure, companies wouldn't be liable for injuries caused by a component of the vaccines, such as thimerosal, a mercury-based vaccine preservative that is the basis for dozens of suits that claim it has caused autism in children. Instead, such claims would have to go through the federal compensation program set up for childhood vaccines.

Sen. Frist proposed the measure as part of earlier legislation, contending that the law creating the compensation program was intended to cover vaccine components as well as the vaccines.

Opponents contend the provision, which is expected to nullify continuing lawsuits, was slipped in with no debate. Jim Manley, a spokesman for Sen. Ted Kennedy, a Massachusetts Democrat, called it "a special-interest provision put in at the behest of Eli Lilly," which used to manufacture thimerosal and is one of the companies facing lawsuits.

A spokesman for Eli Lilly & Co., Indianapolis, said the company had sought the provision, although not for its inclusion in the homeland-security bill.

The Associated Press State & Local Wire

The materials in the AP file were compiled by The Associated Press. These materials may not be republished without the express written consent of The Associated Press.

November 15, 2002, Friday, BC cycle

6:28 AM Eastern Time

SECTION: State and Regional

LENGTH: 365 words

HEADLINE: Mercury-containing dental fillings still considered safe by the government

DATELINE: WASHINGTON

BODY:
The government still considers mercury-containing dental fillings safe and is awaiting results from two major studies of children's cavities that may settle lingering public doubts.

Amalgam fillings, sometimes called silver fillings, are made of a mixture of mercury and other metals, and have been used by dentists for over 100 years.

Critics argue that mercury may leach from those fillings and cause brain disorders such as autism. Some families of autistic children have sued dentists, and legislation introduced in Congress last spring seeks to ban the fillings by 2007. Repeated reviews from federal health officials have found no proof the fillings are dangerous, officials from the Food and Drug Administration and National Institutes of Health told a congressional committee Thursday.

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The studies, funded by NIH in 1996, are measuring levels of mercury in the children's bodies, and giving them IQ tests and other brain assessments.

Special oversight boards review the children's medical records every year, and "to date there have been no harmful untoward effects attributable to amalgam noted in either trial," Tabak told the House **Government Reform Committee.**

Mercury is a toxic metal that can be absorbed from different sources, such by eating fish from polluted waters. Indeed, the FDA warns pregnant women and young children to avoid certain fish species that contain high mercury levels.

Why, wondered the committee chairman, Rep. Dan Burton, R-Ind., is the FDA is worried about one type of mercury and not another.

"Mercury is mercury," said Burton, a comment echoed by other mercury critics at the hearing. "Shouldn't we exercise abundance of caution and hasten the use of those (mercury-free) alternatives?"

The American Dental Association argued that the mercury in fillings is a different form of the metal that is safe to use, and that amalgam fillings are both cheaper than other types and the best option for certain cavities.

The New York Times
nytimes.com

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November 15, 2002

National Briefing: Plains

OKLAHOMA: PANEL HALTS BOMBING INQUIRY
A Congressional committee has halted an inquiry into accusations of a wider conspiracy in the 1995 Oklahoma City bombing, and its chairman, Representative Dan Burton, Republican of Indiana, asked the Justice Department to investigate whether a policeman had provided false information. The officer, J. W. Reser, who works at Tulsa International Airport, told the staff of the House Government Reform Committee that he had seen a videotape of a Middle Eastern man leaving the truck used in the bombing.
(AP)

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☐ The Associated Press State & Local Wire

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November 15, 2002, Friday, BC cycle

2:59 AM Eastern Time

SECTION: State and Regional

LENGTH: 246 words

HEADLINE: Airport authority fires officer accused of fabricated testimony

DATELINE: OKLAHOMA CITY

BODY:
The Tulsa Airport Authority has fired a police officer who was accused of lying to Congress about the Oklahoma City bombing.

J.W. Reser was terminated for "acts on or off the job which would bring embarrassment, distrust or discredit to the city of Tulsa," Kathy McNair, attorney for the airport authority, said Thursday. The former Oklahoma City police officer had worked at Tulsa International Airport since March. He could not be reached for comment.

Reser, 55, said in a sworn statement that he saw a video of a Middle Eastern man getting out of the passenger side of the bomb truck seconds before the April 19, 1995, explosion.

The bombing killed 168 and injured more than 500.

Reser said he saw the surveillance video in Washington while working as a consultant for the Navy.

He is accused of fabricating those claims and of lying about his background to the House **Government Reform Committee.**

U.S. Rep. Dan Burton, the committee chairman, asked Attorney General John Ashcroft last week to investigate "these false statements" and to prosecute Reser if it is warranted.

The committee is investigating the possibility of foreign involvement in the Oklahoma City bombing.

But Burton, R-Ind., said the committee will be hampered in its efforts "if people are allowed to fabricate allegations of government misconduct, fabricate their own credentials and work history to give their allegations credence, and then walk away without consequences."

LOAD-DATE: November 15, 2002

◀ prev **Document 3 of 5** next ▶

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Ex-officer misled panel, Burton tells Justice Dept.

Washington — A House committee has asked the Justice Department to investigate a former police officer it alleges misled congressional investigators by claiming he saw a videotape of a Middle Eastern man leaving the truck used to bomb the Oklahoma City federal building in 1995.

J.W. Reser, the ex-policeman, told investigators he viewed the surveillance tape while working as a contract employee for the government, including Army and Navy intelligence, but officials from both services said they knew nothing about Reser or the tape, the committee said.

The House Government Reform Committee, chaired by Rep. Dan Burton, R-Ind., provided The Associated Press with the lawmaker's criminal referral to the Justice Department and other documents, including a sworn statement that Reser provided to the committee.

Reser is a one-time Oklahoma City police officer who left the force more than a decade before the April 19, 1995, bombing.

Burton, in a letter to Attorney General John Ashcroft, said that in addition to Reser's statements about viewing the surveillance tape, he made false statements about his personal background.

"I write to bring these false statements to the attention of the Department of Justice for investigation and, if warranted, prosecution," Burton wrote. Committee officials said Reser and others had contacted the panel this year seeking a fresh look at any possible conspiracy.

INDY STAR NOV 14, '02 A7

Mutton, Nick

From: Foster, Jason
Sent: Friday, November 15, 2002 11:20 AM
To: Rethmeier, Blain; Mutton, Nick
Subject: Airport authority fires officer accused of fabricated testimony

November 15, 2002, Friday, BC cycle

2:59 AM Eastern Time

SECTION: State and Regional

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THE WALL STREET JOURNAL.

MARKETPLACE

THURSDAY, MAY 10, 2001 B1

Media: *News Corp. net income fell 63% as print, film divisions faltered* **Page B9.**

Health: *Researchers report new Parkinson's treatment is promising* **Page B9.**

Dentists Battle 'Gag' on Warning About Mercury

By KATHRYN KRANHOLD
Staff Reporter of THE WALL STREET JOURNAL

Dentists are suing state regulators over what they contend is a gag order preventing them from discussing with patients the potential health hazards of the most common form of dental filling.

At issue are those silver-colored fillings that dot most people's teeth. Referred to by the dental profession as silver amalgam, the fillings are actually about half mercury, with some silver, copper, tin and zinc mixed in.

Mercury opponents argue that mercury vapor coming from the fillings seeps into the body, contributing to a range of health problems from fatigue and immunity suppression to neurological diseases such as Parkinson's and Alzheimer's. The dental establishment, including the American Dental Association, argues that the low level of vapor causes no harm and that raising such safety issues with patients would unduly alarm them. The science on the issue is inconclusive.

The suit was filed yesterday in federal court in Greenbelt, Md., by five dentists and seven patients claiming injury from the mercury in their fillings. The plaintiffs argue that dental regulators use "control of dental licenses to punish, or to threaten punishment of, dentists who criticize mercury amalgam," violating the dentists' First Amendment rights. In 1999, for example, the suit claims that the Maryland Board of Dental Examiners ordered dentist Bill DeLong to stop testing his patients to determine whether mercury vapor was coming off their fillings. (The case was eventually dropped.)

The dentists' attorney, Charles Brown of Washington, D.C., says the plaintiffs want the court to order licensing boards to stop enforcing any policy that "prevents, limits or intimidates dentists" from discussing the controversy or advocating "mercury-free" dentistry. The suit also seeks certification as a defendants' class action naming 50 of the country's 52 licensing agencies.

In a statement released yesterday, Maryland's licensing-board administrator, Art Williams, said the board "acted lawfully and has done so in order to protect consumers."

The dental establishment maintains that some dentists have used the controversy over mercury's safety to encourage patients to remove amalgam fillings and replace them with more expensive materials such as gold, porcelain and a tooth-colored resin composite. Resin, the least expensive alternative, costs as much as 25% more than fillings containing mercury.

J. Rodway Mackert Jr., a professor at the Medical College of Georgia who is an ADA spokesman, says that discussing mercury when patients are in the dentist's chair would be a disservice to them. "If you have one side claiming it isn't safe,

Please Turn to Page B4, Column 3

Dentists Battle 'Gag' on Mercury Warning

Continued From Page B1

that doesn't mean that side is right," he says.

Nevertheless, state legislatures in New York and Maine are debating bills that would require dentists to disclose to patients the makeup of their fillings. New York Assemblyman Richard Brodsky's bill would also ban dentists from filling cavities in pregnant women and children with mercury. A Vermont bill would require dental offices to track how much mercury they use in fillings. And California's dental board is considering spelling out the pros and cons of different fillings in a consumer fact sheet.

Minnesota's dental board may also become more amenable to alternatives to mercury. In 1999, Minneapolis dentist Ronald King, who advertises "dental care that integrates conventional and alternative philosophy," was appointed to the board by Gov. Jesse Ventura. He is now on a committee that hears complaints about dentists, including mercury-free dentists. Dr. King says other board members now see him "as a colleague instead of a weird guy with his own agenda."

The Amalgam Wars began in the mid-1800s, when dentists first started using mercury-based material to treat tooth decay. Originally, it was the dentists who used mercury who came under fire from colleagues who didn't believe it was as safe as gold or tooth extractions. But soon, mercury became the material of choice, mostly because it was cheaper and easier to use—and it was less painful than having hot gold poured into a tooth. In 1976, when the U.S. Food and Drug Administration began regulating medical devices, it grandfathered in mercury-based fillings as an approved dental material.

The ADA, which once had a patent on mercury fillings, maintains that mercury is safe once it is mixed with other metals and set in teeth, but it warns dentists about the "potential hazard of mercury vapor" when they handle the material.

In a 1999 report, the Agency of Toxic Substances and Disease Registry, a division of the U.S. Department of Health and Human Services, concluded there is no apparent health hazard but urged further study to "determine the possibility of more subtle behavioral or immune-system effects, and to determine the level of exposure that may lead to adverse effects in sensitive populations." Fillings could contribute as much as 75% of a person's daily mercury exposure, the report said, noting that the vapor is released during chewing and because of corrosion.

A 1999 report concluded there was no apparent health hazard, but it urged further study.

Judith Baker, a South Bend, Ind., accountant and a plaintiff in the Maryland suit, was so sick she had her gallbladder removed in 1999. But another doctor later diagnosed her with mercury poisoning stemming from a new filling containing mercury and the replacement of two old mercury fillings with a larger one. Ms. Baker says she was skeptical and had her well water tested for mercury and her house tested for fumes before asking a dentist to remove her fillings earlier this year. She says she is starting to feel better after going through mercury detoxification treatment.

Boyd Haley, a University of Kentucky chemist who has published several studies using rats and human brain samples, says his work shows that brain tissue exposed to mercury develops the same biochemical defects seen in Alzheimer's disease. But even Dr. Haley doesn't theorize that the fillings cause significant adverse health effects in everyone. "Certain patients, due to genetics or illness or other toxic exposures, could be more sensitive to the amount of mercury normally released from dental amalgams," he says.

The ADA responds by pointing to a study published in its journal that concluded that mercury in fillings "does not appear" to be a factor in the development of Alzheimer's disease. But one of the study's authors, chemist Charles Cornett, is wary of that conclusion. He says the study failed to evaluate how different people process mercury, among other factors.

Two large clinical trials sponsored by the National Institutes of Health are now under way with the goal of determining how school children with and without mercury fillings develop. Results of those studies won't be known until at least 2005.

Meanwhile, the Maryland board is proposing a new rule that states that removing "serviceable mercury amalgam restorations" is unprofessional without informed consent that includes telling the patient that "there are no verifiable systemic health benefits resulting from the removal."

Dr. DeLong strongly disagrees. After he removes their mercury-base fillings, he says, patients "report not only feeling better but having whatever problems they came in with disappear over time."

LOS ANGELES TIMES

A10 THURSDAY, JUNE 6, 2002 / NA

Dentists Called Biggest Mercury Polluters in U.S.

Health: Study says the metal, widely used in fillings, eventually ends up in waste water.

By ELIZABETH SHOGREN
TIMES STAFF WRITER

WASHINGTON — Coal-fired power plants are notorious for being the biggest source of mercury pollution in the air. But now, new attention is being directed at another, much less known source of mercury contamination in water—dentists.

A new report shows that dentists are the largest single source of mercury pollution in waste water funneled into the nation's treatment plants.

Mercury is a potent toxin that can damage the human brain, spinal cord, kidney and liver, and is especially dangerous for unborn children.

While many other sources of mercury pollution have drastically cut their use of the heavy metal, dentists continue to use it widely in fillings.

"Pretty much all the mercury they're using gets released into the environment. Why aren't they doing more to reduce that use?" said Michael Bender, director of the Mercury Policy Project, a foundation-funded group that was one of the authors of the study.

Power plants emit mercury into the air and it falls into streams and rivers. Many dentists flush it down their drains and it goes directly into waste-water treatment plants, which do not effectively filter it from the water.

In a statement responding to the report, the American Dental Assn. said it was aware that some particles from fillings end up in waste water, and it urges dentists to follow proper procedures for handling and recycling the composite used for fillings, which they refer to as "amalgam."

But the association argued that the mercury from their fillings remains in a form that is not harmful to humans.

"However, a 1996 study found that when amalgam particles were subjected to simulated waste-water treatment processes, no soluble mercury was detected, even at a concentration of 1 part per billion," according to the statement.

The group stressed that it was currently implementing a new plan to address the problem.

The new report's authors said that dentists, through voluntary or mandatory measures, should trap their waste mercury before it flows into plumbing fixtures that have been contaminated with mercury for years.

The report referred to a 2001 study by the Assn. of Metropolitan Sewerage Agencies that evaluated seven major municipal waste-water treatment plants and determined that dental uses were "by far" the greatest contributors to the mercury reaching their facilities. They were responsible for 40% of the load, three times more than the next largest contributor.

Several other countries regulate releases of dental mercury. In Canada, a new standard requires dentists to trap the pieces of filling before they go down the drain. The goal is to reduce releases by 95% by 2005.

In May, the New Hampshire Legislature became the first in the nation to pass legislation governing disposal methods for dental mercury.

The California state Assembly considered a measure to phase out the use of mercury in fillings but did not adopt it.

The report suggests that mercury in dentistry has become the exception while other major users of mercury have changed their practices.

In 1985 dental facilities used 3% of all the mercury used nationwide. Last year, although dentists used less mercury, their use accounted for 20% of all uses. Only two other industries—wiring devices and switches and chloralkali—used more.

Gina Solomon, a physician who focuses on the health effects of mercury for the Natural Resources Defense Council, said that there was still controversy about whether the fillings put dental patients at risk.

And she stressed that those who have such fillings should not get them removed, because taking them out heightens the chance of exposure.

However, she said the science is clear that the mercury that goes down the drain can end up in the food chain.

"There is scientific consensus that mercury that ends up in the waste water and water bodies will accumulate in the fish and pose a direct human health problem to people who eat the fish; that is uncontroversial and is something that can be fixed," Solomon said.

Cleveland Plain Dealer 6/11/02

Limits proposed on mercury fillings

A growing national effort to restrict use of mercury in dental fillings soon will make its way to the Ohio legislature.

"Alternatives are available today, and they should be used," said State Rep. Annie Key, the Cleveland Democrat who cosponsored the bill, at a news conference yesterday.

Silver fillings are made from metals combined with mercury. The American Dental Association maintains that the fillings are safe and cause toxic reactions only in rare cases. Critics believe the mercury is harmful to patients' health and the environment.

The proposal would ban dentists from using mercury in children 18 and under and in women who are pregnant or under 45. It also would require dentists to post a warning in their office about potential dangers of mercury exposure.

Similar bills have been proposed in Alabama, California, Georgia and Illinois, and disclosure bills have been passed in Maine and New Hampshire, Key said.

Chicago Tribune SOUTH FINAL
WEDNESDAY, AUGUST 22, 2001

Health risks of mercury in fillings debated

By Karen Brandon
Tribune national correspondent

SAN DIEGO—Mercury, used o fill tooth cavities for 14 centu ies, is at the center of a politi al and legal debate over its use n modern dentistry.

An estimated 100 million U.S. esidents have fillings made of malgam, a silver-colored alloy ontaining about 50 percent nercury. The American Dental ssociation says amalgam is afe and is the least expensive, nost durable way to fill cavties. But opponents say denists are downplaying the potential risks of using mercury, a ighly toxic metal that can amage the brain and senses, articularly in developing fetuses.

The fillings slowly release tiy amounts of odorless, colorss mercury vapor. Their effect n health has been the subject f scores of conflicting studies, nd no federal agency has oved to prohibit the fillings.

"You can't say mercury fillngs are bad for you," said Dr. lyron Bromberg, a dentist in eseda, Calif., and spokesman r the Academy of General entistry, an industry group. ou can't say it because it's inxurate. . . . I have silver fillgs in my mouth. I have silver llings in my kid's mouth. If ere were any problems with em, I wouldn't use them."

Yet in the past year, Maine d Arizona have passed laws quiring dentists to give paents more information about e potential risks of mercury, irroring a measure passed

EASE SEE FILLINGS, PAGE 36

FILLINGS: Dentists say fears unwarranted

CONTINUED FROM PAGE 1

several years ago in Colorado. Rhode Island this year began requiring insurers to cover more expensive alternative fillings that do not use mercury.

Several countries, including Germany, Sweden, Austria and Canada, have found no widespread problems with amalgam fillings but recommend they not be used in treating pregnant women and young children.

The California State Assembly was so irritated by the state dental board's nine-year failure to comply with a law requiring it to prepare a fact sheet about potential health risks from mercury that it voted in July to oust the board.

The Democratic state senator who wrote the dental fact sheet law, Diane Watson, is now in Congress, and she plans to introduce national legislation to force Medicaid to pay for more expensive alternative fillings, a move driven mainly by her concern over the potential health risks of mercury-based fillings.

Lawsuits filed

Recently, an advocacy group opposed to amalgam fillings has filed lawsuits in California and Maryland, contending that the dental profession has deliberately minimized the potential risk to patients and has in effect gagged dentists who advocate mercury-free fillings by revoking or threatening to revoke their licenses.

The Chinese first used mercury to fill decayed teeth in the 7th Century. But its use in dentistry has been controversial since the mid-1800s, when one dental society's decision to require its members to pledge not to use it led to the organization's demise and the rise of the ADA.

The present debate comes as environmental organizations are questioning the use of mercury where alternatives exist, such as replacing mercury thermometers with digital ones in hopes of keeping mercury out of the environment.

At the same time, the popularity of amalgam fillings is waning in favor of natural-appearing fillings made of resins and glass. Dentists say that these composite fillings are more popular for cosmetic reasons but that they do not last as long, are more expensive and are mo difficult to put in teeth.

Though research into amalgam fillings is continuing, it is difficult to measure its impact. Patients can be exposed to mercury by a wide variety of sources, such as contaminated fish and other seafood.

Conflicting studies

Mercury opponents point to studies linking the metal's presence in fillings to an array of ailments, such as increased resistance to antibiotics, impaired kidney function, heart attacks, Alzheimer's disease and fetal abnormalities.

But amalgam supporters question the procedures used in many of those studies and point to other studies rebutting their results. Defenders of amalgam

AP photo by Rich Pedroncelli

Dental assistant Sandy Silva looks at a television monitor to inspect a silver filling in the tooth of Megan Karr, 5, in Sacramento. Some fear the mercury used in fillings could be harmful.

say that if there were any health problem from the fillings, they would be obvious by now.

A national panel convened by the U.S. Public Health Service to study amalgam fillings found no pattern of problems, except for rare allergic reactions.

"For the last six years, the U.S. Public Health Service has fixed its sights on the issue of potential health risks from the use of dental amalgam," wrote Elizabeth Jacobson, the panel's chairwoman, in its 1997 report. "One can and perhaps should ask the legitimate question of why."

But a 1999 report by the Agency for Toxic Substances and Disease Registry, an arm of the U.S. Department of Health and Human Services, concluded that more research is warranted, especially into how fillings might affect pregnant women or young children.

Fillings called outdated

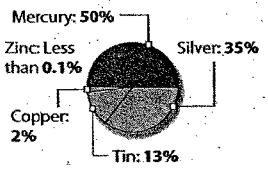
Charles Brown, the lawyer for Consumers for Dental Choice, a coalition that filed the suits in California and Maryland, contended that mercury fillings are outdated.

"What other aspect of the industry of medicine is still using the same basic manufactured material that they used 150 years ago?" he asked.

More mercury than silver in fillings

Amalgam, the "silver" alloy used to fill cavities, is actually 50 percent mercury. While the vast majority of dentists rely on the metallic mixture, a growing number are concerned about possible mercury toxicity.

COMPOSITION OF AMALGAM DENTAL FILLINGS*



*Percentages vary slightly between manufacturers.

Sources: American Dental Association, World Health Organization

AMOUNT OF MERCURY IN ...

Average amalgam filling **0.5 grams**

Mercury thermometer **0.5 grams**

Fluorescent light **0.04 grams**

The average American adult has 8 fillings

He charged that many patients are confused when dentists refer to the fillings as silver and do not mention mercury's presence.

The ADA insists there is no gag order prohibiting dentists from explaining the benefits and risks of types of fillings. But the group does prevent dentists from suggesting that a patient remove their amalgam fillings to cure health problems.

"There have been some notorious dentists who made quite a bit of money by suggesting to patients every ill they had was created by amalgam fillings," said Peter Sfikas, the ADA's general counsel, adding that many of them rightfully lost their licenses.

But Michael Ziff, a retired dentist in Orlando, said he endured a nearly four-year legal battle in the mid-1990s with the Florida dental board because two other dentists complained he was misleading people about mercury's risks.

"It is my belief that patients have to be told that there's mercury in the fillings and the mercury comes out," he said. "I was not claiming that it would cause [multiple sclerosis] or that patients should get all their [amalgam] fillings removed."

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May 23-29, 2002

cover story

Biting Back

Photo By: Christina M. Felice
Local activists say your mercury amalgam fillings could be poisoning you. And they're fighting the ADA to prove it.

by Juliet Fletcher

Dr. Andrea Brockman finally conceded there was a problem with the mercury bottles nestled in her cabinet when she realized nobody wanted to know they were there.

The silver-colored metal, in its liquid globular form, is as familiar a sight to scientists as the tiny orange skull and crossbones on each bottle that mark it as a hazardous toxin. So Brockman, a dentist, was all too eager to pass the bottles over to whichever environmental agency would take them off her hands.

She called the city. She called refineries, manufacturers and environmental agencies. Her inquiries were greeted with a surprising reply: The Environmental Protection Agency (EPA) and the city's Department of Public Health told her that they wouldn't retrieve such hazardous material from her workplace without a fee. Finally, in exasperation, she allowed her assistant to call the Public Health Department to ask what she should do if she found mercury in her apartment. Protocol kicked in: "OK, don't do anything. Don't touch it. We'll come and get it."

Hazmat team: Drs. Vincent DiLorenzo and Andrea Brockman in front of their holistic dental practice.

Photo By: Christina M. Felice

No health organization will dispute that mercury is a toxin: It arguably ranks as the second-most-poisonous compound on earth, after plutonium. What Brockman and her husband, Dr. Vincent DiLorenzo, discovered, in the years spent running a practice near Chestnut Hill, was that mercury inside a dental office is treated squarely as an industrial material; yet dentistry, they argue, is one of the few industries that has not sought to eliminate mercury from its day-to-day procedures. While Mercurochrome is no longer used in hospitals to disinfect cuts, nor are thermometers filled with the metal, the same mercury is habitually mixed with other metals and placed inside the mouths of patients, in one of the most common dental treatments: a "silver" filling.

There is no greater debate in modern dentistry than over continued use of this sort of filling, each of which contains roughly half a gram of mercury. On one hand, the American Dental Association (ADA), the premier governing body of dentistry, approves mercury amalgam fillings, finding no admissible science linking the roughly 50 million grams of mercury placed in mouths every year to possible exposure. ADA spokesperson Dr. Terry Donovan says,"Based on 150 years of effective use and a lot of scientific study, we believe amalgam is perfectly safe." On the other, small groups of consumers and concerned dentists have taken root, claiming that exposure through dental work has caused health problems ranging from skin irritation and memory loss to fertility and children's developmental disorders. Other research correlates symptoms of mercury poisoning with systemic illnesses, such as autoimmune disease and Alzheimer's.

Once trained as a nurse, Brockman recalls how hospital wards would be quarantined at the drop of a thermometer, for fear that mercury vapor, given off continuously by the metal, would poison those nearby. On starting dental school at Temple, however, she saw "how we were taking the same mercury that we weren't allowed to touch in the hospital and squeezing it in cheesecloths with our hands" as they prepared the amalgams. By the time she had completed dental school in 1979, an alarming range of health problems had convinced her that daily contact with the compound would pose a continual danger to her health. She had developed panic attacks, visiting the emergency room on several occasions, and later suffered a miscarriage. As the couple decided to begin practicing mercury-free in the late '70s, they both were aware that the ADA gave its seal of approval to the products that the EPA classified as hazardous; they could not yet know that, by 1986, proposing the removal of a patient's amalgam fillings purely out of concern about toxicity would contravene ADA regulations.

Now, 20 years on, DiLorenzo and Brockman stand by their decision to abolish use of the metal at their own level. Their efforts are now joined with those of other area residents -- both dentists and patients -- to do the impossible: to give consumers the chance to buck 150 years of traditional dentistry. Their movement has not gone unnoticed. A bill currently sits before Congress demanding the abolition of mercury use in dentistry.

Mercury was first introduced as a filling component in the 1800s from France, and American dentists adopted it soon after. The new technique was greeted enthusiastically. Mixed with powdered metals, its liquid consistency at room temperature solidified to a malleable paste that could be set in a tooth cavity. Until the advent of this method, the only means of filling a tooth had been with molten metal.

Essentially, the technique for so-called "silver" fillings has remained the same to this day, and mercury continues to be the predominant ingredient. The Department of Health and Human Services stated, in its 1999 Toxicological Profile for Mercury, that an amalgam filling contains approximately 50 percent mercury, 35 percent silver and lesser amounts of tin, copper and zinc. To mix these together, DiLorenzo remembers adding "droppersful" of mercury to powdered alloy, before allowing a machine to shake them together. Once done, the mixture would be wrung out -- and, he explains ruefully, it was years after their training that gloves were commonly worn for such preparations. In 1998, the ADA ruled that dentists discontinue using bulk mercury to reduce the risk of exposure from handling, choosing capsulated mercury instead, though it maintains that the amalgam is largely inert once mixed. Other filling materials, including porcelain, composite and gold, are now available.

Yet the ADA has long had to answer questions from concerned dentists such as Brockman, who eventually called the ADA to ask whether daily exposure to mercury might contribute to her health problems. "I was told there was nothing to worry about, that they'd get back to me with more information. But their stance didn't make sense to me." The response from her professors at Temple, who assured her that mercury was "locked into" amalgam, didn't make much sense to her either. Though a heavy metal, mercury is extremely volatile, releasing toxic vapor continuously while in its liquid state. This volatility is tempered when it bonds with other metals, but a recently developed method measuring intra-oral levels of mercury vapor has proven that emissions are given off after the amalgam is mixed and set.

An astonishingly simple chain of logic eventually led Brockman to the heart of the issue. Though she and DiLorenzo had turned away from placing mercury fillings in their patients, they were not yet free from the metal. During the late '70s and early '80s, they were still drilling out old fillings from patients' mouths. Knowing mercury behaved like other compounds, they surmised that the heat and pressure of a dental drill would accelerate the chemical reaction, increasing the chances that vapor would be released during these dental procedures. And yet, knowing what they did of the wear and tear that teeth withstand, particularly through chewing and contact with hot foods, they began to articulate a barely whispered question: What if mercury exposure did not stop with the dentist, but was continuously absorbed by the patient, once they were carrying mercury inside their mouths?

In 1991, nearly a decade later, the World Health Organization (WHO) estimated that the body absorbed roughly 3 micrograms to 17 micrograms of mercury per day from amalgams. Health and Human Services, summarizing data from recent studies in 1999, cited the report and estimated that a person's exposure to mercury from amalgams may account for 53 percent to 87 percent of their daily mercury exposure. By comparison, the second greatest source quoted was dietary content, specifically from fish and seafood, contributing only 2.31 micrograms per day. Airborne vapor concentrations, as assessed by the EPA in 1984, should not exceed 0.3 parts per million.

None of this history was known to Freya Koss when she slipped into the dentist's chair in March 1998. Arriving all the way from Wynnewood for her appointment with her Bronx-based dentist, she learned that the pain in her mouth was originating in one of her upper-left molars, which was in serious need of repair: Beneath an old amalgam filling, a cavity had continued to grow. She says that with peremptory speed the dentist drilled out the weathered portion, removed the decay and sealed up the tooth with new amalgam. At one point, Koss says, she asked him why he hadn't used a dental dam, which catches the metal shrapnel before it disappears into the patient's mouth. "He told me that, frankly, they were a pain to use. He hadn't fitted one in all the time he'd been practicing." Koss would not name the dentist.

To Koss, who, as an events planner, was used to noting details above all else, this seemed unusual. Other signs of sloppy procedure were there: Koss says she found out later that the dentist had mixed alloy with bulk mercury from a bottle, rather than using the neater -- and ADA-approved -- method of pre-measured capsules. Most of all, she laments, she "had no idea what questions to ask" her dentist -- and so had no idea what was going wrong.

Seven days later, she was returning to her car after an evening at the ballet when she was stung by an attack of dizziness. As the fog cleared, she found she could no longer see the oncoming cars clearly: They appeared in double vision, the headlights multiplied so many times that she could hardly see the road. Apprehensive, she went to her optometrist for tests; on examining Koss' eyes, the specialist appeared concerned and told her that she shouldn't leave without first making an appointment with a neuro-ophthalmologist. The next day, she underwent tests at the Hospital of the University of Pennsylvania; within a week, she had the results back. Out of the blue, the doctor diagnosed her with either multiple sclerosis or lupus.

Absolute disbelief was her first reaction, which quickly hardened into determination: "I could not comprehend how I'd developed an autoimmune condition, such as MS, seemingly overnight," Koss recalls. So she initially refused the prescription of medication and steroids meted out by the doctors, and she set about doing her own research. Her touchstone, she says, was the Internet: She sat up for three days in a row, searching medical databases and newsgroups for some link between her stunning diagnosis and its manifestation -- now-drooping eyelids and worsening vision. She could barely see, but she donned an eye patch to minimize the blur and began to read, as she puts it, "with an open mind."

It didn't take her too long to find a kindred spirit by spreading her net of research internationally. A woman in the U.K. was the first to match Koss' symptoms and MS diagnosis against her own experience with heavy metal toxicity. Anecdote after anecdote provided Koss with a window on other sufferers whose symptoms had been exacerbated after visiting a dentist.

What she hadn't realized was how far the U.S. dental establishment differed from health organizations and agencies abroad in its support of mercury-based fillings: Sweden, Germany and Canada,for example, no longer allow application of amalgam, while other nations, such as Norway and Australia, have adopted warnings against its use in children and pregnant women. By contrast, roughly 96 million amalgam fillings were placed in the U.S. in 1990, according to a 1993 Health and Human Services study, and it is currently the treatment afforded by most basic insurance policies. Furthermore, it seemed to Koss no coincidence that research from other countries, notably from Canada and Sweden, was making bolder statements on the transmission of mercury from amalgams throughout the body. A 1989 University of Calgary study planted amalgam fillings in sheep's mouths to study the effects of chewing on vapor release. The mercury, tagged radioactively, could be followed through the animals' systems over a 29-day period -- rapidly accumulating in the liver and kidneys, as well as lung and jawbone tissue. A further Calgary study found similar buildup in pregnant ewes, while their fetuses had high mercury levels in the liver and the developing brain's pituitary

gland.

Pinning down symptoms for mercury poisoning is almost impossible: Since it can accumulate in different tissues, its effects can be unpredictable, and very localized. In Koss' case, the shifting diagnoses from her doctors only made her more inquisitive. "As I learned more about mercury, I kept thinking back to that day at the dentist, so soon before my vision deteriorated." While a succession of doctors refused her offers to show them dental journal studies regarding mercury toxicity in relation to amalgam, she was told eventually that, in spite of her initial test results, she was unlikely to have MS; instead, a condition known as myasthenia gravis, another autoimmune disease which controls muscle function, particularly near the eye, was more probable.

The illness hit Koss hard. While she spent months trying to work out what caused her loss of vision, she let slip her career planning events, for the National Museum of American Jewish History and, later, through her own business, for clients such as the Annenberg Center. As she started to come to terms with what had happened to her -- aided by the eventual diagnosis by an environmental physician of a high mercury body burden, based on tests that drew out the metal from her tissues -- she found herself drawn to the idea of spreading the word. For, in the process of gathering background on what she calls a "deliberate cover-up" of the content of mercury fillings, she stumbled across a national organization, the Dental Amalgam Mercury Syndrome (DAMS), that offered support and information for victims of poisoning. It seemed almost preordained that she would get involved: The vice president of the organization, Carol Ward, turned out also to live in Wynnewood, only a few miles from Koss' house.

Ward received a call at 10:30 one night. It was Koss, having just been misdiagnosed with MS, distraught at what she was learning about the potential risk of amalgams. It only took a few moments for Ward to recognize what she was hearing. "In all the people who call me, I've started to notice a few patterns," she says. She was prepared to suggest to Koss that, yes, she might have mercury poisoning: "We're not doctors or dentists here at DAMS, so we always qualify it that way, but we can say, ŒWhat worked for me...."

What worked for Ward had been, in the end, complete removal of her mercury amalgam fillings, some of which she had had since she was 7, others which had been put in at age 47. She had been prone to infections throughout her teens and, after having dental work done in her 20s, she noticed she was unable to sleep and was losing her hair. By 1985, her hectic life, working as the branch administrator at the Cobbs Creek Free Library, or hiking, playing the piano and jogging in her free time, was starting to take a downward slide. She noticed she was having equilibrium problems, which she knew might signal the start of MS. Again, her trips to various doctors yielded no answers, and it was only a consultation with a nutritionist that first threw up the putative diagnosis of adverse reaction to amalgam. Having found herself exhausted, housebound and virtually incapable of moving about, Ward undertook a regimen of vitamins and supplements aimed at strengthening her system and helping to detox. Then, referred to a mercury-free dentist in Bala Cynwyd, she was able to have her amalgams removed. It took time, since the necessary drilling-out is considered to be a flashpoint for vapor exposure, so a mouthful such as Ward's 16 fillings were removed by quadrant (a quarter-mouth at a time). The results were undeniably remarkable: Within a couple of visits, her continuous vision impairment receded, allowing her to take up reading again. Even more extraordinary, she reports experiencing her vision field return to normal in the car on the way home from the last appointment, allowing her to see the horizon properly. A practical person, not seemingly given to exaggeration, she puts it quite simply: "Getting rid of a substance that is known to be toxic allowed me to heal." After detox, she found her hands could reach the intervals in a piano concerto once again.

Koss was initially drawn to DAMS as an outlet for her zeal. She subscribed to its mailing list, produced every three to four months, and used its database of

mercury-free practitioners to find someone who could remove her amalgams safely. Yet her efforts were taken in a different direction, after a chance suggestion that she get in touch with Anita Tibau, based in California and working as West Coast representative of the anti-amalgam movement's lobbying arm, Consumers for Dental Choice.They met; shortly thereafter, Koss began working for the nonprofit as director of development, organizing fundraising and outreach as Tibau's East Coast counterpart.

Charles G. Brown, former attorney general of West Virginia and now a D.C.-based lawyer, has represented Consumers for Dental Choice since 1996. Its national counsel for legislation, he remembers how the organization got started. "We wanted to create a level playing field for mercury-free dentists. We knew the ADA was harassing those dentists, and so the situation was in defensive mode." Brown points to what he terms the "gag rule" as evidence of the ADA's suppression of mercury-free practice. In its Code of Ethics and Professional Conduct, the organization ruled in 1986 that to recommend the removal of amalgam restorations "for the alleged purpose of removing toxic substances from the body... is improper and unethical." According to Brown, the ADA amended this clause in May this year -- it now applies not only to amalgam but to all materials. The actual bestowing of licenses to practice dentistry is handled at the state level, by the dental boards. Yet the national ADA, in an "outrageous partnership" with the state boards, Brown says, can pursue a dentist to the point of revoking his or her license, if, unsolicited, the dentist so much as nudges a patient in the direction of a contents list, for amalgam or any other material. The ADA's Donovan confirms that certain dentists have had their permits revoked, after recommending "unwarranted" amalgam removal. Consumers for Dental Choice argues that until dentists can discuss filling materials openly with the patient, consumers are expected to make treatment decisions without necessary information.

The Pennsylvania Dental Board refers to its code of professional conduct on this issue, wherein it states, "The Board has neither the resources nor the mandate to make or endorse scientific findings on this issue." It recommends that dentists follow certain guidelines, including explaining the current state of research to a patient and referring a patient to a physician for recommendations on treatment before proceeding with removal. Brown cites its stance as one he respects: "They, unlike some other dental boards, do not seek to rule what the dentist can say on the issue."

Bitter pills: Freya Koss with the dozens of vitamins and supplements prescribed since 1998 to help her detox.

Photo By: Christina M. Felice

There are signs that cooperation between other state boards and the ADA is starting to crumble. In March, the ACLU won an Oregon lawsuit that forced the dental board to rescind its rule that discussion of amalgam replacement constituted "fraud" because it violated dentists' First Amendment rights.

However, Brown sees other instances of the ADA using its established reputation to preserve the status quo: In its code of ethics, "unsubstantiated representations" regarding the dentist's "capacity to cure or alleviate diseases" refers to any statements not supported by "accepted scientific evidence" -- which, in Brown's eyes, has been any research the ADA wishes to discredit. "[It's] an amazing

position for a group that claims to have an interest in science. They do not have an interest in science; their interest is economics." The ADA held patent on two amalgam products until 1994 and 1995 respectively.

Lawsuits filed in other states, such as California and Maryland, challenge the ADA on scientific and economic grounds. The suits allege that the ADA engaged in "deceptive" business practices by referring to the fillings as "silver" rather than "mercury." Furthermore, in some cases, the suits claim, exposure from mercury coming partly from amalgams contributed to cases of childhood autism. The ADA claims the suits are without basis.

Besides autism, Alzheimer's has been the focus of research for its connection to mercury toxicity. Boyd Haley, chair of the University of Kentucky's department of chemistry and one of the movement's scientific big hitters, has pioneered research into the biomarkers for this neurological condition -- chemical changes in the body that might give some clue as to the cause of the disease. These biomarkers -- two proteins, tubulin and creatine kinase -- were found to be suppressed in sufferers of Alzheimer's: The lower the tubulin uptake, the more likely the formation of "tangles" of protein in the brain, a classic indicator of the disease. "We found there was only one heavy metal which repeatedly was causing those proteins to be suppressed," explains Haley. "It was mercury."

Government reaction to the anti-amalgam movement has been slow. A five-year study begun in 1997 and funded by the National Institutes of Health is measuring the behavioral, renal and neurological effects of amalgams -- on two groups of children, one in Boston and Maine, one in Lisbon, Portugal. Opponents of the study point to its relatively short time-span, which may not yield results of long-term exposure. Meanwhile, the House Committee on Government Reform held hearings in 2001 examining increased rates of autism in the U.S. Haley addressed the hearings, as did the ADA president, Dr. Robert Anderton. Haley later wrote a letter of rebuttal to the ADA, challenging his statements. As he puts it, "This was toxicology research being presented by a dentist, not a toxicologist."

Against this stormy backdrop, the introduction of a federal bill aimed at abolishing the use of mercury in dentistry by 2006, and immediately issuing warnings on the product against using the material for children and pregnant or nursing women, appears timely. Remarkably, the bill has bipartisan support: Democratic Rep. Diane Watson and Republican Rep. Dan Burton worked together to introduce it to the House. While Watson has been actively working toward disclosure legislation regarding mercury amalgam since her days in the California legislature, Burton became aware of the issue through its relation to the controversy over thimerosal (a mercury compound) used in vaccines. Both sides of the issue, it seems, are ready for a fight: While Watson says that the dental establishment "wrongly" calls amalgam "silver," the ADA counters by stating that "Watson's attempt to ban dental amalgam would effectively deprive patients of an essential treatment that is clinically and scientifically substantiated to be safe." For his part, Brown says that common sense disputes this assertion: "What pregnant woman, who won't even have a glass of wine, would want a known neurotoxin in her system?"

The Watson-Burton bill has been referred to the Committee for Energy and Commerce; in the meantime, while Koss and Tibau have spent time lobbying for its support on Capitol Hill, Consumers for Dental Choice is also focusing on state bills, such as the one Watson brought in California in 1992. Three more have been passed, in Arizona, Maine and, most recently, New Hampshire; Brown says states like New York and Pennsylvania are natural contenders to follow the "trendsetter state" of California because of their educated consumer base and active environmental movements.

Until the current climate relaxes, however, practitioners such as Dr. Blanche Grube know that mercury-free dentistry must tread softly. In 1984, she moved from New York with her husband, a chiropractor, down to Scranton, "a secluded community." In 1992, her 20 years of practicing conventional dentistry was brought to an abrupt halt. Grube and her husband came across a patient of his, with a mouthful

of fillings, whose toxicity was affecting her muscles. Once she had familiarized herself with the prevailing research, Grube stopped practicing altogether for a time. "I was devastated to think that, while I had been hoping to help my patients, I might have put them at risk." When she returned to work, after traveling to classes and seminars to educate herself further, she realized the benefits of her location. "Scranton has always been very separate from the rest of the world. It's a good place for a holistic dentist to hide."

She, like Brockman and DiLorenzo, learned about mercury exposure up close. She recalls bouts of hives on her arms while working as a dental assistant in Queens, N.Y., that corresponded to dermal contact with liquid mercury; carpets would soak up mercury spills, and waste amalgam was flushed down the drain or thrown in the trash. Now, she says, there's increased concern regarding pollution from dental offices entering the environment. Though she says that the EPA continues to leave its guidelines at the door of dental practices -- "mercury is classed as hazardous before it's placed, and hazardous waste once it's removed" -- a voluntary statewide cooperation was launched in May 2000 by the Pennsylvania Department of Environmental Protection and the Pennsylvania Dental Association to cut down on pollutant dental waste.

Grube's long-term view of the need for holistic dentists who follow extremely stringent standards in removing amalgams is reflected in her work environment: No carpets -- and oxygen tanks and gas masks sit ready for use when drilling into mercury. She categorically states that it is not safe for the public to demand amalgam removal by a conventional dentist. Careless removal, as Koss' story illustrates, can result in acute exposure. Her advice is simply for patients to be aware -- and to avoid amalgam placement where possible. (For fear of reprisals for her mercury-free policy, Grube takes most of her patients on referral from physicians, to work out whether they are suffering mercury toxicity.) In allying herself with holistic dental organizations, she also acknowledges the educational void surrounding issues of toxicity in dental care. "As long as the ADA accredits dental schools, I don't believe the revolution can start there." For that reason, she, together with Brockman and DiLorenzo, sits on the board of the newly initiated Institute for Natural Dentistry, an Academy of General Dentistry-accredited organization wherein dentists can learn to reconcile their concerns about toxicity with the available research and practical applications of holistic treatment.

She sees the movement gaining pace, at its grassroots as much as at its federal figurehead: for better or worse, not everyone can spend 10 years educating themselves now, as she did. "The fear," says Grube, "is that when the public finds out that there's a neurotoxin in a dental filling, there'll be a panic. Who'll be there to extract them safely, if we don't learn now?"

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IOWA Life
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The Des Moines Register
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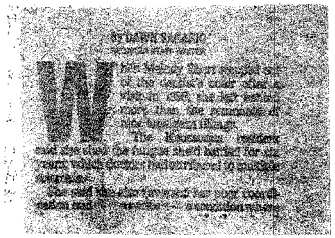
TUESDAY
May 7, 2002

Some dental patients say amalgam fillings are making them sick. Dentists insist the fillings are safe. Questions over the fillings' safety are making more people say . .

Uh-oh, silver!



MAY 7, 200

When Melody Ebert stepped out the dentist's chair after a visit in 1996, she left behind more than the remnants of nine amalgam fillings.

The Keosauqua resident said she shed the fatigue she'd battled for six years, which doctors had attributed to multiple sclerosis.

She said she also reversed her poor coordination and endometriosis — a condition where the uterine lining grows outside the normal area in places that include the ovaries, bowel and bladder.

A year after removing the amalgams, she claimed almost all of her energy had returned. Since then, the 36-year-old added, her immune system has improved.

Ebert is one of a number of patients nationwide who say amalgams — composed mainly of mercury — are at the root of their ailments. Dental amalgam — commonly referred to as "silver" fillings — are comprised of about 50 percent mercury, along with silver, copper and tin.

Controversy is brewing as opponents of amalgam insist they are dangerous to the health of the millions of Americans who have them. They also say patients are unaware of the toxicity.

Several medical experts disagree.

They say amalgam has proven to be a safe material for more than 150 years. They tout its durability and ease of use, saying that only in rare cases have patients had allergic reactions to the fillings.

They say there currently is no concrete evidence linking the mercury in amalgam to chronic diseases like Alzheimer's and multiple sclerosis.

In March, the Food and Drug Administration, in conjunction with other organizations of the U.S. Public Health Service, released a statement saying that while they continue to investigate the safety of amalgams, there is no valid proof that they cause harm, except in rare cases of allergy.

Complaints recently filed in Georgia against the American Dental Association are claiming that mercury in the fillings of some mothers caused their children to be born with autism.

One Altoona woman is part of a lawsuit filed against the Maryland State Board of Dental Examiners, claiming that the board supports a "gag rule" enforced by the American Dental Association that prevents dentists from

See FILLINGS, Page 2E

Comparison of types of filling material

FACTORS	AMALGAM	COMPOSITES	ALL PORCELAIN	GOLD ALLOYS
Description	Mercury and silver alloy powder that forms a hard solid metal filling. Self-hardening at mouth temperature.	Submicron glass filler and acrylic resin that forms a solid tooth-colored restoration. Self- or light-hardening at mouth temperature.	Porcelain, ceramic or glass-like fillings and crowns.	Alloys of gold, copper and other metals. Strong, effective filling, crown or bridge.
Principal uses	Dental fillings and back tooth restorations.	Aesthetic dental fillings and veneers.	* Inlays, onlays, crowns and aesthetic veneers.	Inlays, onlays, crowns and fixed bridges.
Durability	Good to excellent in large restorations.	Good in small-to-moderate size restorations.	Brittle material, may fracture with heavy biting. Strength depends on quality of bond to tooth.	High corrosion resistance prevents tarnishing; high strength and toughness resist fracture and wear.
Resistance to wear	Highly resistant. Brittle, subject to chipping on filling edges, but good bulk strength in larger high-load restorations.	Moderately resistant.	Highly resistant, but porcelain can rapidly wear opposing teeth if the surface becomes rough.	Resistant to wear and gentle to opposing teeth.
Tolerance	Well tolerated with rare occurrences of allergenic response.	Well tolerated with rare occurrences of allergenic response.	Well tolerated.	Well tolerated.
Aesthetics	Silver or gray metallic color.	Mimics natural tooth color and translucency, but can be subject to staining and discoloration over time.	Color and translucency mimic natural tooth appearance.	Metal colors do not mimic natural teeth.
Cost	Generally lower; actual cost of fillings depends on size and the time spent by the dentist.	Moderate; actual cost of fillings depends on size and technique.	Higher; requires at least two office visits and laboratory services.	Higher; requires at least two office visits and laboratory services.
Average number of visits to complete	One.	Minimum of two; matching aesthetics of teeth may require more visits.	Minimum of two; matching aesthetics of teeth may require more visits.	Minimum of two.

* Inlays, onlays and crowns are types of restorations that are produced in a laboratory, and are later cemented onto the tooth.

SOURCES: AMERICAN DENTAL ASSOCIATION, DR. MARK LATTA, ASSOCIATE DEAN FOR RESEARCH, CREIGHTON UNIVERSITY, SCHOOL OF DENTISTRY

Safety of fillings is in question

FILLINGS, from Page 1E

initiating conversations with patients regarding the mercury amalgam controversy.

The mercury in amalgam is inert, and therefore nontoxic, a Chicago physician said.

"There's been no cases that have been documented where we can show that amalgam has caused a disease process," said Dr. Alan Boghosian, a researcher in dental materials in the division of dental surgery at Northwestern University Medical School.

He said there have been fewer than 50 cases of an allergic reaction to dental mercury to date, versus the more than 1.5 billion amalgams placed.

While fillings daily emit amounts of mercury vapor, the levels are safe and do not compromise individuals' health, Boghosian said. There has been only anecdotal evidence showing that the removal of amalgams has helped cure disease.

Dr. George North of Allison said he routinely uses amalgam in his practice.

"I've looked at literally thousands of patients, and I've seen absolutely no adverse effects at all" from amalgam fillings, said North, vice chairman of the Iowa Board of Dental Examiners.

The board's current rule says it is "improper and unacceptable" for dentists to remove fillings or recommend it as a way to remove toxic substances from the body when the patient is not allergic to amalgam.

"It's unethical for a dentist to tell a patient to have all of their fillings taken out just because they're silver fillings," said Dr. Mark Latta, associate dean for research at the Creighton University school of Dentistry.

Opponents of amalgam like Florida dentist Michael Ziff say the mercury in fillings is toxic. Doctors are obligated to fully disclose that information to patients, he said.

"It's like saying it's OK to hold seven, leaking mercury thermometers in your mouth, 24 hours a day, 365 days a year," said Ziff, executive director of the International Academy of Oral Medicine and Toxicology.

He said the average American has seven of the mercury-based fillings.

Studies have shown that the mercury in fillings causes the same type of pathological damage seen in Alzheimer's patients, he said.

While amalgam is still used by many dentists nationwide, an Iowa City physician predicts a gradual phasing out of the material in the next five to 10 years.

Composites can now replace amalgam in many situations but still has its limitations, said Dr. Jerry Denehy, chairman of the department of operative dentistry at the University of Iowa College of Dentistry.

What patients don't understand is that right now there is no universal alternative for amalgam that is as durable, cost effective and versatile, he said.

Alternatives like composites and porcelain are more expensive, and may not be as durable in some situations.

"If a dentist wants to phase amalgam out of their practice and can properly use the alternative material in the manner which they are attended and has the expertise, then I don't have a problem with the amalgam-free practice," said Denehy, an expert in restorative surgery.

Dentists should tell their patients about the choices available, a Fairfield physician said.

Dr. Robert Yudin said he prefers using composite fillings and most of his patients request them.

Determining whether dental mercury is the main cause for an individual's ailments is difficult, Yudin said. Some people naturally process out heavy metals like mercury with more ease than others, making it hard to determine how much mercury is in a person's system.

Yudin cautions that while white fillings are currently presumed to be safer than amalgams, it's still unknown whether the plastic used in composites will cause problems later on.

In 1990, Altoona resident Mary Davis replaced 13 amalgams with composites. Davis, who was suffering from multiple sclerosis, had the amalgams removed after an acquaintance suggested they could be affecting her health.

Davis said her dentist at the time was against her decision, saying it would be a waste of money.

"I felt very much like I wasn't living in a free country, when all I wanted to do was get my fillings replaced," said Davis, 41.

The West Des Moines dentist who did the procedure told her "there was no guarantee that this would help my health whatsoever," Davis said.

But since removing the fillings, Davis said she's had more energy, sleeps more soundly and has a stronger immune system.

"There's no such thing as whether or not you're allergic to mercury," said Davis, who is president of the Des Moines chapter of Dental Amalgam Mercury Syndrome. "It's like saying you're allergic to arsenic. Mercury is not an allergen. It's a toxin."

Reporter Dawn Sagario can be reached at (515) 284-8361 or sagario@dmreg.com

Some dentists and doctors are charging for calls

By BOB LAMENDOLA
SOUTH FLORIDA SUN-SENTINEL

Fort Lauderdale, Fla. — Just like banks or phone companies, doctors and dentists are charging fees for services they used to perform for free.

A small but growing number of physicians bill patients for nonemergency telephone consultations – especially on weekends — and for answering e-mails from patients. More commonly, they charge for repeated missed appointments.

Likewise, many dentists now include on their bills an "OSHA fee" or "infection control fee" of about $20 that covers the cost of meeting stiffer federal rules for disposing of biomedical wastes, such as bloody gauze or even pulled teeth.

These fees are not covered by insurance and come straight from patients' wallets.

"Lawyers have done this for years. They turn on the time clock as soon as they pick up the phone. Now it's the doctors' turn," says Anthony Ruffino, a retired dentist in Delray Beach, Fla., who was surprised by fees on his bill. "It never would have occurred to me to have these charges. It would embarrass me, but some guys will charge it."

Medical practitioners do not love adding fees, but say it has become necessary because of shrinking managed care reimbursements, rising malpractice insurance and other factors.

Doctors say they may field 20 or more phone calls a day from patients, which can represent one-third of their patient contacts.

"We support the idea that physicians be properly compensated for their time," says Lisette Gonzalez, with the Florida Medical Association.

The FMA and the American Medical Association have passed resolutions that formally urge Medicare, Medicaid and private insurers to reimburse for phone consultations. None does.

Phone contact or e-mail may be the best way to handle a patient's need, especially if it's a simple question from a patient or a follow-up matter, says Dr. Linda Cox, a Fort Lauderdale allergist. "The way we get paid now is a little archaic, where everything has to be done face to face."

Many dentists and doctors oppose add-on fees. Some believe patients are losing confidence in their relationship with the medical profession.

The Atlanta Journal-Constitution
Tuesday, April 9, 2002

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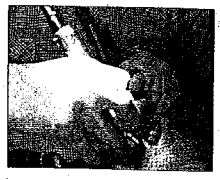
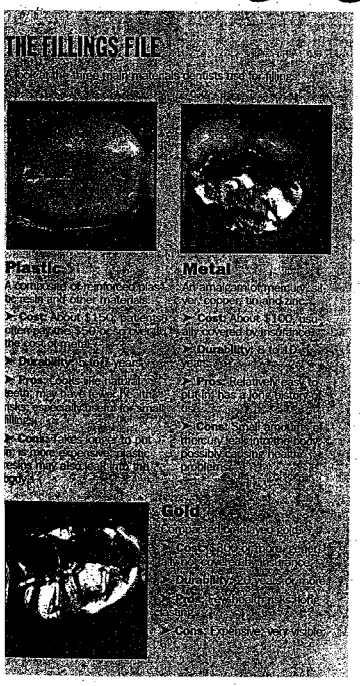
fill it up



Nowadays, repairing a dental cavity can mean deciding among three main types of fillings.



but with what?

As concern over dental mercury grows, many dentists avoid it, but most say it's safe and effective

By DAVID WAHLBERG
dwahlberg@ajc.com

Pamela MacArthur was a healthy artist who loved to ballroom dance when a trio of bizarre symptoms stopped the music.

Her body suddenly started to twitch, she had nightmares and her face erupted in boils so painful that it hurt to roll over in bed and touch the pillow.

Doctors suggested drugs for acne and psychological disorders, but MacArthur turned instead to her dentist. He removed nine metal fillings and replaced them with plastic substitutes, and soon she was doing the tango again.

MacArthur, 40, of Alpharetta is one of a growing number of people who believe their medical problems are caused by mercury in dental fillings. Even though dentists often refer to metal fillings as "silver," they are an amalgam of half mercury and the other half a mixture of silver, copper, tin and zinc.

The dental community is divided over whether mercury in fillings is harmful. The American Dental Association stands firmly behind such fillings, saying they only rarely cause problems, in people with mercury allergies, and are more durable than the alternatives. Meanwhile, a legion of "mercury-free" dentists insists that their mercury-using colleagues are slowly poisoning patients because the fillings release the element into the blood. Research findings are mixed.

Lawmakers are starting to say that patients have a right to hear about the pros and cons of mercury fillings. A bill introduced in the Georgia Legislature in March would require dentists to tell patients about the risks of, and alternatives to, the fillings. The bill, by Rep. Bob Holmes (D-Atlanta), also would ban mercury fillings in children and in women age 45 or younger. Last fall, a California congresswoman announced a bill to ban dental mercury nationwide.

Meanwhile, the U.S. Food and Drug Administration is proposing to strengthen its dental mercury regulations with new guidelines for labeling and reporting of side effects, and the National Institutes of Health is spending $9 million for two large studies of mercury fillings in chidlren.

Last week, lawsuits were filed against dental groups on behalf of nine Georgia children with autism, claiming that mercury from their mothers' fillings caused the disease and arguing that dentists deceive patients by

➤ Please see MERCURY, F7

Healthy Living *Your Tuesday guide to medicine and health care*

Mercury fillings raise concern

➤ Continued from F1

calling the fillings "silver." Suits in California and Maryland have accused the American Dental Association of imposing a "gag rule" forbidding anti-mercury dentists from having open discussions with patients.

Caught in the middle are the patients, who don't know whether to rush out and get rid of those shiny spots in their teeth. Some dentists suggest that symptomatic people such as MacArthur, who may have a mercury allergy, should consider getting fillings removed. This is even more true if fillings are old and need to be replaced anyway.

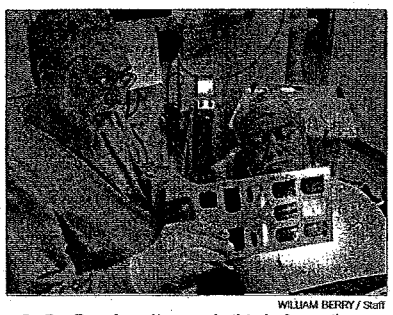
But because removing fillings can actually release more mercury into the body temporarily, the procedure is more risky for people who feel fine.

What is clear is that mercury fillings do release small amounts of colorless, odorless mercury vapor into the bodies of the 100 million Americans who have them, especially after chewing food or brushing teeth. And mercury is a known neurotoxin. The question is whether the emissions are high enough to cause health problems.

Giving 'false hope'

Dr. Michael Ziff, a retired dentist who fought a four-year legal battle over mercury with the dental board in Florida, is now executive director of the Orlando-based International Academy of Oral Medicine and Toxicology, a leading anti-mercury group that has about 400 dentist members. The average American has seven mercury fillings, Ziff said. "It's kind of like holding seven [illegible]king mercury thermometers [illegible]our mouth 365 days a year, [illegible]hours a day."

Dr. Rod Mackert, a dentistry professor at the Medical College of Georgia and one of the ADA's main spokesmen on the issue, said the fillings emit from 1 to 3 micrograms of



WILLIAM BERRY / Staff

Dr. Ron Dressler, a Norcross dentist who frequently replaces metal fillings with mercury-free ones, dicusses the procedure with patient **Michael Warnke.**

test to determine how much mercury vapor is in the mouth. Holding a boxy instrument, he scrapes a straw-like device around the gums, and the detector registers the gas.

Mercury fillings are generally removed in groups, one-fourth of the mouth at a time. They're usually replaced with composite fillings of reinforced plastic resin or, sometimes, with other materials such as gold or porcelain. During metal filling extraction, dentists use vaccuums, air filters, eye covers, oxygen masks and rubber dams over teeth to protect the patient from exposure to excess mercury.

But the process can increase the body's mercury load before decreasing it. To reduce systemic mercury, patients are advised to use some form of chelation, in which drugs that bind to metals are taken orally or intravenously, eliminating the metals through the urine.

Dr. Mark Merlin, a physician at the Atlanta Center for Alternative Medicine in Dunwoody, who tests many patients for mercury, said chelation is crucial when fillings are removed. "You have to get [the mercury] out of the body:

doctors who put her on mind-numbing sedatives and painkillers. Her dentist was at first reluctant to take out her seven fillings but eventually agreed.

"Within six months, there were no headaches," said Meeks, 48, of Austell, an office manager for an Atlanta wood products firm. "It has totally changed my life."

Felicia Gaston of McDonough believes that her 3-year-old daughter Tylicia's autism was caused by mercury in fillings that seeped into breast milk. She is one of the plaintiffs in the Georgia lawsuits.

"I should have been aware" that metal fillings contain mercury, Gaston said. "I feel like her life has been taken away from her."

Some mercury-free dentists say they're treated like pariahs by their peers, and many are unwilling to speak publicly for fear of reprisal. Dr. Wayne King, a Marietta dentist who opposes mercury, said that, several years ago, the Georgia Board of Dentistry threatened to punish him after he ran a newspaper ad depicting a skull and crossbones with the questions, "Is there poison in your mouth? Do you have swim-

dental mercury and the conditions leading to Alzheimer's disease, while another report at the same school, relying on brain autopsies, found no connection. Research by University of Georgia microbiologist Anne Summers suggests that mercury from dental fillings makes the body more resistant to some antibiotics.

Yet some studies indicate that plastic fillings also may leak hazardous substances into the body, such as xenoestrogens that can disrupt cell activity, said Mackert, the professor and mercury supporter. "Everything has a theoretical risk," he said.

The U.S. Public Health Service says there is no evidence to support claims of adverse effects from mercury fillings except in cases of allergy.

A few countries, such as Sweden and Denmark, recommend that dentists try to use alternative fillings, especially for children and pregnant women. Arizona, California, Colorado and Maine have laws requiring dentists to explain potential mercury risks to patients, said Charles Brown, a lawyer with Consumers for Dental Choice. Brown, a former attorney general of West Virginia, has represented the group in lawsuits in California and Maryland contending that the dental profession threatens dentists who oppose mercury and deceives patients by referring to fillings as "silver."

Last year, the California State Assembly disbanded the state's dental board over the mercury issue. A state senator who took part in that action, Democrat Diane Watson, is now a U.S. representative and, in November, announced a bill calling for stricter warnings, an immediate ban on mercury fillings in children and pregnant women, and an eventual ban for everyone.

In February, the FDA announced a proposal to upgrade dental mercury from a Class 1 to a Class 2 medical

from 1 to 3 micrograms of mercury a day, while people take in 5 to 6 micrograms a day through food, water and air. The ADA prohibits its members from suggesting that patients have fillings removed, though members can comply if a patient requests it.

Mercury fillings have been used for at least 150 years, Mackert said.

"It is unethical to allow the removal of fillings for the curing of any disease, because there is no evidence linking it to systemic disease," he said. "It would be giving the patient a false hope."

A January survey by the Chicago-based Dental Products Report found that 20 percent of dentists no longer use mercury fillings. Among those who do, two-thirds use them in fewer than half the fillings they place.

Dentists who frequently remove mercury fillings, such as Dr. Ron Dressler of Norcross, usually do so for patients who are referred by doctors who treat chronic pain. The doctors run hair or urine tests to detect mercury levels, and high amounts lead to a suggestion to remove fillings.

Dressler performs another [the mercury] out of the body; it's been leaking into the body for years."

Merlin prescribes amino acids, herbs, vitamin C and intravenous drips of DMPS, a chelating agent. The treatments cost at least $1,000 over several months and often aren't covered by insurance. Health plans generally cover the cost of about $100 per mercury filling, but they often don't pay the additional cost of plastic fillings. Those fillings may run $150 or more.

'Time bomb' in mouth?

Many patients who have had their mercury fillings removed and undergone chelation say the process is worth the price. MacArthur, the ballroom dancer, had her fillings out nearly three years ago. Her nightmares and body twitches disappeared immediately, and her facial boils gradually went away.

"I had a time bomb ticking in my mouth," she said. "You could never convince me that it wasn't mercury."

Hyacinth Meeks, a patient of Merlin's, had a similar experience. Plagued by migraines that made her head throb when she walked even a block, Meeks became frustrated with mouth? Do you have symptoms of mercury poisoning?"

King was merely given a letter of reprimand, he said, and records show no official sanctions against him by the dental board. But to King, the don't-rock-the-boat message was clear. "They're afraid to let patients know what we're doing to them," he declared.

Conflicting research

The research is inconclusive, with studies both suggesting and seemingly refuting links to various ailments. The debate even divides institutions: One chemistry study at the University of Kentucky found a relationship between

device, which would require the makers of metal fillings to list all product ingredients on labels and encourage dentists and patients to report side effects.

Mackert said patients should ask their dentists about mercury fillings if they're concerned. Most dentists will say the fillings are safe and more durable than plastics, especially for large fillings, but they may grant a patient's request for an alternative.

And a sea change may be beginning. When Mackert needed repair of a tiny mercury filling a few weeks ago, he went with plastic.

ment-cutting machinery.

The existing U.S. garment industry is geared toward mass production, said Chui Tsang, dean of the School of Applied Science and

ness to overseas manufacturers unless it retrains employees to become high performance workers and retools to be competitive in a high technology environment."

S.F. May Forbid Dentists From Dumping Fillings

By Sabin Russell
Chronicle Staff Writer

Faced with stringent new requirements to cut discharges of mercury into the bay, San Francisco authorities are considering rules that would bar dentists from flushing ground-out tooth fillings down the drain.

Although the dental profession says the mix of silver and mercury used to fill cavities is harmless in the mouth, the Department of Public Works believes there is evidence that the same material could become toxic when it mixes with sewage.

Used tooth fillings amount to little actual waste, but the problem they now pose is not trivial to San Francisco dentists. Among the solutions under consideration in both San Francisco and Seattle is a requirement that each dentist's office install special centrifuges that remove all traces of mercury. Similar devices used in Germany cost between $2,000 and $4,000.

Dentists are not happy at the prospect. "It has been met with mixed enthusiasm," said Dr. Peter Jacobson, director of the Oral Medicine Clinic at the University of the Pacific School of Dentistry in San Francisco.

"The jury is still out on whether this is even a problem," said Mark Rubin, chairman of the American Dental Association's Amalgam Waste Task Force.

For more than 100 years, dental fillings have been made of an amalgam of about one-half mercury and one-half silver. Dentists say that, locked into this alloy, the mercury is harmless to patients.

But those attempting to clean up the nation's waterways are concerned that the alloy can break down in the caustic mixture of chemicals, cleaners and solvents found in urban sewage — potentially freeing the mercury to contaminate fish and wildlife.

A study by the San Francisco Department of Public Works found that dental amalgams made up between 8 percent and 13 percent of the mercury-containing waste coming into city treatment plants. Two-thirds of the treated waste is discharged into San Francisco Bay, and the rest is piped into the Pacific Ocean.

Daniel Rourke, water pollution prevention program manager for the public works department, said the effort to rid the sewer system of dental fillings is being driven by tough new standards that will limit the amount of mercury that city sewer plants can discharge into the bay. The limit is now a 30-day average of one part per billion mercury. The proposed new threshold is 0.21 parts per billion.

EAST BAY PEOPLE IN THE NEWS

Boy Scout Bert Thomas Jr., 18, of Oakland's Allen Temple Scouts, has attained the rank of Eagle Scout, the scouts' highest honor. Only about 2 percent of all Boy Scouts become Eagle

in Washington later this month. Hynes, a Moraga resident, will moderate the session, "Critical Issues in Deaning."

If you have information that could be in-

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MONDAY, OCTOBER 25, 1999

COLUMN ONE

A Debate on Mercury in Fillings

■ The highly toxic metal is part of the traditional mixture that's packed into cavities. Some dentists say it is no longer necessary, and that patients should be warned of possible dangers.

By AMY PYLE
TIMES STAFF WRITER

SAN FRANCISCO—Seated in dentist Robert Hepps' chair with a cavity in need of attention, you are sure to hear about the beauties of porcelain, and will probably see a gruesome video of teeth deteriorating around black metal fillings.

Hepps believes porcelain fillings are healthier for teeth and—since traditional fillings are half mercury—possibly for the rest of the body. He believes patients have a right to know that, and the law is on his side.

But the mild-mannered Hepps tiptoes around the health issue, focusing on porcelain's aesthetic advantages out of fear that total honesty could put his license at risk.

The problem is that despite California laws requiring full disclosure of the dangers of toxic substances, state dental regulators are committed to the use of mercury-based fillings. At a hearing last March, Board of Dental Examiners president Robert Christoffersen summarily dismissed mercury-free dentistry, saying it "does not fit the current practice of dentistry."

Christoffersen's statement kicked up a furor inside and outside the dental community. It unleashed the feisty Consumers for Dental Choice lobby group on California, where it has petitioned the Board of Dental Examiners to require dentists to warn patients about mercury's health hazards, sued the board alleging that it illegally discriminated against another dentist at the March hearing, and asked the state attorney general to get involved in the issue.

All three actions are aimed at heightening public awareness of the state's 1993 law requiring such warnings, and of the state Department of Consumer Affairs' assertions that not telling patients violates the anti-toxins initiative approved by voters 13 years ago.

The debate over what patients should be told and when has even injected free-speech issues into what is typically among the least controversial branches of health care.

"We have been really quite stunned; at least among the conservative dental establishment, there is active hostility to informing consumers," said James Wheaton, president of the Environmental Law Foundation in Oakland. Wheaton's firm was a lead plaintiff in lawsuits related to Proposition 65, the 1986 initiative that requires workplace warnings for the presence of toxic substances, including mercury.

At one extreme in the debate are the dental regulators, who take their cue from the American Dental Assn. It considers tradi-

Please see MERCURY, A10

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Mercury brochure at dentists' advised

Panel concerned about risks in fillings

By Michael O'D. Moore
Of the NEWS Staff

AUGUSTA — A legislative committee unanimously recommended ednesday that a brochure be cre- ed for dentist's offices to warn out possible health risks of fill- gs containing mercury.

Members of the Natural esources Committee supported s bill after hearing from state perts that scientific studies show at the fillings contribute to a per- n's mercury exposure even here's no conclusive evi- t the fillings cause harm. which still must be passed the Legislature, directs the reau of Health to develop the chure.

In many ways we are taking a at step forward compared to it's been done across the coun- said Sen. John Martin, D-Eagle e.

rances Millano, executive direc- of the Maine Dental Associa- , said the group would support ffort to have a brochure avail- for distribution. The MDA ts the brochure to be based on table science, and it wouldn't l including disclosure of the risks of other filling materials, she said.

Some types of mercury in high enough concentrations, have been shown to be harmful to the nervous system. It's particularly harmful to the young, whose systems are still developing.

At Wednesday's session, Dr. Andrew E. Smith, state toxicologist, said studies about the risks from the type of mercury in fillings haven't been conclusive. There have been contradictory results, and the size of the studies have been too small to be definitive, he said.

In an interview after the session, Smith said studies scheduled to be finished in the next two to three years should provide much better scientific footing to decide how serious the health threat is from fillings containing mercury.

Doing some rough calculations, Smith said that consuming one 6-ounce can of tuna per week equals the amount of mercury vapor ingested weekly by a person with several fillings containing mercury. The vapor is absorbed by the body even more readily than if a person swallowed mercury from a ther-

See Mercury, Page A10

Mercury

Continued from Page A1

mometer, he said during the hearing.

Because scientific investigators don't agree on the dangers of the type of mercury in fillings, there is much uncertainty, he said.

Smith helped develop state recommendations on the number of meals of freshwater fish caught in Maine that people should consume. Warm-water fish such as pickerel and bass contain more mercury pound for pound than cold-water fish such as trout and salmon. The recommendations also call for fewer meals of fish caught in Maine's fresh waters for women of childbearing years and children.

Dr. Dora A. Mills, director of the Bureau of Health, said with the scientific uncertainty, the bureau would not support banning mercury from fillings in Maine. But she said the bureau supports the idea of a brochure, which likely would be more effective than requiring a poster on the walls of dental offices describing potential dangers of the fillings.

A brochure, she said, could be crafted in a way to be understandable to the general public and would allow more space for an explanation of the risks and benefits of certain types of fillings, she said.

A couple of committee members, who quoted from studies they had highlighted, said the bureau and committee should go further in educating and protecting Mainers about the possible risks.

"I'm concerned it does not go far enough," said Rep. Joanne Twomey, D-Biddeford. She said she wants to at least protect pregnant women and young children, and she scolded Mills for not doing enough to protect the public from fillings.

She said that after reading the medical research about the possible dangers of mercury in fillings, in the future she would pay close attention to her grandchildren's dental work.

"When it comes time, I'm convinced you're not going to put [mercury] in their mouths," Twomey said.

"I am overwhelmed with the stories and the experiences that have come to us from basically around the world and from right here in Maine," said Rep. Christina Bakes, D-Bangor.

Twomey persuaded the committee to listen to Shannon Johnson of Harpswell, even though the public hearing was held the week before.

Johnson told the committee that her son has autism that she believes is linked to transmission of mercury from her fillings to him while he breast-fed.

"I would never have put mercury in my mouth [had I known]," she said.

Smith said after the meeting that he is unaware of any link between mercury fillings and autism.

Sen. Martin said that just as cancer and cigarettes weren't readily linked, mercury fillings and health problems long went undiscussed.

"When I asked my dentist a number of years ago what my fillings were, he said silver," said Martin. "I never heard the word mercury."

Martin said he expects dentists soon will voluntarily raise more details about the potential dangers of filling materials, if only to minimize legal challenges in the future.

BANGOR DAILY NEWS • THURSDAY, APRIL 12, 2001

Rising mercury

Despite protests from the American Dental Association, any country that seriously discusses doing away with mercury thermometers because of their potential impact on health cannot be long from restricting the use of mercury dental fillings. Congress will soon work on the question while Maine reviews LD 1409, a concept bill that seeks to examine the long-term effects of these fillings and the steps the state should take to protect residents and the environment.

For one expert who testified last week, the answers are clear. Dr. Boyd Haley, chairman of the Department of Chemistry at the University of Kentucky, concludes that normal body loads of mercury in older adults produce two diagnostic hallmarks for Alzheimer's disease. Further, he says, in a test for mercury in the blood and urine of more than 1,000 U.S. soldiers, the vast majority, more than 87 percent, was traced to dental amalgams. Further still, the primary source of mercury in wastewater treatment plants came through feces and urine of people with these fillings. That is, he and other reputable scientists are identifying dental amalgams as a major source of this toxin in humans and in the environment.

The ADA will have none of this. It says 150 years of dentistry show that the amalgams are not a problem, as evidenced by the dentists themselves who spend a career around these products. Individual dentists in Maine, however, sometimes tell a different story. They note that the alternatives to the mercury amalgams are more expensive but that they are safer for their patients, themselves and their staff, and for the environment. The Legislature's job in this case is not to start an argument among dentists but to look at the relative risk of mercury to the public and the level of importance of dental amalgams in contributing to that risk.

Mercury can be toxic to the nervous system. U.S. dentists, according to the U.S. Geological Survey, annually use a total of between 40 and 60 metric tons of mercury in their practices but other sources have attracted the attention of regulators. Bills in Congress would more tightly regulate mercury emissions from power plants and incinerators, would reduce mercury in light bulbs and eliminate it in thermometers, switches and other household products. Rep. Tom Allen, who has followed the mercury issue closely, will reintroduce a mercury-reduction bill after the congressional break that for the first time encourages states, communities, dentists and dental associations to work toward eliminating the mercury filling.

The potential for environmental damage alone would make mercury from dental offices endangered. A fair review of the studies of its human health effects by the Bureau of Health would take only several months. If the work by the bureau turns out as scientists like Dr. Haley suspect it will, lawmakers should begin a reduction and phase-out of this type of dental fillings.

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Neurobehavioral effects from exposure to dental amalgam Hg°: new distinctions between recent exposure and Hg body burden

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ABSTRACT **Potential toxicity from exposure to mercury vapor (Hg°) from dental amalgam fillings is the subject of current public health debate in many countries. We evaluated potential central nervous system (CNS) toxicity associated with handling Hg-containing amalgam materials among dental personnel with very low levels of Hg° exposure (i.e., urinary Hg <4 μg/l), applying a neurobehavioral test battery to evaluate CNS functions in relation to both recent exposure and Hg body burden. New distinctions between subtle preclinical effects on symptoms, mood, motor function, and cognition were found associated with Hg body burden as compared with those associated with recent exposure. The pattern of results, comparable to findings previously reported among subjects with urinary Hg >50 μg/l, presents convincing new evidence of adverse behavioral effects associated with low Hg° exposures within the range of that received by the general population.—Echeverria, D., Aposhian, H. V., Woods, J. S., Heyer, N. J., Aposhian, M. M., Bittner, A. C., Jr., Mahurin, R. K. Neurobehavioral effects from exposure to dental amalgam Hg°: new distinctions between recent exposure and Hg body burden. *FASEB J.* 12, 971–980 (1998);**

Key Words: behavior · elemental mercury · dentists · DMPS

THE CRITICAL TARGET organ of elemental mercury vapor (Hg°)[2] is the central nervous system (CNS) (1). Although there is little debate regarding the toxicity of exposure to Hg° associated with urinary Hg concentrations above 50 μg/l, no consensus exists with respect to a safe lower Hg° exposure level among either dental populations that handle Hg amalgam or the general population with amalgam restorations. Hg° exposures in this study are relevant to both groups, since they were assessed in a dental population but extend over a continuum of urinary Hg levels from 0 to 4 μg/l, comparable to the low exposure levels observed in the general U.S. population. General population levels provided by Dr. P. Factor (personal communication) and Dr. A. Kingman (2) range respectively from 1.3 to 18 μg/l (mean=9 μg/l creatinine corrected) and from 0 to 34 (mean=3.1 μg/l). Thus, this study addresses public health concerns for Hg° toxicity of dental amalgams.

Interpretation of health effects observed among people with Hg° exposures resulting in urinary Hg levels of less than 50 μg/l has previously been hampered by the inability to distinguish behavioral effects associated with recent exposure vs. those associated with chronic body burden. This study adopted a novel approach to distinguish between these effects by examining differences in behavior in relation to urinary Hg concentrations measured both before (prechelation) and after (postchelation) treatment of subjects with the Hg mobilizing agent, sodium 2,3-dimercapto-propane-1-sulfonate (DMPS). Urinary mercury levels (HgU) subsequent to DMPS challenge have been reviewed extensively (3, 4) and shown to constitute a better approximation of Hg body burden (5).

A central question is the validity of using prechelation HgU as a proxy for CNS dose. This indirect measure has been commonly accepted, because the lipophilic property and low vapor pressure of Hg° (0.005 mm Hg° at 37°C) permit 76–80% of the vapor to be absorbed through the lungs. The dissolved vapor is oxidized primarily in erythrocytes into mercuric ions by the hydrogen peroxide-catalase pathway (i.e., $Hg^0 \rightarrow Hg^{1+} \rightarrow Hg^{2+}$) (6). The oxidation process

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[2] Abbreviations: NES, Neurobehavioral Evaluation System; Hg°, mercury vapor; CNS, central nervous system; DMPS, sodium 2,3-dimercapto-propane-1-sulfonate; HgU, urinary mercury levels; POMS, Profile on Mood State.

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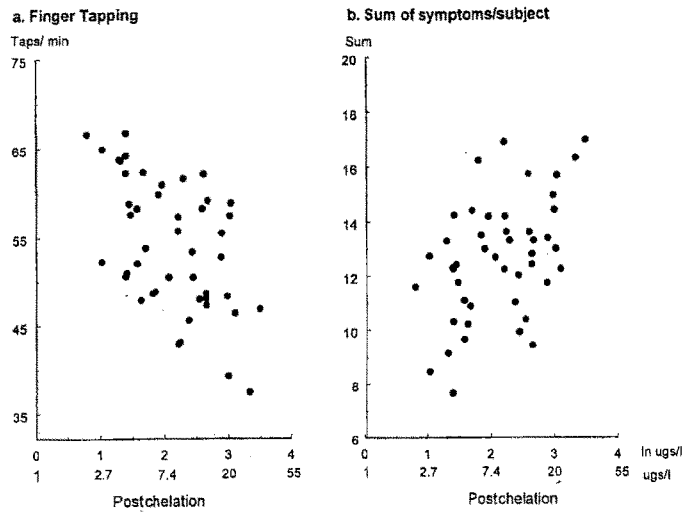

Figure 3. Exposure-effect relationships between postchelation HgU levels and the number of taps/min for finger tapping (*a*) and the sum of symptoms reported per subject (*b*).

tions with Hg body burden. These results suggest that distinctions between recent and long-term exposure could prove even more relevant at higher levels of exposure.

Unlike the other three behavioral domains, the cognitive regression models included the log SRT of the nondominant hand to control for potential misinterpretation associated with slowed motor response. Only one association was observed between Hg body burden and the number correct for word recognition memory, a measure of verbal memory. Associations with recent exposure were found for switching attention, a measure of selective attention; trailmaking parts A and B, measures of psychomotor speed and cognitive flexibility; and the Visual Retention Memory Test, a measure of visual memory. The subtle impairments across this set of cognitive tests suggest diffuse nonspecific alterations in task performance that are potentially associated with aspects of attention. These cognitive effects were selectively associated with recent exposure, with no detectable contribution from Hg body burden, whereas verbal memory was associated only with long-term exposure or Hg body burden, as measured by postchelation Hg levels.

The observed pattern of statistically significant results for prechelation HgU had coefficients that were relatively strong for POMS mood scores (median beta=0.45, range 0.29–0.56) and moderate for the more objective domains of motor function (median beta=0.42, range=0.30–0.55) and cognitive tasks (median beta=0.31, range=0.26–0.38) (see Table 2). Associations with postchelation HgU showed the standardized beta coefficients in each domain were also moderate for symptoms (median=0.31, range 0.28–0.32), relatively strong for mood though less pronounced than the prechelation coefficients for mood (median=0.40, range 0.36–0.42); moderate for motor function (median=0.30, range=0.25–0.30; and sparse but moderate for one cognitive task (beta=0.31). One interpretation of these variations in strength of associations between pre- and postchelation HgU is that urinary Hg from recent exposure is more likely to be available to the CNS and should be more strongly associated with preclinical effects, with less contribution from stored Hg as body burden.

Good occupational work practices further reduce urinary Hg levels given the behavioral effects associated with low levels of HgU (see Table 1). The variation of HgU in a national sample of 6925 dentists participating in the American Dental Association Health Screening Program was related to the variation in air Hg levels, and industrial hygiene surveys among dental offices show that 6–16% of dental practices exceed exposure levels permissible by OSHA

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is dose dependent in that low doses result in a higher proportion of Hg^{2+} in blood than do higher doses approaching saturation (7). Blood Hg levels in dental personnel populations range from 1.2 to 14 μg/l (8), well below saturation levels, assuring that the oxidative pathways in the kidney and brain are also below saturation. Thus, HgU varies with occupational Hg^0 exposure and provides an effective measure of current dose. With respect to the CNS, the rate of oxidation is slower than circulation time from the lung to the brain, allowing unoxidized Hg^0 to pass through the blood–brain barrier, where it is then oxidized to the divalent form (Hg^{2+}), complexed, and retained. Controlled radioactive Hg^0 inhalation studies in humans indicate that the brain retains Hg for approximately 21 days (9), providing for CNS accumulation and stabilization over approximately 1 month. This compares well to the 2 month half-life of Hg in urine. These factors have collectively supported the validity of using prechelation HgU as an indicator of CNS dose associated with recent subchronic Hg^0 exposure.

Behavioral studies that rely on prechelation HgU are necessarily limited to evaluations of recent exposure because of the relatively short residence or half-life of Hg in the urine compared with that accumulated in soft body tissues. Aposhian et al. (5) have demonstrated that administering DMPS at a dose of 300 mg p.o after an 11 h fast effectively mobilizes Hg from soft tissues, which is then excreted in urine over the subsequent 0–6 and 6–24 h periods. The postchelation HgU level reflects the decrease of Hg in both the kidney and cellular fraction of blood, suggesting that DMPS reduces the renal whole-body burden of mercury in humans (10). Examining CNS effects in relation to both pre- and postchelation measures in this study permitted differentiating CNS effects associated with recent subchronic Hg^0 exposure from those associated with body burden, which are attributable to more persistent long-term exposures.

Studies assessing CNS preclinical effects among subjects with urinary Hg concentrations in the range of 50–200 μg/l support four aspects of frank mercurialism (11): *1)* psychosomatic symptoms (salivation, insomnia, and loss of appetite); *2)* alterations in affect or emotional liability [mood swings, irritability, fatigue, loss of interest, withdrawal, and sweating and blushing (erethism)]; *3)* motor effects (in the arms, progressing to uncoordination, imbalance, and cerebella ataxia and tremor in muscles that are highly enervated and perform fine motor control of extremities such as fingers, eyelids, and lips); and *4)* insidious loss of mental capacity (progressively affecting memory, logical reasoning, or intelligence).

Occupational studies assessing urinary Hg^0 levels between 2 and 200 μg/l have demonstrated impressive consistency with the four aspects of mercurialism summarized above. Alterations of emotional state, mood, and symptoms have been the most frequently reported effects at HgU levels ranging between 30 and 100 μg/l (12–18). Six dental studies have previously examined mood (19–24) where scores on the Profile on Mood States (POMS) (25) and aggression were higher than controls, supporting our choice of using POMS in this study.

Deficits in motor function were first reported as finger tremor among felters and later as hand tremor among chloralkali workers (26). However, losses in hand steadiness, finger tapping (27, 28), and manual dexterity (29, 30) have also been reported at lower levels of exposure. Among dentists with mean urinary levels of 26 μg/l, statistically significant losses in performance in hand steadiness (known to be correlated with tremor) were also found (30). These studies support a comprehensive evaluation of motor function at even lower levels of exposure as a threshold level of effect remains to be determined.

Determinations of a lower threshold for cognitive effects are complicated by mixed results among several chloralkali worker studies at low exposure levels ranging between 0.025 and 0.076 mg/m^3 (10–19.9 μg/l in blood) (31–33). These conflicting results may be better addressed by studying more uniform subjects, such as dentists, who have similar economic and educational backgrounds. For example, our own pilot dental studies have detected a reduction in cognitive skills (22–24) similar to that seen in other dental studies (19–21). The largest dental study (19) conducted in Singapore examined 98 dentists and 54 nondentist controls, where mean exposures of 16.7 μg/m^3 Hg^0 in air were associated with differences in trailmaking, digit-symbol, digit span, logical memory delayed recall, and visual reproduction. Two other dental studies (20, 21) also found associations between chronic exposure with visuographic memory deficits by using the Bender-Gestalt (21) (one of four tests) and Rey's recurrent figures (20) tests (one of six tests), which also included the PASAT, Rey's AVL, finger tapping, and the grooved peg board. These findings support placing emphasis on the cognitive domain.

The evidence for potential impairment among the four domains provides the basis for test selection on an anticipated continuum between preclinical effects and clinical deficits. Along this continuum, a preclinical effect is defined as a subtle adverse change in performance not usually detected by clinical examination because the observed effect falls within the range of normal performance on tasks. However, preclinical effects can be demonstrated by showing that the variation in cognitive task performance, though well within the normal range, is correlated with exposure to Hg. Preclinical effects range between 3 and 18% when compared to a zero or low-exposure group. Deficits

exceeding 18% are likely to border on clinical significance, and effects of less than 2% are not likely be occupationally relevant (34).

The broad diversity in clinical effects coupled with the evidence from epidemiologic studies indicates more than one mechanism of toxicity is involved, covering several areas of the brain. Consequently, we base our behavioral hypothesis on the results discussed above, which suggest that low-level Hg^o exposures may increase symptoms, alter mood, decrease manual coordination, increase tremor, and cause deterioration of cognitive skills requiring visual-spatial memory and attention. We consider adverse effects on these four domains to be selective, leaving language and retrograde memory largely intact. This justifies the use of each subject's vocabulary score as an available measure of premorbid intelligence or a 'hold test' not expected to be adversely affected by exposure. Our test battery was designed to cover the four domains with adequate redundancy to detect subtle effects and to discriminate between areas resistant to Hg insult. Tests were selected for their sensitivity to Hg^o; their ability to be adapted for joint human/animal assessments, which provides a broader understanding of the results; previous validation by the World Health Organization (35) and the Agency for Toxic Substances and Disease Registry (ATSDR) (36); and use in quantifying neurotoxic effects attributable to low-level exposures.

MATERIALS AND METHODS

The study population and test procedures

Thirty-four practicing dentists and 15 dental assistants were selected to participate in this study. The study group was administered a pretest questionnaire that medically screened subjects for preexisting clinical disorders that may interfere with performance on the test battery such as physical injury, diabetes, epilepsy, alcoholism, multiple sclerosis, encephalitis, manic depression, and use of medications that produce drowsiness or otherwise affect performance. Two subjects were eliminated: one was diabetic, the other was an alcoholic. The study population was predominantly male (69%), Caucasian (92%), middle-aged (mean age=49), native English speaking, right-handed (88%), and consumed a moderate number of alcoholic beverages per week (n=8, SD=4.5). This dental population is an ideal study population; with characteristics that improve detection of subtle preclinical effects, as they have Hg^o exposures within the range of interest (prechelation HgU < 4 μg/l), are highly educated, have excellent test-taking skills, and have well-developed motor skills.

Prior to the DMPS challenge, participants signed a consent form in accordance with the Declaration of Geneva of the World Medical Assembly, and completed a questionnaire covering occupational and medical work histories and work practices (37). Subjects also completed an assessment of symptoms and the POMS. This process was followed by a 1 h test battery described in greater detail below. After the test session, participants were administered DMPS (300 mg, p.o.) after an 11 h fast. Urine was collected from −11 to 0 h prechelation and from 0 to 6 h postchelation. Test administrators were blind with respect to subjects' HgU status.

The behavioral test battery

The test battery described below evaluated symptoms, mood, motor function, and cognition, using the Neurobehavioral Evaluation System (NES) vocabulary score (38) as an estimate of premorbid intelligence.

Symptoms (22)

The symptom questionnaire was adapted from several previous questionnaires that were designed to evaluate potential CNS effects of mercury. Responses to persistent symptoms that last for more than a year were collected on a continuous scale that permits evaluations of both the extent and severity of symptoms among subjects.

Profile of mood states (25)

The self-administered mood scales include 65 mood descriptors, which are rated on a 5-point scale from 'none at all' to 'extreme'. The items comprise six mood scales: total mood (sum of all mood scales except vigor), tension, depression, anger, fatigue, and confusion.

The hand steadiness battery (39)

This task requires subjects to place pins in a series of holes with decreasing diameters in a prescribed manner as quickly as possible, where the number of hits and latencies for eight holes are recorded.

Simple reaction time NES (38, 40)

This computerized NES task requires subjects to press a button with the index finger of the right and left hands every time a stimulus appears on the screen.

Finger tapping NES (38)

This computerized NES task measures motor quickness and accuracy. It requires subjects to tap a button as many times as possible in 10 s under three conditions (dominant index finger, nondominant, and alternate two-button tap with dominant index finger).

Tremor Analysis Test System: acceleration finger tremor (41)

The subject was asked to keep still for three 10 s trials, with a 15 s rest period between trials. Resting tremor (of the dominant and nondominant hands) was recorded by a two-axis microaccelerometer embedded in the tip of a 12 cm × 0.8 cm pencil. The accelerations are normalized by using Fourier analysis to get the power distribution in the frequency band of 0.9–15 Hz. The tremor spectra show absolute and relative power over the range in 0.2 Hz bands, encompassing the 6.5 Hz region previously found to be affected by mercury. Tremor intensity was determined by the root-mean-square of accelerations over the data collection period. The accelerometers have a sensitivity of 85 mV per Gauss and a frequency response rate of 1–830 Hz. A sample rate of 60 Hz reduces noise from power lines. The fast Fourier transform used a sample size of 512. At 60 Hz, each sample of 512 requires 8.53 s of data col-

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lection, which is amplified, processed, and transferred to a portable IBM-compatible computer.

One-hole pins (pins/min) (42)

This computerized task requires subjects to place pins in a hole in a prescribed manner as fast as possible for five 1 min trials. The posture of the subject is controlled by having the dominant hand pick up pins while the other is resting on a fixed plate. Secondary measures include the time to 'grasp', 'move', 'position', and 'reach' for each pin.

Vocabulary NES (38)

The NES computerized test is a modification of the Armed Forces Qualifying Test. Twenty-five words are presented by computer, and the subject is asked to select, from a set of four words, the synonym for the word originally presented. This 'hold' test was not expected to vary with Hg exposure, and serves as a measure of premorbid intelligence and user schooling.

Recognition memory test (for words) (43)

This is a word memory test in which subjects are asked to correctly recall 50 words that are administered in a fixed sequence.

Trailmaking A and B (44)

This paper-and-pencil test is an executive function task assessing cognitive tracking. In A trails, the subject must track a numeric sequence on a spatial array. In B trails, the subject must alternate meaningful sequences of numbers and letters on a spatial array. Both tasks were scored for the number of errors and response time.

Visual retention test NES (38)

The NES computerized test requires the subject to memorize a picture and then select the correct one of four possible choices. Over the course of 12 trials, the pictures become more complex. This test is a computerized version of the Benton Memory Task.

The switching task (45)

This computer-presented task requires subjects to press a 'same' or 'different' button when confronted with a pattern comparison, semantic letter comparison, or semantic graphical comparison. Items are presented in apparent random order, but actually follow a complete Latin square procedure balanced for residual effects. This test modifies the traditional design by inserting extra trials to achieve greater stability of the estimates of switching between tasks and to avoid the ability of subjects to predict the next task. These additions provide a total of eight repetitions for the six switching combinations and between 10 to 16 repetitions for the three control conditions.

Symbol-digit NES (38)

This coding task requires the subject to enter the number that matches a symbol by using a matched set printed at the top of the screen. The task requires fine manual dexterity, visual scanning, and motor speed. A visual memory component increases performance speed if used by the subject.

Exposure to urinary mercury

HgU was analyzed by using cold vapor atomic absorption (5). Both occupational and nonoccupational sources of Hg exposure were covered in questionnaires, including the number of amalgam fillings in the subject's mouth and seafood consumption. Hg speciation analysis revealed that organic intake of Hg was negligible. Personal habits and detailed work practices were later used in regression models to determine factors predicting HgU levels.

Statistical methods

Multiple regression was used to evaluate log-linear, dose-effect behavioral relationships for pre- and postchelation urinary Hg values, controlling for age, race, gender, vocabulary, alcohol consumption, and wearing of eyeglasses (46). Regression models for cognitive outcomes also included the log SRT of the dominant hand to control for motor subcomponents of the cognitive tasks. Summary factor scores (30) were created to reduce multiple outcomes to single scores on select tests with enhanced reliabilities (hand steadiness, finger tapping, tremor, and switching attention). Paired t tests between pre- and postchelation HgU coefficients were used to evaluate whether the two dose measures differed significantly in predicting specific test performance. Standardized beta coefficients are a partial correlation coefficient, indicating the unique variance associated with each measure of exposure when all other variables in the model have been accounted for (47). Standardized beta is a metric that can be appropriately compared across independent variables and different domains.

RESULTS

Work-related and personal factors (including postchelation HgU levels and number of amalgam fillings in one's mouth) were determinants of prechelation HgU levels

There was an order of magnitude difference between pre- and postchelation urinary Hg concentrations (**Fig. 1**). The correlation between the two samples ($r=0.53$), although significant, indicated that different parameters were being assessed, given very high reliabilities of urinary Hg assessments across a day in a previous report (27, 28). HgUs of the dentists and dental assistants did not differ pre- or postchelation (prechelation: dentists=0.89 μg/l, SD=0.51; dental assistants=1.07 μg/l, SD=0.93; postchelation: dentists=10.08 μg/l, SD=7.37; dental assistants=8.07 μg/l, SD=5.99). Several work-related factors that are amenable to intervention were significantly associated with prechelation HgU as well as one personal source of exposure (**Table 1**). These factors include the number of restorations placed per week, the use of dispensers vs. capsules, and the irregular use of a mask while handling Hg, as well as the number of

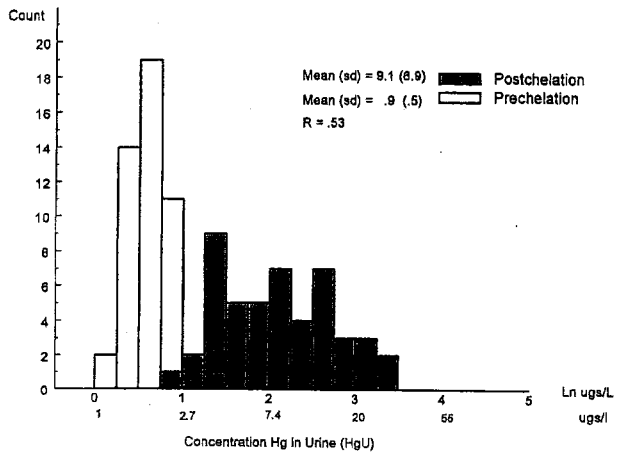

Figure 1. Histograms of pre- and postchelation urinary mercury levels (HgU).

amalgam fillings in one's mouth. All personnel wore gloves.

Pre- and postchelation HgU levels result in distinct patterns of preclinical effects, providing evidence of associations with recent exposure and chronic body burden

The patterns of association between symptoms, mood, motor function, and cognition with pre- and postchelation urinary Hg measures were distinct. Standardized beta coefficients for pre- and postchelation urinary Hg levels showed that all four domains were associated with Hg^0 exposure (**Fig. 2**). However, an overview of standardized betas indicates that the relative sensitivity of the two urinary measures differed considerably for individual tests.

Persistent symptoms involving memory and headaches, lightheadedness, and dizziness were selectively associated with postchelation HgU (**Table 2**). In contrast, transient mood scores were associated with both pre-and postchelation HgU values, where the associations for all five mood scales were robust and uniformly associated with prechelation HgU (exceeding all other test scores).

The motor function results showed that finger tapping is also more strongly associated with prechelation HgU, but has a lesser statistically significant association with Hg body burden. Hand steadiness had mixed associations with pre- and postchelation HgU levels, but differences in the strength of the association between recent exposure and Hg body burden were less pronounced (beta=0.39 vs. beta=0.30, respectively). Resting tremor, a clinical measure frequently found affected in cases of severe neurodegenerative disease, was not affected as anticipated.

In contrast, cognitive function as measured by switching attention, trailmaking A and B, and visual retention memory was selectively associated with prechelation HgU. One exception to this trend was the number correct in the Word Recognition Memory Test, the only test dependent on words and memory, which was associated with postchelation HgU. Symbol-digit response time was not associated with either measure of exposure to Hg.

The log-linear relationships throughout the range of postchelation HgU values are illustrated by finger tapping (right/left/alternate number of taps) and the total number of symptoms associated with postchelation HgU (**Fig. 3**). No evidence of a threshold of effect appeared across the body of our results; relationships were smooth and generally conformed to a log-linear trend (i.e., there was no evidence of subpopulation clustering).

DISCUSSION

This is the first behavioral study to distinguish recent Hg exposure from Hg body burden when examining subtle changes in preclinical behavior associated with very low levels of Hg^0 exposure. The results are striking in that statistically significant dose-effect relationships were found with prechelation HgU (ranging

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TABLE 1. *Work-related and personal factors associated with prechelation HgU*[a]

Factors	Mean	SD	$b_{U\text{-}HgU}$	SE	β
Postchelation HgU	9.1	6.9	0.16	0.04	0.43***
No. of amalgams placed/wk	16.1	8.2	0.01	0.00	0.34***
Do not wear a mask (7/49)	15%		0.38	0.12	0.32***
No. of amalgams in own mouth	1.6	0.8	0.08	0.03	0.25**

[a] The mean and standard deviation for each factor in the model is accompanied by the regression coefficient for prechelation HgU, the standard error, the standardized Beta coefficient that presents the unique partial correlation for each factor in the model, and the level of significance. Even controlling for Hg body burden does not eliminate the importance of associations between recent exposure, current work-related factors, and the number of amalgams in one's mouth. *** $P < .005$, ** $P < .05$; full model $R^{2l} = 0.61$.

from 0 to 4 μg/l) and postchelation HgU (ranging from 1 to 32 μg Hg/l). These prechelation HgU concentrations were previously thought to be trivial in terms of potential health risks. The modest correlation between pre- and postchelation HgU measures (6) supports the view that the Hg present in body tissues may contribute to apparent associations with recent exposure, as measured by prechelation HgU.

Similar increases in symptoms (12–23), alterations in mood (19–24), reduction in speed and accuracy in motor function (20, 21, 24, 30), and subtle losses in memory and visuospatial cognitive skills (19–23) have been reported in studies of dental professionals (highly consistent with our present findings). However, mean urinary Hg levels among subjects in these studies was higher (>20 μg/l) than found among

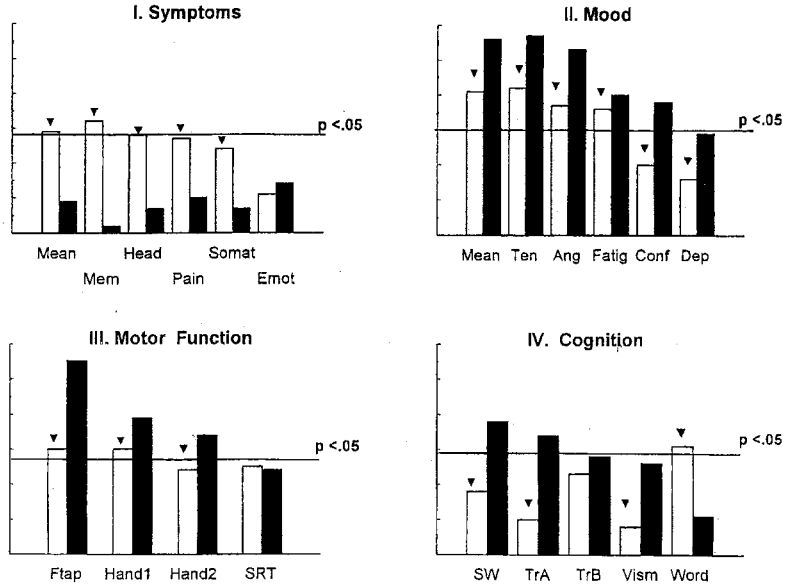

Figure 2. A comparison of standardized beta coefficients across regression models (a partial correlation coefficient) for pre- and postchelation HgU levels in regression models evaluating symptoms, mood, motor function, and cognition. Statistical differences between the two urinary measures are noted by (▼) where the dark bars represent postchelation HgU levels; the horizonal line reflects the significance level at a $P < 0.05$ for each association for both pre- and postchelation HgU levels (n=48).

TABLE 2. *Associations for pre- and postchelation urinary mercury (HgU) values with symptoms, mood, motor function, and cognition*[a]

Test variable	Prechelation HgU					Postchelation HgU		
	Mean	SD	b_{lnHg}	SE	β	b_{lnHg}	SE	β
Symptoms								
Mean number of symptoms/subject	0.30	0.13	2.44	4.37	0.09	0.005	0.03	0.29*
Memory	1.39	1.22	2.59	19.52	0.02	14.63	6.91	0.32**
Headaches, lightheaded, dizzy	2.39	1.33	7.12	15.27	0.07	10.88	5.46	0.28**
Mood (POMS)								
Total mood	11.65	4.82	−11.21	2.80	−0.56***	−3.07	1.15	−0.41**
Tension	3.04	1.40	−3.33	0.83	−0.57***	−0.91	0.34	−0.42**
Anger	2.08	0.92	−1.97	0.52	−0.53***	−0.51	0.21	−0.37**
Fatigue	2.15	2.15	−3.57	1.14	−0.40**	−1.18	0.44	−0.36**
Confusion	0.12	0.33	−1.19	0.45	−0.38**	−0.23	0.20	−0.20
Depression	2.02	0.98	−1.14	0.63	−0.29*	−0.24	0.24	−0.16
Motor								
Finger taps[+] (right/left/alternate)	61.1	9.1	−2.66	0.71	−0.55***	−0.49	0.27	−0.30*
Hand steadiness[+,L] (7, 8, 9 hole/s)_1	5.80	13.70	1.08	0.41	0.39**	0.28	0.15	0.30*
Hand steadiness[+,L] (7, 8, 9 hole/s)_2	5.80	13.70	1.15	0.54	0.34**	0.27	0.19	0.24
Simple reaction time[+,L] (R/L s)	0.355	0.039	1.07	0.70	0.24	0.38	0.23	0.25*
Resting tremor[L] (center frequency)	6.98	0.97	0.31	0.29	0.25	8.19	8.85	0.26
One-hole pins (pins/min)	34	6	−0.001	0.17	−0.01	−0.27	1.75	−0.03
Cognition								
Visual processing/attention								
Switching attention[L] (ms)	0.792	0.198	1.58	0.76	0.38**	0.17	0.30	0.18
Trails A (s)	26.20	7.60	10.13	4.56	0.34**	1.14	1.93	0.10
Trails B (s)	66.10	22.32	25.99	15.22	0.28*	7.99	5.84	0.23
Visual retention test[L] (number correct)	5.30	1.50	0.27	0.13	0.26**	0.03	0.05	0.08
Symbol-digit time[L] (s)	22.60	4.20	0.11	0.09	0.16	0.01	0.03	0.03
Verbal processing/attention								
Word memory (number correct)	47.60	2.90	−1.37	1.96	−0.11	−1.38	0.71	−0.31*

[a] Symptom, mood, and motor function regression models include vocabulary, age, gender, race, alcohol, and wearing of glasses; cognitive regression models include simple reaction time (dominant hand), vocabulary, age, gender, race, alcohol, and wearing of glasses. [+] Factored scores; [L] log transformed. * $P < 0.10$, ** $P < 0.05$, *** $P < 0.01$.

subjects with comparable preclinical effects reported here. Likewise, comparable CNS effects have been consistently reported among subjects with urinary Hg levels above 50 µg/l (1, 11). These studies collectively support our prechelation HgU behavioral findings in each domain and point to a potential log-linear continuum of health effects from low to high Hg exposure.

However, questions remain unanswered concerning the lower threshold of Hg^0 exposure for behavioral effects, as we found no indication of a lower boundary in any of our subjective or objective results (see Fig. 3). This inability to detect a threshold exposure level strengthens the hypothesis that subtle preclinical effects found at very low levels of Hg^0 exposure appear on a continuum with the far more severe clinical deficits. Of equal importance, we also found no evidence of special susceptibility within a subset of this dental population. Behavioral responses typically increased with exposure in a fairly uniform manner, indicating a more general response, as illustrated in Fig. 3.

The patterns of subjective responses associated with HgU differed. Persistent symptoms that appear over a year were selectively associated with Hg body burden; this finding suggests that symptoms may remain undetected in evaluations that rely solely on prechelation urinary measures of Hg^0 exposure. In contrast, the more transient nature of the POMS was found to be more strongly associated with recent exposure, with a smaller but statistically significant contribution from Hg body burden. This pattern suggests that prechelation HgU levels, which are partially dependent on the 2-month half-life, are more strongly associated with mood; one may speculate that the amount of Hg stored as body burden is less associated, as it may be biologically less available to the CNS.

This study comprehensively assessed fine manual speed, accuracy, and coordination, measures of particular relevance for dental professionals who work with handheld tools. Among the five motor function tests, individual and factored performance scores for finger tapping and hand steadiness were also associated with recent exposure, as measured by prechelation HgU. The standardized beta of −0.55 for finger tapping was comparable to a beta of −0.56 for total mood, indicating a relatively strong association. Similar to the results for mood, performance on both motor tests also had smaller but detectable associa-

(37). This reinforces the need to comply with industrial hygiene guidelines in dental offices.

The distribution of HgU in the national HgU sample had a range of 0 to 104 μg/l and was not distributed normally: 10% had levels >10.4 μg/l, 3% had levels >18.8 μg/l, 2.5% had levels >20.4 μg/l, and 1% had levels >33.4 μg/l. In this study, our mean prechelation urinary Hg concentration of 0.94 μg/l (SD=0.50) corresponds to the lowest 10th percentile of dentists in the United States. Further, as noted earlier, general population HgU levels (P. Factor, personal communication; ref 2) overlap with these occupational levels, supporting a public health concern for very low-level Hg^0 toxicity.

Concern for very low-level Hg^0 toxicity is supported by our observations of associations at HgU levels well below the proposed biological standard of 25 μg/l (16, 17) and below urinary levels that would be expected at the OSHA permissible exposure limit of 50 μg Hg^0/m^3 in air (48). The low Hg^0 exposures between 0 and 4 μg/l were partially attributable to the number of Hg amalgam fillings in the dental group (as seen in Table 1). The apparent association between HgU and personal risk factors argues for future studies to examine the potential for similar adverse effects in the general population from Hg amalgam fillings. Some might argue that the present findings have immediate implications regarding the continued use of Hg amalgam in dental restorations (49). We are divided on this issue, inasmuch as there are currently unanswered toxicological questions regarding chronic Hg body burden, dose-rate, and potential differences in modality of exposure derived from amalgam restorations alone. Two clinical trials regarding the safety of dental amalgams among children, a potentially more susceptible population, will not be completed for several years (50). Nevertheless, it is clear from the present study that comparing associations with pre- and postchelation urinary Hg levels revealed patterns of previously unobserved effects. These would not have been identified if they had been evaluated in relation to the traditional prechelation urinary Hg levels alone. Thus, the DMPS chelation technique enhances interpretation of observed associations with low-level cumulative Hg^0 exposure.

In conclusion, by using an approach that distinguishes recent Hg exposure from Hg body burden, we have observed subtle associations between Hg and symptoms, mood, motor function, and nonspecific cognitive alterations in task performance in an occupationally exposed group with HgU levels comparable to the general U.S. population. Application of this approach may be particularly useful in defining thresholds of Hg^0 toxicity and for establishing safe limits of exposure to mercury from dental amalgam material, the restoration itself, diet, and other sources. EJ

Supported by National Institutes of Health grants DE11712, ES04696, ES04940, and by the Wallace Research Foundation. Support was also provided by the University of Washington Center for Ecogenetics and Environmental Health (P30 ES07033). We thank Heyl Co., Berlin, Germany, for the gift of DIMAVAL® (DMPS).

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Received for publication December 1, 1997.
Revised for publication March 27, 1998.

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Neurotoxicology and Teratology, Vol. 20, No. 4, pp. 429–439, 1998
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0892-0362/98 $19.00 + .00

PII S0892-0362(98)00006-3

Behavioral Effects of Low-Level Exposure to Hg^0 Among Dental Professionals: A Cross-Study Evaluation of Psychomotor Effects

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Received 13 June 1997; Accepted 13 January 1998

BITTNER, A. C. JR., D. ECHEVERRIA, J. S. WOODS, H. V. APOSHIAN, C. NALEWAY, M. D. MARTIN, R. K. MAHURIN, N. J. HEYER AND M. CIANCIOLA. *Behavioral effects of low-level exposure to Hg^0 among dental professionals: A cross-study evaluation of psychomotor effects.* NEUROTOXICOL TERATOL 20(4) 429–439, 1998.—A cross-study design was used to evaluate the sensitivities of five psychomotor tasks previously used to assess preclinical effects of low-level Hg^0 (urinary ≤55 μg/l). Pooling dental professional subject populations from six studies conducted over the last 6 years, a larger study population was obtained with a high degree of uniformity (N = 230). The five psychomotor tests were: Intentional Hand Steadiness Test (IHST); Finger Tapping: The One-Hole Test; NES Simple Reaction Time (SRT); and Hand Tremor. Multivariate analyses were conducted following the hierarchical analysis of multiple responses (HAMR) approach. First, multiple scores of each test were combined into a single-factor (or related summary) variable and its reliability was estimated. Second, multiple regression analyses were conducted including log-transformed [Hg^0]U levels, age, gender, and alcohol consumption in each model. Computed were both B and b_{ss}, the magnitudes of the log-Hg^0 standardized coefficient, respectively uncorrected and corrected for dependent variable attenuation due to unreliability. Results indicated remarkable differences in the effects of relative level of Hg^0 on psychomotor performance. Significant associations were found for the IHST factor (B = 0.415, $p < 10^{-6}$), followed by finger tapping, which was relatively meager and insignificant (B = 0.141, p = 0.17). The IHST results hold the greatest occupational relevance for dental professionals who rely on manual dexterity in restorative dentistry. Further, this statistical approach is recommended in future studies for condensation of multiple scores into summary scores with enhanced reliabilities useful in correcting for attenuation relationships (B_{ss}s) with exposure levels. © 1998 Elsevier Science Inc.

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OCCUPATIONAL studies assessing urinary Hg^0 levels between 50 and 200 μg/l have demonstrated impressive consistency with the four domains of mercurialism (37). Specifically, these include: 1) increases in psychosomatic symptoms (salivation, insomnia, and loss of appetite); 2) alterations in affect or emotional stability (mood swings, irritability, fatigue, loss of interest, withdrawal, sweating, and erethism); 3) insidious loss of mental capacity (progressively affecting memory, logical reasoning, and intelligence); and 4) motor effects (in the arms, progressing to uncoordination, imbalance, and cerebella ataxia, and tremor in muscles that are highly enervated and perform fine motor control of extremities such as fingers, eye-

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EXHIBIT 2

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lids, and lips) (17). Some studies also report visual disturbances that could impact psychomotor performance at higher levels (8). These four domains provide the clinical basis for test selection on an anticipated continuum between preclinical and clinical effects, where a preclinical deficit is defined as an adverse change in performance that is not usually detectable by a clinical exam. Preclinical effects of Hg^0 have been typically observed to range between 3% and 18% when compared to a zero or a low-exposure group (1,2,9,12–14,18). The current article focuses on the psychomotor domain as the first in a series of across-study evaluations that will address preclinical effects on each of the four domains (symptoms and mood domain reports in preparation).

Deficits in motor function were first reported as finger tremor among felters (27) and later as hand tremor among chloralkali workers (32). These findings were confirmed with more sophisticated acceleration tremor and surface electromyography (EMG) measures (11,24), supporting a biological action level of 100 μg/l. Similarly, EMG and peripheral nervous system (PNS) disturbances (4) have also been associated to mean urinary Hg levels about 93.4 μg/l (SD = 30.4). However, deficits in hand steadiness, finger tapping (22,28), and manual dexterity (22,39) also have been reported at lower levels of exposure. Even workers with remote exposures (15–25 years earlier) with urinary Hg levels of 171 μg/l (2) had some residual deficits in acceleration tremor and manual dexterity. Between 50 and 100 μg/l, finger tremor (15) still appears more sensitive to Hg^0 exposure than hand tremor or coordination (22,29). Performance on the less sensitive Santa Anna dexterity test appeared worse (although not statistically significant) among subjects exposed at the 50 μg/l level (33) than among referents, suggesting that poor coordination and lower speed may occur at low exposures.

Among dentists with mean urinary levels of 26 μg/l significant deficits in hand steadiness have been found (9). Deficits in electrophysiologic tests, indicating slower aural sensory (of 2 ms^{-1}) and median motor (of 2 ms^{-1}) conduction velocities also have been reported among dentists, though these results are less impressive, as reported differences were within the range of the control subjects (31). These studies generally support a comprehensive evaluation of motor function at even lower levels of exposure where a threshold level of effect remains to be determined. This evidence has led to use of selected sets of psychomotor tests across six studies conducted over a period of 6 years (Table 1). Four of these, it is noteworthy, were conducted at annual meetings of the American Dental Association (ADA 1991 to 1995) and two were conducted in conjunction with chelation studies (U of A 1995 and 1996). Taken together, these studies provide substantially greater numbers of subclinically exposed dental professionals than any of the single constituent studies. Cross-study analyses of the data consequently provide an important opportunity to both explore and evaluate the relative use of psychomotor tests for detection of preclinical effects of Hg^0.

The primary goal of this article is to compare the relative sensitivities of five psychomotor tests for detection of adverse preclinical psychomotor effects attributable to low-level Hg^0 across a body of six studies. A second goal, within the context of these studies, is to explore the effects of test reliabilities on sensitivity and test utility. The overall objective is to provide a methodological basis for selecting psychomotor measures for study of the preclinical effects of Hg^0.

METHOD

This section describes six methodological aspects in turn. Delineated in the first section are the study designs of both the current across-study investigation and the six constituent studies (outlined in Table 1). The second section describes the subject populations of both the constituent and present overall study. In the third, fourth, and fifth sections, the urinary mercury, performance, and medical personal habits assessment methods are characterized. This characterization includes procedures employed in the constituent studies as well as the psychomotor test battery from which the constituent studies generally drew. Data analysis methodology is presented in the sixth section.

Study Design

A cross-study design was used to evaluate the sensitivity of and intercorrelation between five psychomotor tasks previously used to assess preclinical effects (Table 1). This design is consistent with several guiding principles. First, by pooling similar dental professional subject populations across six studies, we have comprised a larger study population with a relatively high degree of uniformity. This serves to amplify the

TABLE 1
LIST OF PSYCHOMOTOR TASKS ADMINISTERED TO EACH STUDY POPULATION AND THE DISTRIBUTION URINARY Hg FOR EACH TASK

Study	Psychomotor Task				
	Finger Tapping	Hand Steadiness	Hand Tremor	One Hole	Simple Reaction Time
ADA 1991 (n = 33)				+	+
ADA 1992 (n = 28)				+	+
ADA 1993 (n = 49)	+	+			
ADA 1995 (n = 75)		+	+		
U of A 1995 (n = 25)	+	+		+	+
U of A 1996 (n = 20)	+	+	+		+
<1 μg Hg/l	46	52	42	46	53
<20 μg Hg/l	22	74	41	6	19
>20 μg Hg/l	26	43	12	34	34
Total number of subjects	94	169	95	86	106

ADA = American Dental Association; U of A = University of Arizona, Tucson.

ibility of detecting preclinical psychomotor effects. Sec- an exposure gradient is studied instead of the more trou- esome comparisons with a control group that may differ from the exposed group in unknown and unmeasured ways. As such, this study design provides for estimation of dose–effect relationships using a relatively large, uniform group. Finally, this study builds on a consistent set of well-characterized measures of psychomotor function, delineated in the description of the psychomotor test battery, that had been previously selected based on earlier clinical and epidemiological study results (13).

Table 1 lists the six studies from which data were extracted and compiled. Each of these studies, conducted between 1991 and 1996, had psychomotor assessments administered by our colleagues or us. For each of the studies, salient institutional human subjects use committees successively and independently reviewed the research protocols [i.e., for the ADA 1991 to 1995, Battelle and University of Washington (UW); and for U of A 1995 and 1996, University of Arizona, UW, and Battelle]. The bottom row of the table shows the enhanced numbers of screened subjects across all six studies by psychomotor task. These enhanced samples provide for significant increases in the power and sensitivity of subsequent analyses to detect potential psychomotor effects of Hg^0 exposure.

The first four studies listed in Table 1 (ADA 1991, ADA 1992, ADA 1993, and ADA 1995) were stratified cross-sectional studies conducted as part of the ADA Health Screening Program. This program, it is noteworthy, is offered to all members of the ADA who attend annual sessions. A voluntary spot sample urinary mercury analysis, with the concentra- (μg/l) usually available within an hour of collection, has a routine component of the program. At the 1991, 1992, 993, and 1995 annual sessions our research group was invited o conduct a behavioral assessment battery among a selected group of dentists participating in the screening program. A battery, which included several tests of psychomotor function, was administered to assist in the determination of the health significance attributable to urinary mercury levels.

Urinary mercury levels were quantified on-site and names of eligible subjects with both criterion and nondetectable levels were posted at the exit gates. For ADA 1991, ADA 1992, and ADA 1993, dental professionals with urinary Hg levels of 20 μg/l or greater were asked to participate, along with an equal number of randomly selected subjects with nondetectable urinary mercury levels. In ADA 1995, the study goal was to test as many subjects as possible, with special attention aimed at testing those individuals with urinary Hg levels above 20 μg/l. In all ADA studies, persons who agreed to participate—after a standardized briefing on the performance testing—were directed to the test area and a time was arranged for completion of a 1-h test battery. During the assessment period, each participant signed the voluntary consent form and brief medical and work history questionnaires, followed by the behavioral battery. Both test administrators and test participants were blind with respect to participants' urinary Hg levels. Subjects were informed of their exposure status after completion of the 1-h assessment (exit letters later provided health screening results to all participants). Participation by all subjects consequentially was informed and completely voluntary.

Dr. V. Aposian at the University of Arizona conducted the aining two studies listed in Table 1 (U of A 1995 and U of 996). Each study was conducted over a 2-day period and volved urinary Hg determinations for each subject as well as completion of a behavioral test battery similar to that used in the previously described ADA studies. Each test session consisted of signing a voluntary consent form subsequent to informing the volunteers on the methods, procedures, and risks of the study, completing a brief medical and work history questionnaire, and completing the behavioral test battery. However, unlike the ADA studies, participation of subjects was not dependent on the individual's urinary Hg level.

Subjects

Table 2 presents demographic data for each of the six constituent study populations as well as the compiled data for the composite population (bottom row). As can be seen, the studies were conducted in a variety of locations throughout the US. The number of participants in each study varied from 20 to 75, resulting in an overall study population of 230 subjects.

The mean participant age also varied slightly from study to study, from 46 to 53 years, cumulating in a composite population mean age of 50 years. Five of the six study populations were comprised predominately of males, reflected in the overall percentage of males equal to 81%. A comparison of exposure across studies reveals that three of the six studies (ADA 1991, ADA 1992, ADA 1993) had an even percentage of subjects above and below 20 μg/l urinary Hg. As discussed above, this is consistent with the design of these studies, which specified that half of the tested participants have urinary Hg levels above 20 μg/l and half below this level. The remaining three studies (ADA 1995, U of A 1995, U of A 1996) did not impose these exposure stipulations on their study populations, reflected by the disproportionate percentage of subjects with urinary Hg levels less than 20 μg/l. Figure 1 portrays the overall distribution of subjects by urinary Hg^0 level. The great majority (93%) of the overall study population was below 55 μg/l and consequently well suited for the evaluation of the effects of low Hg^0 exposure levels on psychomotor motor performance.

Urinary Mercury Analysis

Individual urinary mercury levels were quantified for each subject just prior to their psychomotor assessments. For the four ADA studies (ADA 1991, ADA 1992, ADA 1993, ADA 1995), initial on-site urinary Hg concentrations were determined within about an hour of collection. Specimens were initially analyzed using a cold-vapor atomic absorption spectrophotometer (Coleman Mercury Analyzer System 50-A) in accordance with procedures outlined in Naleway et al. (25). Because on-site urinary mercury results tend to slightly underestimate the total mercury content due to lack of time needed for sample digestion, ADA specimens have previously been reanalyzed to provide a check of the on-site values

TABLE 2
DEMOGRAPHICS OF THE STUDY POPULATIONS

Study	Study Location	*N*	Mean Age (SD)	Percent Male
ADA 1991	Seattle, WA	33	50 (14)	73
ADA 1992	Orlando, FL	28	53 (14)	89
ADA 1993	San Francisco, CA	49	51 (12)	80
ADA 1995	Las Vegas, NV	75	47 (11)	91
U of A 1995	Tucson, AZ	25	52 (9)	100
U of A 1996	Tucson, AZ	20	46 (11)	26
Total		230	50 (12)	81

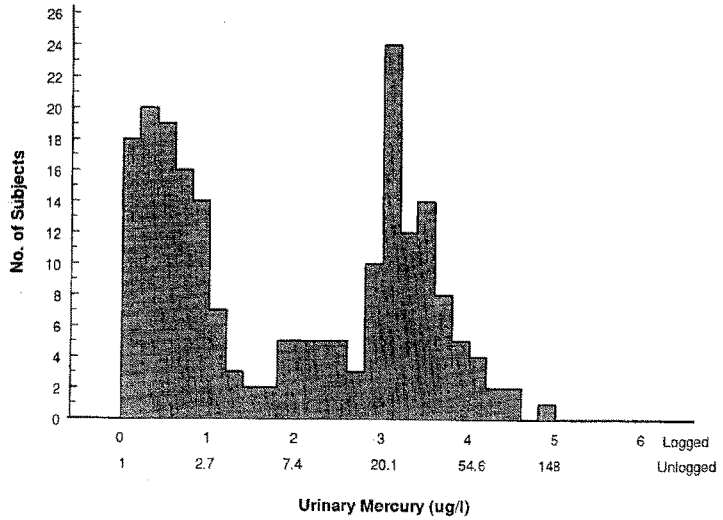

FIG. 1. This histogram of HgU displays the distribution urinary mercury levels for the entire study population (n = 230). The upper x-axis is displayed in logged units, which were preferred in the statistical analysis. The lower x-axis is displayed in unlogged units for easier interpretation of the results.

(vs. those with complete sample digestion). This reanalysis was conducted using the conventional Hatch and Ott cold vapor atomic absorption spectrophotometric method (20). The two methods have been shown to provide highly comparable results (±1 μg/l) with a correlation coefficient of ~ 0.90 (26). The remaining two studies (U of A 1995, U of A 1996) involved quantification of urinary Hg levels in accordance with procedures described in Gonzales-Ramirez et al. (18), which we have found equivalent to our own laboratory method. The urinary mercury level quantification methods consequently are comparable across the six studies.

Psychomotor Test Battery

The six studies employed five varied psychomotor combinations as shown in Table 1. The following is a brief description of each task, including how the test is scored, and the time taken to complete the test:

Finger tapping (5). This test is a measure of simple motor quickness and accuracy. It requires the subject to tap a lever as many times as possible with the index finger. The subject is timed for 10 s. The test is performed using the index finger of the dominant hand and repeated with the index finger of the nondominant hand. This test has been found to be sensitive to mercury (12,28). Scores: the number of taps per trial for each hand. Time: 1 min. Studies: ADA 1993, U of A 1995, U of A 1996.

Intentional hand steadiness test (IHST). This test requires the subject to insert and hold a metal stylus in a series of six increasingly smaller holes in a metal stand for 15-s intervals (23). The stylus is connected to a monitor, and the subject's arm is not braced or supported during the task. The test is performed once using the subject's dominant hand and once using the nondominant hand. This test is a measure of static tremor/control that has been evaluated as predictive of restorative dental task capabilities by study team members using task-analytic methods (35). Scores: number of hits and latency (or duration of touches) for each hole and each hand. Time: 4 min. Studies: ADA 1993, ADA 1995, U of A 1995, U of A 1996.

The one-hole test (30). This test independently assesses component task elements such as the time it takes to grasp, move, position, and reach while transferring small pins from a large target to a small target hole. The test has been found sensitive to neurotoxicants such as toluene and ethanol (16), as well as to mercury in exposed workers (38). Scores: the four response times to grasp, move, position, and reach as well as the number of pins. Time: 7 min. Studies: ADA 1991, ADA 1992, U of A 1995.

NES simple reaction time (SRT) (5). This computerized task requires subjects to press a button every time a stimulus appears on the screen with the right and, later, the left index finger. This test was previously found sensitive to mercury in exposed workers (10). Scores: reaction time for each hand. Time: 4 min. Studies: ADA 1991, ADA 1992, U of A 1995, U of A 1996.

Hand tremor (36). This test is used to measure tremor ac- in the hand. Subjects are first required to hold a Tremor in their dominant hand exactly as an ordinary pen is held. The pen is held horizontal to the ground, at the waist and parallel to the body for 10 s. Hand vibrations are recorded and displayed real-time in a time–axis plot on the computer screen. This is repeated with the subject's nondominant hand. Scores: tremor intensity, center frequency, dispersion of power, harmonic index, and tremor index for each hand. Time: 12 min. Studies: ADA 1995, U of A 1996.

Medical and Personal Habits Questionnaire

A medical and personal habits questionnaire was administered to all subjects across the six constituent studies (13). The questionnaire was completed on a computer with the assistance of a test administrator who clarified questions as required, and input subject answers. The medical portion of the questionnaire was designed to evaluate variables that may influence test performance. Variables of interest included age, race, gender, education, and medical history of neurologic disorders, hypertension, diabetes, and pharmaceutical use. The personal habits section contained questions covering both current and past consumption of alcohol, caffeine, and use of nicotine as well as exposures resulting from recreational activities and hobbies. The medical history of neurologic disorders, hypertension, diabetes, and pharmaceutical use was used to screen data to eliminate potential confounding due to such factors, whereas alcohol use and age were later used as control variables.

n Analyses

Multivariate analyses were conducted following the hierarchical analysis of multiple responses (HAMR) approach, which has been shown to enhance the sensitivity of environmental exposure in other investigations with multiple criteria (6, 21). During the first phase, the multiple test scores of each test were typically combined into a single-factor (or related summary) variable with an expected greater reliability than any of the individual scores (19). Specifically, principle factor analyses (PFAs) were performed separately on the multiple scores of each psychomotor test (34). Continuing this analysis process, PFA factor scores were generally computed for the first unrotated factor using the regression method and its reliability was computed using one of two methods. The One-Hole Test was an exception where both the first and second unrotated factors were extracted and used to estimate the reliability of the traditional summary measure: number of pins. When only two scores were involved (e.g., left and right finger tapping scores), reliability was estimated using the Spearman–Brown equation (3) applied to their cross correlation. When multiple scores were involved, factor reliability was separately estimated from the factor-score variance (Minres regression method). Consequently, the first phase of analysis served to condense each psychomotor test's multiple measures into one summary score with estimated reliabilities.

Multivariate regression analyses were conducted during the second phase using the psychomotor test factor scores variables as dependent variables (34). Independent variables generally included: the log-transformed urinary Hg^0 levels (μg/l), age, gender, and drink frequency. Pertinently, age, der, and drink frequency had previously been found re- d to psychomotor performance (12–14); thus, they gener- lly served as control variables. Regression model coefficients, as part of the program output, were estimated and their statistical significance tested, taking all other dependent variables into account. Subsequently B_a, the magnitude of the log-Hg^0 standardized coefficient corrected for dependent variable attenuation, was computed using the classical correction (3) (i.e., by dividing the uncorrected standardized log-Hg^0 coefficient by the square root of the respective dependent variable reliability estimated during the first phase of analysis). This correction for dependent variable attenuation provides an estimate of the underlying strengths of relationship independent of specific test reliabilities. The second phase of analysis evaluated the relationship between log-Hg^0 levels and the psychomotor summary score variables without, and with, correction for attenuation due to the factor unreliabilities.

The final stage of analysis evaluated the correlations between the extracted psychomotor factor-score variables. To set the stage for comparison, the correlations between the factor variables were estimated based on all pairwise cases, as a variety of other more sophisticated estimates yielded very similar results. Individual correlations were then both individually evaluated for statistical significance and jointly considered via a secondary PFA of the matrix of factor scores. The third stage of analysis provides a basis for later understanding the patterns of relationships revealed during the second analytic phase.

RESULTS

Multivariate analyses for the individual performance tests are presented in the body of this section. Specifically, the results of the first two phases of analysis—PFA and multivariate regression analyses—are presented in turn for the five psychomotor performance measures: Intentional Hand Steadiness Test, Finger Tapping, The One-Hole Test, NES Simple Reaction Time (SRT), and Hand Tremor. These individual results are followed by results of the final stage of analysis that evaluated the patterns of correlation between the psychomotor summary-score variables.

Intentional Hand Steadiness Test (IHST)

PFA was first conducted on the 24 log-transformed hand steadiness scores (number of hits and latency scores for the six hole sizes by dominant/nondominant hand combinations). This analysis revealed three component factors with eigenvalues (≥1.0) of 13.6, 4.3, and 1.7 respectively, representing 56.7%, 18.0%, and 7.1% of the total variance. Loadings on the first unrotated factor (i.e., correlations with this general factor) ranged between 0.49 and 0.86 with higher loadings associated with the nondominant hand, latency, and most particularly the more difficult (smaller) hole sizes. The Minres estimated factor score reliability (r = 0.999) was anticipated given the large number of scores and the range of factor loadings. Though our primary focus was on the first unrotated factor variable, we did explore the utilities of the three unrotated variables—in conjunction with age, gender, and alcohol consumption—to jointly predict log-transformed urinary mercury. This analysis revealed that the second and third unrotated factor variables did not significantly add to the prediction by the first unrotated factor, essentially validating our focus. Consequently, The Intentional Hand Steadiness Test general factor variable was judged to be particularly suitable for multivariate regression analysis.

Multivariate regression analysis revealed a highly significant and substantial relationship between the IHST general factor variable and the independent variables log-transformed urinary Hg^0 levels (μg/l), age, gender, and drink frequency

TABLE 3
INTENTIONAL HAND STEADINESS (IHST) BATTERY COEFFICIENT ANALYSIS

Model	Unstandardized Coefficients B	SE	Standardized Coefficients Beta	t	Sig.
(Constant)	−1.557	0.520		−2.511	0.014
LSPOT	0.332	0.073	0.415	4.539	0.000
Age	1.670E-02	0.008	0.210	2.087	0.040
Drink freq.	−7.838-02	0.065	−0.112	−1.201	0.233
Gender	0.384	0.215	0.172	1.784	0.078

($R^2 = 0.232, p < 0.005$). Table 3 provides a summary of standardized and unstandardized model coefficients and their respective levels of statistical significance. Examining this table, it may be seen that age is significantly ($B = 0.21, p < 0.04$) related to decreasing IHST performance (as higher scores reflect poorer performance). However, far more substantial and highly significant is the relationship of increasing LSPOT1 (log-transformed urinary Hg^0 level) to decreasing IHST performance ($B = 0.415, p < 10^{-6}$). This LSPOT–IHST relationship would be expected to be only slightly enhanced with a correction for the attenuation due to the reliability of LSPOT1 ($r = 0.999$): $B_a = 0.415+$.

Finger Tapping

PFA was conducted on the two finger tapping scores (left- and right-hand scores). As expected, this analysis revealed a single component factor with an eigenvalue of 1.60 representing 80.2% of the total variance. Loadings on the first unrotated factor (i.e., correlations with the general factor) were both 0.895 and the Spearman–Brown estimated factor score reliability was $r = 0.890$. The finger tapping general factor variable was judged to be well-suited for multivariate regression analysis given its estimated reliability.

Multivariate regression analysis revealed a highly significant and substantial relationship between the finger tapping general factor variable and the independent variables log-transformed urinary Hg^0 levels ($\mu g/l$), age, gender, and drink frequency ($R^2 = 0.169, p < 0.002$). Table 4 provides a summary of standardized and unstandardized model coefficients and their respective levels of statistical significance. Examining this table, it may be seen that three of the independent variables are significantly related to finger tapping: age ($B = -0.30, p < 0.012$); drink frequency ($B = 0.21, p < 0.040$); and gender ($B = -0.407, p < 0.001$). However, the relationship of LSPOT1 to finger tapping performance is nonsignificant ($B = 0.141, p = 0.17$). This LSPOT–finger tapping relationship would be little enhanced with a correction for the attenuation due to the finger tapping reliability ($r = 0.890$): $B_a = 0.149$.

The One-Hole Test

PFA was conducted on the four log-transformed One-Hole subtask scores (grasp, move, position, and reach). This analysis revealed two component factors with eigenvalues (≥ 1.0) of 1.55 and 1.25 respectively, representing 41.5% and 33.6% of the total variance. Primary loadings on the first unrotated factor were 0.92 for log-move and 0.84 for log-reach, whereas, for the second factor, they were 0.74 for log-grasp and 0.81 for log-position. However, attention was primarily directed at the log-transformed numbers of pins rather than at these two factor variables because "log-pins" was 1) a traditional summary variable, and 2) almost totally explained by the four log-transformed subtask scores ($R = 0.999$). This log-pins relationship was anticipated given that the time for a pin cycle is the sum of the associated four subtask times. The reliability of the log-pins variable was estimated from its relationship with the two component factors ($R = 0.85$). Although our primary focus was on log-pins, we did separately explore both the utilities of the two factor variables and the four subtask scores—in conjunction with age, gender, and alcohol consumption—to predict log-transformed urinary mercury. These analyses did not reveal any relationship beyond that for log-pins, supporting our choice of this as the summary variable for the One-Hole Test. Consequently, the One-Hole's log-transformed numbers of pins variable was judged to be sufficiently reliable for multivariate regression analysis.

Multivariate regression analysis revealed a highly significant and substantial relationship between the log-pins variable and the independent variables log-transformed urinary Hg^0 levels ($\mu g/l$), age, gender, and drink frequency ($R_2 = 0.226, p < 0.0005$). Table 5 provides a summary of standardized and unstandardized model coefficients and their respective levels of statistical significance. Examining this table, it

TABLE 4
FINGER TAPPING COEFFICIENT ANALYSIS

Model	Unstandardized Coefficients B	SE	Standardized Coefficients Beta	t	Sig.
(Constant)	1.908	0.791		2.413	0.018
LSPOT	9.593E-03	0.007	0.141	1.383	0.170
Age	−2.615E-02	0.010	−0.300	−2.584	0.011
Drink freq.	0.152	0.072	−0.206	2.116	0.037
Gender	−0.907	0.265	−0.407	−3.416	0.001

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TABLE 5
ONE-HOLE COEFFICIENT ANALYSIS

Model	Unstandardized Coefficients B	SE	Standardized Coefficients Beta	t	Sig.
(Constant)	3.810	0.138		27.601	0.000
LSPOT	−1.16E-02	0.011	−0.109	1.053	0.296
Age	−5.97E-03	0.002	−0.438	−3.770	0.000
Drink freq.	1.250E-02	0.014	0.092	0.895	0.374
Gender	−1.19E-02	0.057	−0.024	−0.208	0.835

may be seen that age is very highly related ($B = -0.438$, $p < 0.0005$) to decreasing performance (log-pins). In contrast, the relationship of LSPOT1 (log-transformed urinary Hg^0 level) to log-pins is far from significant ($B = -0.109$, $p = 0.30$). This LSPOT relationship with log-pins would be expected to be only slightly enhanced with a correction for the attenuation for log-pins reliability: $B_u = -0.118$.

NES Simple Reaction Time (SRT)

PFA was conducted on the two log-transformed SRT scores (left- and right-hand scores). This analysis revealed a single component factor with an eigenvalue (≥1.0) of 1.70 representing 85.0% of the total variance. Loadings on the first unrotated factor, correlations with the SRT general factor, were both 0.921 and the Spearman–Brown estimated factor score reliability was $r = 0.918$. The SRT general factor variable was judged well-suited for multivariate regression analysis given its estimated reliability.

Multivariate regression analysis revealed a nonsignificant relationship between the SRT general factor variable and the independent variables log-transformed urinary Hg^0 levels (μg/l), age, gender, and drink frequency ($R^2 = 0.071$, $p = 0.117$). Table 6, the summary of standardized and unstandardized model coefficients and their respective levels of statistical significance, provides some indication of relationships between SRT general factor variable with age ($B = 0.238$, $p < 0.036$) and gender ($B = 0.215$, $p = 0.062$). However, the relationship of LSPOT1 to SRT general factor performance is clearly nonsignificant ($B = -0.110$, $p = 0.28$). This LSPOT–SRT relationship would be little enhanced with a correction for the attenuation due to the SRT reliability ($r = 0.917$): $B_u = -0.115$.

Hand Tremor

PFA was first conducted on the 10 log-transformed tremor scores: tremor intensity, center frequency, dispersion of power, and harmonic index, and tremor index by right- and left-hand combinations. This analysis revealed three component factors with eigenvalues (≥1.0) of 3.0, 1.9, and 1.5 respectively, representing 30.1%, 18.8%, and 14.9% of the total variance. Loadings on the first unrotated factor, correlations with this general factor, ranged between 0.28 and 0.83 after rotating the harmonic index scores to reflect the directionality of the dispersion indices. Loadings, it is noteworthy, tended to be higher for the left-hand scores (vs. right hand). The Minres estimated factor score reliability ($r = 0.907$) was not surprising given the numbers of scores and the range of the factor loadings. The Hand Tremor general factor variable was consequently judged to be suitable for multivariate regression analysis.

Multivariate regression analysis revealed no significant relationship between the tremor general factor variable and the independent variables log-transformed urinary Hg^0 levels (μg/l), age, gender, and drink frequency ($R^2 = 0.067$, $p = 0.46$). Table 7, which provides a summary of standardized and unstandardized model coefficients and their respective levels of statistical significance, reflects this general result with only one suggestion of a weak relationship with drink frequency ($B = 0.251$, $p = 0.083$). The relationship of the hand tremor general factor with LSPOT1 is clearly nonsignificant ($B = -0.063$, $p > 0.68$). This LSPOT–tremor general factor relationship would be expected to be meagerly enhanced with a correction for the attenuation due to the reliability of the hand tremor general factor variable: $B_u = -0.066$.

Psychomotor Summary Variable Relationships

The relations between the psychomotor summary-score variables were evaluated during the final stage of analysis. Initially, summary variables correlations were estimated based on all pairwise cases. Examining the results, it was found that only two of the individual correlations are statistically significant ($p < 0.05$) or more than modest in magnitude (>0.2); these were −0.38 and −0.31 between One-Hole log-number

TABLE 6
SIMPLE REACTION TIME (SRT) COEFFICIENT ANALYSIS

Model	Unstandardized Coefficients B	SE	Standardized Coefficients Beta	t	Sig.
(Constant)	−1.953	0.742		−2.631	0.010
LSPOT	−7.973E-03	0.007	−0.110	−1.088	0.279
Age	1.871E-02	0.009	0.238	2.133	0.035
Drink freq.	0.113	0.076	0.144	1.480	0.142
Gender	0.498	0.264	0.215	1.885	0.062

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TABLE 7
HAND TREMOR COEFFICIENT ANALYSIS

Model	Unstandardized Coefficients B	SE	Standardized Coefficients Beta	t	Sig.
(Constant)	−0.188	1.062		−0.177	0.860
LSPOT	−6.053E-02	0.146	−0.063	−0.416	0.680
Age	−5.038E-03	0.013	−0.059	−0.395	0.694
Drink freq.	0.212	0.120	0.251	1.766	0.083
Gender	−0.226	0.349	−0.103	−0.647	0.520

of pins and the finger tapping and tremor summary scores, respectively. These correlational results were not the result of attenuations due to unreliabilities; reliabilities were found quite substantial in the earlier individual analyses ($r = 0.85$). These results strongly suggested that the separate psychomotor factors, and the five tests from which they were derived, largely assess different psychomotor capabilities. This suggestion was explored via a secondary PFA of the matrix of psychomotor factor score correlations. This secondary PFA revealed three modest component factors with eigenvalues (>1.0) of 1.52, 1.23, and 1.12. Not surprisingly, two components reflected the modest relationships between the one hole and the finger tapping and tremor summary scores. The final component was defined by the hand steadiness summary score, which was seen to have no absolute correlational relationship exceeding 0.16 with any of the other summary variables. PFA results further indicated that the separate psychomotor summary scores, and tests from which they were derived, assess largely independent psychomotor capabilities.

DISCUSSION

The current article focuses on the psychomotor domain in an across-study evaluation addressing the preclinical effects of low-level Hg^0 in dental professionals. The body of six studies, each drawing upon a common set of five selected psychomotor tests, provides for joint analyses with substantially greater numbers of subclinically exposed dental professionals than afforded by the constituent studies (see Tables 1 and 2). These enhanced numbers, it is pertinent to note, are well-poised for use in addressing preclinical effects at low levels as Hg^0 exposures are largely below 55 μg/l (see Fig. 1). The enhanced numbers consequently offer a unique opportunity to compare the relative sensitivities of five psychomotor tests for detection of adverse preclinical psychomotor effects of low-level Hg^0, a primary goal of the present study. These numbers also provide a unique opportunity to explore the effects of test reliabilities on sensitivity, and test utility, a secondary goal of this study. These, and a discussion of the occupational relevance of the present results, are presented in the body of this section. Following this is a discussion addressing the overall purpose of the present study, the selection of psychomotor measures, and other methodologies for future study of the preclinical effects of low-level Hg^0.

Relative Psychomotor Test Sensitivities

Direct comparison of the analytic results indicates quite remarkable differences in the relative sensitivities of five psychomotor tests for detection of adverse preclinical psychomotor effects of low-level Hg^0. Specifically, the relationship between the IHST factor variable and log-transformed urinary Hg^0 level, with control for age and other confounders, was both highly significant and substantial ($B = 0.415$, $p < 10^{-6}$), whereas the largest relationship for any of the other four psychomotor summary variables, finger tapping, was seen to be relatively meager and insignificant ($B = 0.141$, $p = 0.17$). The potential for such divergence in results was anticipated both when the tests were originally selected to measure separate capabilities and after earlier examination of summary variable relationships. However, reflecting only the sensitivities of the current tests and their reliabilities, such direct comparisons only tell part of the story. They do not provide an assessment of the underlying or potential test sensitivities that might be obtained with enhancements of the extant reliabilities (e.g., through lengthening of tests or otherwise reducing measurement error). In the present study, this would not appear to be a large problem given the generally substantial test reliabilities ($r = 0.85$–0.99). However, we directly addressed this potential limitation by computing B_u, the magnitude of the log-Hg^0 standardized coefficient corrected for dependent variable attenuation using classical methods (3, Figure 2, summarizing the values of the resulting unattenuated B_u^2, shows in terms of relative proportions of explained variance that the direct results were not largely influenced by differences in the reliabilities of the psychomotor tests. The IHST factor variable clearly possesses far more sensitivity to low-level Hg^0 level than either currently exists or might be expected with reliability enhancement of the other four psychomotor tests.

Occupational Relevance

The findings of this study would hold greatest relevance for occupations where Intentional Hand Steadiness (IHST-like) requirements are substantial and Hg^0 exposures are comparable or exceed those herein. Paradoxically, dental professionals—engaged in the exquisitely challenging manual aspects of restorative dentistry involving amalgams—would be those for whom the current results are most relevant. Pertinently, such dental professionals would not be expected to show physical and higher level compensations for the effects of low-level Hg^0 exposures as often occurs with other toxic insults. This, it is noteworthy, is because the very nature of their activities means that they have continued to spend much of their work time engaged in manual activities that would be expected to transfer to IHST. Indeed, in light of this continued manual activity, it could be conjectured that the substantial relationship between exposure and IHST ($B = 0.415$, $p < 0.10^{-6}$) includes any compensations expected with extended manual skills practice. Conversely, exposure impacts on IHST would be even more profound in less skilled and practiced populations with comparable exposures. Unfortunately, th conjecture cannot be explored with the data in the present

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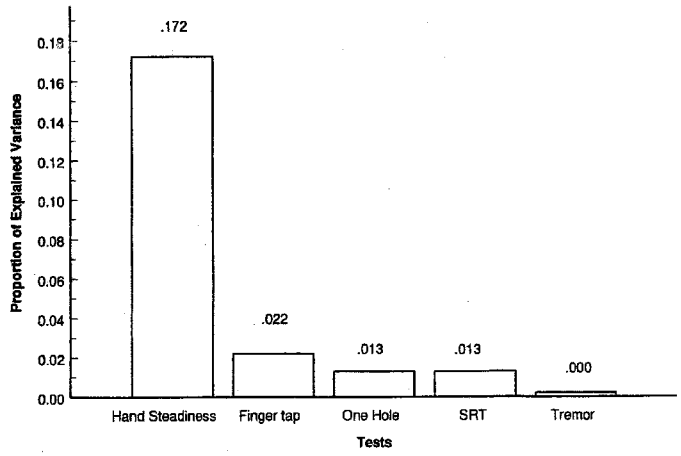

FIG. 2. This graph displays the proportion of log Hg-explained variance for each motor test after correction for attenuation for each of the five independent models corresponding to each motor test. An examination across tests indicates that the Intentional Hand Steadiness Test accounts for more of the log Hg-explained variance.

study; it remains for future research with dental professionals to address it. The present study's results do argue for stringent practice to minimize personal exposures when working with Hg^0 amalgams.

Measures and Methodologies for Low-Level Hg^0 Studies

The results of the present study provide a basis for recommendations of measures and other methodological aspects of future studies of preclinical effects of low-level Hg^0. The recommendations regarding measures fall into two recommendation categories. First, based on the relative magnitudes of B_u (Fig. 2), the IHST can be very strongly recommended for inclusion due to its potential for providing sensitive measure of psychomotor function. Indeed, given the strength of its relationship in the current study ($B = 0.42$, $p < 10^{-6}$), it appears sufficient for analytic evaluation of a threshold of effect (21). Second, also based on the relative magnitudes of B_u (Fig. 2), only finger tapping of the remaining tests could be marginally recommended. Specifically, power calculations indicate that finger tapping would have about an even probability of just detecting an effect with a sample size of 200 (even if maximum reliability and $B_u = 0.022$ were realized). At least twice that number (ca. 400) would be required for any of the remainder (40). These estimates of required sample sizes are conservative in that they would likely require considerable increase if the study population were not as relatively homogeneous as dental professionals employed herein, or the study did not employ factor analysis methodologies, which served to condense test scores into a single highly reliable score.

The results of the present study consequently support the continued use of both dental professionals (or another similarly homogeneous group) and statistical methodologies to take full advantage of the data collected. Related to this, the computation of reliability and corrected B_u values can also be recommended as they provide a basis for not continuing to use a relatively insensitive test. In this study, for example, the computation of B_us indicates that doubling, tripling, or even longer increases in the lengths of finger tapping and other unrecommended tests was unlikely ever to be productive. This is in contrast to the frequent *argumentum ad ignorantum* that increasing the test length and sample size would yield positive results.

In sum, the present results generally support both use of IHST for low-level Hg^0 assessments, and statistical methodologies for condensations of multiple measures and assessments of their utilities. This would be consistent with hierarchical analysis of multiple responses (HAMR) and related approaches (6,7,21).

Conclusions

Taken together, the results of this study support three general conclusions and recommendations. These include:

1. The Intentional Hand Steadiness Test (IHST) factor summary score is very highly related ($B = 0.42$, $p < 10^{-6}$) to the log-transformed urinary Hg^0 at low levels (> 55 μg/l) and holds occupational relevance for dental professionals.

2. Use of dental professionals or another similarly homogeneous group is recommended for future studies where low-level Hg^0 exposure and threshold effects are of concern.
3. Statistical methodologies are recommended for use in future studies for condensation of multiple scores into summary scores with enhanced reliabilities, computation of these reliabilities, and use of these to derive correction for attenuation relationships (B_{ij}s) with environmental exposures levels.

ACKNOWLEDGEMENTS

This research was supported by National Institutes of Health grants ES04696, ES04940 and DE11712.

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Controlled Clinical Trials 23 (2002) 301–320

Controlled Clinical Trials

Design paper

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children

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Manuscript received July 23, 2001; manuscript accepted November 25, 2001

Abstract

The Casa Pia Study of the Health Effects of Dental Amalgams in Children is a randomized clinical trial designed to assess the safety of low-level mercury exposure from dental amalgam restorations in children. It is being carried out in 507 students (8 to 12 years of age at enrollment) of the Casa Pia school system in Lisbon, Portugal, by an interdisciplinary collaborative research team from the University of Washington (Seattle) and the University of Lisbon, with funding from the National Institute of Dental and Craniofacial Research. Since the goal of the trial is to assess the safety of a treatment currently in use, rather than the efficacy of an experimental treatment, unique design issues come into play. The requirements to identify as participants children who have extensive unmet dental treatment needs and who can be followed for 7 years after initial treatment are somewhat in conflict, since those

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PII: S0197-2456(01)00206-9

EXHIBIT 3

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with the most treatment needs are usually in lower socioeconomic categories and more difficult to track. The identification of a primary study outcome measure around which to design the trial is problematic, since there is little evidence to indicate how health effects from such low-level exposure would be manifested. The solution involves the use of multiple outcomes. Since there are concerns about safety, multiple interim comparisons over time between treatment groups are called for which, in conjunction with the use of multiple outcomes, require an extension of statistical methodology to meet this requirement. Ethical questions that have to be addressed include whether assent of the children participating is required or appropriate, and whether the director of the school system, who is the legal guardian for approximately 20% of the students who are wards of the state and live in school residences, should provide consent for such a large number of children. Approaches taken to address these and other design issues are described. © 2002 Elsevier Science Inc. All rights reserved.

Keywords: Safety; Dental amalgam; Mercury; Multiple endpoints; Interim analyses; Children; Neurobehavioral test

Introduction and background

Dental amalgam is the most widely used dental restorative material to repair cavities in teeth throughout the world. Approximately 100 million persons have amalgam restorations in the United States alone [1]. In addition to silver and other metallic components, amalgam contains approximately 50% elemental mercury, a known toxic substance that is now banned from most medical uses, and its use in other areas is under increased scrutiny to minimize environmental and occupational exposures. Mercury exists naturally in three forms: metallic or elemental (the form in dental amalgam); inorganic, usually in combination with other elements such as chlorine; and organic including methylmercury. While industrial use is often the source for high-level occupational exposures, mercury is relatively ubiquitous, and almost everyone has some background level of mercury exposure through the environment (air and water) or through their diet (methylmercury, primarily from consumption of fish). It is in the presence of these other background mercury exposures that any potential health effects of low-level mercury exposure from dental amalgam must be evaluated.

Dental amalgam has been in regular use in dentistry for more than 150 years, and while its safety has periodically been questioned, the lack of valid scientific evidence regarding its safety has made evidence-based discussions difficult at best. For many years, amalgam was thought to be relatively inert once it hardened. However, the elemental mercury it contains readily vaporizes under pressure. Recent studies have identified positive correlations between blood and tissue mercury levels with the number and total surface area of amalgam fillings[2,3]. It is postulated that stress on the amalgam surface, such as that produced by chewing, grinding of teeth, or tooth brushing, causes the breakdown of a surface barrier and the release of mercury vapor into the mouth. When this release coincides with breathing through the mouth, inhaled mercury vapor readily diffuses across the alveolar membranes and is distributed mainly in red blood cells to the central nervous system and other target organs.

At times mercury from dental amalgams has been suggested as the cause of disease manifestations that range from mild dermatologic conditions, to chronic debilitating neuromuscular diseases and even acute, life-threatening health outcomes [4–7]. The question of the safety of

dental amalgam as a restorative material was addressed by a Food and Drug Administration Panel in 1991. While this panel recommended the continued use of dental amalgam, it acknowledged the lack of solid research into the issue and voted unanimously for further study concerning the safety of mercury-containing dental amalgam. This need for a research program to examine the potential long-term biological effects of dental amalgam was echoed in a 1993 final report of the Committee to Coordinate Health and Related Programs, Public Health Service, which had been directed by the Assistant Secretary for Health to examine the question of amalgam safety [8].

If there were alternative restorative materials that were entirely equivalent to amalgam in terms of strength, longevity, cost, and ease of use, then the known risk for high-level exposure to mercury suggests that it might be prudent to eliminate low-level exposure from amalgam, even in the absence of documented health effects. However, it is generally recognized that no other material is as easy to apply and, once in place, lasts as long. The use of alternative materials, especially in the absence of ideal conditions and equipment, may result in more secondary decay around restored teeth and the need for more frequent replacement of restorations. Also, the alternative materials have not been thoroughly tested for health effects other than localized allergic reactions, and they may have their own harmful systemic effects. The elimination of dental amalgam as a restorative material could have widespread public health and economic consequences, possibly resulting in higher costs and reduced efficacy for restorations. Thus, the safety of dental amalgam has become an important issue.

In an effort to assess the health effects of dental amalgam, the National Institute of Dental and Craniofacial Research (NIDCR) issued a Request for Applications for a randomized clinical trial to be conducted in children, who are the group receiving most restorations and are thought to be most vulnerable to the effects of mercury during their growth and development. This paper describes issues in design and analysis that had to be addressed in one such trial, called the Casa Pia Study of the Health Effects of Dental Amalgams in Children.

Design and analysis issues for a randomized controlled trial on treatment safety

The issue of safety of a treatment currently in widespread clinical use is an unusual question around which to design a randomized clinical trial. Moreover, given the previous long-term use of the treatment without objectively documented adverse health effects, it was expected that any health effects, if present, would be subtle and therefore difficult to detect. Thus, there were several design and analysis issues that had to be addressed in an unusual manner. This was not to be a treatment efficacy study. The dental treatments to be compared were assumed, because of their long-term use, to be effective in successfully repairing carious dental lesions. There was some question as to which treatment would have greater longevity, but that question was entirely secondary.

The primary question was whether the use of dental amalgam was safe, so this study had to be designed as a safety study. In general, the study was proposed as a randomized clinical trial in which half of the participants would receive treatment that included the use of dental amalgam as appropriate in the standard-of-care (amalgam used for large posterior restorations in molars or premolars, but tooth-colored composite material used in front teeth) and the other half of the participants would receive treatment that included only the alternative

(nonamalgam) composite material. This material consists of resin (i.e., methacrylates) and inorganic filler (quartz, colloidal silica or silica glass). Both treatment approaches are considered acceptable care, so neither group would receive treatment considered experimental. Other issues that required special consideration included: the population/site in which to conduct the trial, the choice of study outcome measure(s), and types of tests, the length of follow-up and frequency of tests and exams, the dental materials to use in treatment, the measures of mercury exposure to use, the statistical test(s) to be employed and, based on that, the sample size to be required.

The population/site in which to conduct the trial

Issues considered in the identification of an appropriate study population included the need to enroll several hundred children who had a considerable number of untreated dental caries in order to provide enough exposure to amalgam through treatment that any health effects, if present, might be manifested. At the same time, the children should not have had prior exposure to amalgam. To monitor for health effects subsequent to treatment, the ability to retain the children in the study for several (5 to 7) years was important. There are no published data that indicate the time course over which adverse health effects associated with the use of amalgam, if any, might occur.

Initial consideration was given to sites and populations within the United States. Experience with outreach activities in the Pacific Northwest and a survey of oral health of third-grade students in the state of Washington indicated that there were children in that area with untreated dental disease and no prior amalgam exposure, but these children were likely to be from low-income and ethnic minority populations. One of the lessons learned from our outreach activities in those populations was that long-term follow-up and retention could be problematic because of frequent relocation and other difficulties in maintaining contact. Instead, an affiliation with the Faculty of Dental Medicine at the University of Lisbon in Portugal, and experience through them with the Casa Pia school system in Lisbon, led us to identify that as an ideal site in which to conduct the study.

The Casa Pia school system in Lisbon includes more than 4000 students in elementary and high school grades in seven schools. It was founded more than 200 years ago to provide an education for orphaned and homeless children in Lisbon, and it has since evolved into a large school system that uses a combination of private and public support to educate children from a much broader variety of backgrounds. Consistent with the original mission of Casa Pia, the school is the official guardian for approximately 20% of the students who are wards of the state and live in residences operated by the school. The other 80% live at home, including many from middle- to upper-socioeconomic backgrounds whose families pay tuition for their enrollment in a school system that is perceived as providing a good education.

There are several reasons why we chose to collaborate with the Casa Pia school system. First, past experience suggested that there was an enormous unmet need for dental restorative treatment. This was confirmed in a small feasibility study in which we examined 41 children in our targeted range of 8–10 years old and observed an average of 6.1 carious teeth, with four of them being permanent teeth. By contrast, the average level of disease noted in the U.S. population for a similar age group, as documented in the NHANES-III study, is 1.57 decayed or filled teeth with 0.56 of those in permanent teeth [9]. Second, among the 41 chil-

dren examined we saw only one amalgam restoration. Also, urinary mercury samples from the children indicated low background levels of mercury from other sources (median urinary mercury level of 2.0 μg/L). This would be important in trying to assess the mercury exposure levels and health effects due solely to amalgams. Third, dental hygienists from the University of Lisbon had previously provided instruction in oral hygiene to students from the Casa Pia schools; so school administrators were enthusiastic about cooperating in a study that could provide needed dental care for a large number of their students. This cooperation was essential in carrying out the logistics of the study, since it allowed students to be transported, tested, and treated during school hours. And finally, the school system, in its admissions process, developed an extensive social network of contacts for each student that would prove to be quite valuable for maintaining contact and follow-up for enrollees, especially for those who leave the Casa Pia school system.

The decision to conduct this trial in a foreign country was not made without regard to ethical concerns or whether the results would be generalizable to the United States. Trials are sometimes conducted in foreign countries to minimize costs. In this case, although the cost of delivering dental care to 500 children in Portugal was less than it would have been in the United States, the additional cost for investigators to travel between Seattle and Lisbon to supervise and coordinate the study somewhat offset those savings, so that cost was not an overriding factor in the decision. For all the reasons described above, it was felt that the scientific quality of the study would benefit from the use of this study population. The main concern was whether a study conducted in another country could be generalized to the U.S. population, so we took care to ensure that the dental practices and materials in the study were not only those used in Portugal, but were also typical of those in the United States. It was established that the racial composition of the Casa Pia population was not markedly different from the general U.S. population, and it was also recognized that if the study were conducted in urban settings in the United States, the known distribution of caries among children suggests that many potential participants would come from recently immigrated families.

The choice of study outcome measures and types of tests

Mercury's toxic effects on human beings can vary with the form, extent, and route of exposure. The fate of mercury in the body, although extensively investigated, remains somewhat unknown. Target organs for elemental mercury include the kidneys and the central nervous system. Information about the deleterious effects of mercury in human beings generally comes from occupational or environmental disasters that have produced very high exposure levels. The study of health effects of mercury exposure from dental amalgam requires the extrapolation of information obtained in such very high exposure levels to low-level exposure where there is little data.

Consideration of study outcome measures in a safety trial such as this is particularly difficult when it is not clear how or when health effects, if any, will be manifested. What is known about mercury toxicity is summarized in Fig. 1, which indicates the urinary mercury levels at which the various signs and symptoms have been documented. At the time the study was being designed, the lowest exposure level at which subclinical changes in behavior had been detected was 36 μg/L of urine, with most of the clinical signs and symptoms documented at levels of 100–1000 μg/L [10]. In a study of exposure from amalgam, the urinary

mercury levels were expected to be less than 10, and probably mostly in the range of 2–5 μg/L. Thus, identification of one or more primary outcome measures required extrapolation to low levels for which, at the time, there was no information. Information in Fig. 1 about motor function (hand steadiness) changes at 26 μg/L [11] and potential preclinical effects on symptoms, mood, motor function, and cognition related to exposures in the range of 0–4 μg/L [12] were published after the study was underway. Based on the toxicology of elemental mercury and information from the studies of high-level exposure, the target organs were felt to be the renal and neurologic systems. Discussions among an interdisciplinary team of experts in toxicology, neuropsychology, neurology, nephrology, epidemiology, and biostatistics led to identification of a constellation of potential primary outcome measures. These included testing performance in three neurobehavioral domains thought to be potentially affected by mercury (memory, attention/concentration and motor/visual motor), measuring nerve conduction velocity (posterior tibial and ulnar nerves) and determining urinary glutathione transferase levels (GST-α and GST-π).

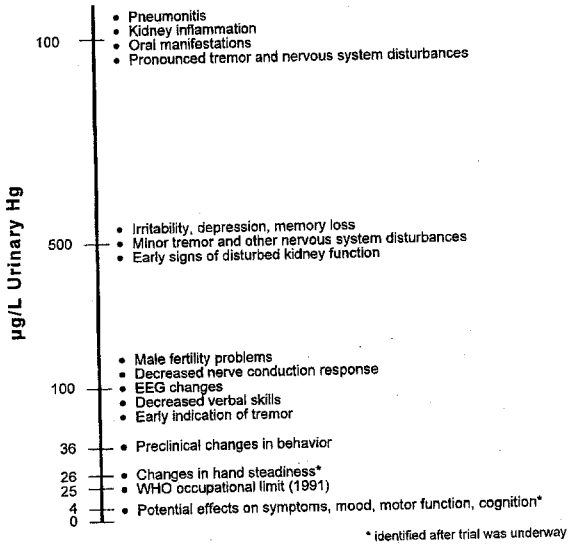

Fig. 1. Signs and symptoms of Hg toxicity by levels of urinary Hg.

The neurobehavioral tests were chosen on the basis of their appropriateness for the age of the children, documented sensitivity to the integrity of brain functions, cross-cultural applicability, and appropriateness for measuring abilities in each of three functional domains (Table 1). The Comprehensive Test of Nonverbal Intelligence was also administered as a preenrollment measure of intelligence quotient (IQ) [13]. IQ itself was considered to be too gross a measure of neurobehavioral abilities and was therefore considered a secondary outcome measure. The focus in the choice of primary outcome measures was to assess attention, memory, and motor/visual motor functions in depth in order to identify possible subtle changes that might occur with mercury exposure. The neurobehavioral battery included: Rey Auditory Verbal Learning Test [14]; Visual Learning and Finger Windows subtests from the Wide Range Assessment of Memory and Learning [15]; Trail Making Test [16]; Stroop Color Word Test [17]; Standard Reaction Time [18]; Finger Oscillation Test [19]; Pegboard, Matching, and Drawing tests from the Wide Range Assessment of Visual Motor Abilities [20]; and Digit Span, Coding and Symbol Search subtests from the Wechsler Intelligence Scale for Children-III [21].

An early deficit produced by mercury on the nervous system is slowing of nerve conduction velocity. Small decrements may be seen before clinical symptoms are produced. An additional feature of nerve conduction velocity is that it provides an objective neurologic measure. We selected the ulnar and posterior tibial nerves as reasonably representative of short and long span nerves, because of well-established norms for these nerves and for ease of test administration.

Subsequent discussions concerning the GST enzymes, which are indicators of damage to specific regions of the renal nephron, led to the conclusion that the enzymes are not only highly elevated when there is permanent kidney damage, but their levels are also likely to increase in response to low-level mercury exposure without permanent damage. Moreover, there was no information available that indicated the levels of the GST enzymes that differentiated permanent renal damage from reversible renal response. Nor was there any information relating the level of GST to clinical symptoms associated with continuous levels of renal function and/or malfunction. Had GST levels been included as a primary outcome measure under those circumstances, the validity of the study could have been jeopardized by the observation of a significantly increased GST level among those exposed to amalgam that may have merely been a confirmation of exposure rather than an indication of any serious renal damage. Once this issue concerning GST levels was fully understood, the GST enzymes were designated as secondary outcome measures, subject to exploratory analyses, along with another renal measure of response to mercury, urinary porphyrin levels. Unfortunately, no renal measure was identified that was sensitive enough to serve as a primary outcome mea-

Table 1. Primary outcome measures

Neurobehavioral: combined Z-scores for sets of tests within three domains:	
1. Memory:	Rey Auditory Verbal Learning, Visual Learning
2. Attention/concentration:	Coding, Symbol Search, Digit Span, Finger Windows, Stroop, and Trails A and B
3. Motor/visual motor:	Finger Tapping, Drawing, Matching, Pegboard, and Standard Reaction Time
Neurological:	
4. Nerve conduction velocities	Average of Z-scores for posterior tibial and ulnar nerves

sure, since anything as definitive as kidney failure was not expected to occur as a result of such low-level mercury exposure.

Although exceedingly rare, mercury-induced autoimmune reactions that can lead to glomerular nephritis have been reported [22]. Therefore, we are measuring urinary albumin to monitor for such potential immunologic reactions associated with mercury exposure, but this is a secondary outcome measure because it is expected to be so rare.

Further discussion of the remaining four potential primary outcome measures did not resolve the issue of which of those measures was most likely to be affected by and sensitive to low-level mercury exposure. Although most clinical trials concerning treatment efficacy are designed around one definitive outcome measure, one consequence of designing a safety trial, as in this case, may be the need to be cautious and include several primary outcome measures. In this case, the decision was made to use four primary outcome measures, as defined in Table 1. Each of these measures is calculated as an average of Z-scores (standardized to have mean 0 and SD 1 across the sample) for tests within a particular domain. The secondary outcome measures are given in Table 2.

The length of follow-up and frequency of tests and exams

Although there was a possibility that any health effects of low-level mercury exposure could be manifested in a relatively short period of time, the expectation was that it would likely take several years to demonstrate any differences in the development of the children. While follow-up until adulthood was perhaps the ideal, that would have required at least 8–10 years of follow-up, which did not seem feasible financially and could mean risking an emotional response to this potentially volatile question prior to the release of objective evidence from the trial. The compromise was to require at least 5 years, and recently approved renewal funding extended it to 7 years.

Practicality solved the question of how frequently to test and examine the children. The neurobehavioral tests could not be repeated too often without the risk of learning effects. They were also affected by development of the children in school, so it was thought important to test the children at approximately the same time of the school year. The children needed to have a dental exam at least annually and, if there was disease progression, be treated. All of these requirements combined led to the development of an annual testing/treatment cycle as optimal.

The dental materials to use

Since the purpose of the study was not to test the efficacy of any specific brands of dental materials but to assess whether dental amalgam as used in practice is safe, the materials chosen were typical of what is employed in practice in Portugal and in the United States, thus

Table 2. Secondary outcome measures

Secondary outcome measures that will be available for descriptive and explanatory purposes include
•IQ
•Clinical neurological exams
•Urinary glutathione transferase analyses
•Urinary porphyrin analyses
•Urinary albumin

NOV-13-2002 10:31 FROM BATTELLE CHHRE SEATTLE TO *64564569120222612/4 P.31/42

ensuring that the results could be generalized. To avoid introducing any unnecessary variability in exposures and potentially in outcome measures, it was desirable to standardize the brands of materials available to the dentists providing treatment. The most important material, of course, was amalgam. Although there are several manufacturers, the mercury content of the different amalgams is approximately the same (50%). The choice of amalgam was the brand most widely used in the United States, Dispersalloy by Dentsply. Similarly, the posterior composite alternative material to be used instead of amalgam was selected because it is the most widely used composite in the United States, Z100 MPq by 3M. The other materials that the dentists could use in treatment, including composite adhesive, glass ionomer base, compomer and compomer adhesive, were also selected to be representative of what is used in U.S. practice, and are given in Table 3. In the protocol, children in the amalgam group were to be treated with amalgam as appropriate in the standard-of-care, meaning large restorations in posterior teeth, but they could at the same time be treated with other materials (composite, glass ionomer, or compomer) for restorations not appropriate for amalgam. Thus, the two treatment groups differed in exposure to amalgam, but they could overlap in exposure to the other materials.

Measures of mercury exposure

While the trial merely randomizes patients to one of two treatment regimens (one including dental amalgam, the other excluding dental amalgam), there is a need in secondary analyses to document the amount of mercury exposure produced by the amalgam treatment and to allow investigation of any dose-response effects. The best measure of exposure depends on the form of the mercury. For example, mercury exposure from diet is predominantly methylmercury, primarily from fish consumption. Because about 90% of methylmercury is found in erythrocytes, analysis of mercury concentrations in blood is one of the best ways to determine recent exposure to methylmercury [23]. Hair samples have also been used to assess cumulative organic mercury levels, although it is considered less reliable due to possible environmental contamination [24,25]. Single-void ("spot") urine samples are predominantly used to assess recent exposure to elemental mercury [26,27].

The main assessment of exposure to elemental mercury from amalgams used in this study is analysis of urinary mercury, determined from samples obtained at baseline (prior to treatment) and at all subsequent annual visits prior to additional treatment. Measurements of urinary mercury concentrations made at these time points should involve the least amount of variability, since there has been a sufficient length of time since the previous treatment to allow body compartments to achieve steady-state mercury levels [28]. Urinary mercury analysis is performed

Table 3. Materials used in treatment

Type of material	Brand name
Amalgam	Dispersalloy (Dentsply)
Posterior composite	Z100 MPq (3M)
Composite adhesive	Scotchbond multipurpose (3M)
Glass ionomer base	Vitrebond (3M)
Compomer	Dyract (Dentsply)
Compomer adhesive	Primabond 2.1 (Dentsply)

NOV-13-2002 10:32 FROM BATTELLE CPHRE SEATTLE TO *6456456912022251274 P.32/42

according to the method of Corns et al. by continuous cold-flow, cold-vapor atomic spectrofluorometry, using a PSA Merlin Mercury Analysis (Questron Corp., Mercerville, NJ, USA) [29]. Urinary creatinine content (used to also provide creatinine-adjusted urinary mercury levels) is determined using the colorimetric determination assay kit obtained from Sigma Chemical Co. (St. Louis, MO, USA).

Diagnoses of dental disease and development of treatment plans are all done by the lead dentist, and all dental care providers in the study are trained to current standards of care in placing amalgam and composite restorations. As a result, no meaningful variation in the quality of care is expected. Also, individual treatment appointments are essentially randomly assigned to the various providers in the study, which should distribute any provider effects equally between the two treatment groups. Any problematic treatments (such as restorations that were significantly "high" upon placement) would be very few in number and would very quickly result in retreatment for any number of clinical reasons including discomfort to the patient, cracking, etc. These issues are not expected to have any impact on the levels of mercury exposure experienced by study participants.

In addition to urinary mercury concentrations, the other measure of mercury exposure is obtained from clinical records of the amalgam restoration surfaces placed. Given the date of the placement of each surface, one can calculate the number of months of exposure contributed by each surface at a given point in time, and the total number of surface-months of exposure contributed by all restorations in a person as a cumulative measure of exposure at a given point in time. To aid in further refining the surface-months of exposure to take into account the size of each restoration, if needed, each restoration is categorized into one of three categories of size (small, medium or large), and these categories could be differentially weighted in determining cumulative weighted surface-months of exposure. While it is unlikely that study participants would receive dental treatment outside of the study, notations are made of all restorations present in the mouth at annual examinations. With this data, it is possible to discern whether an amalgam has been placed outside the study, and if so, include it in measuring amalgam exposure.

While exposure to elemental mercury from amalgam is of primary interest in the study, there was concern that dietary exposure to methylmercury could act as a confounder and mask any effects of amalgam exposure. Therefore, in a sample of 150 of the participants, a dietary questionnaire was administered to assess intake of seafood, and blood samples were taken to measure recent methylmercury exposure. For this, total and organic mercury concentrations in blood samples were directly measured by ethylation–gas chromatography–cold vapor atomic fluorescence spectrometry after alkaline digestion–solvent extraction [30].

The statistical tests employed

There were several issues to consider in determining the statistical approach to use. The first two resulted directly from fundamental decisions made about study design: that there would be multiple (four) primary outcome measures and that the study would be longitudinal, with follow-up and annual testing for 7 years.

Third, a two-sided alternative hypothesis was needed, although the two sides were not considered to be of equal importance. Our expectation was that if the two treatment groups

differed, the difference would be in the direction of amalgam being harmful. This was particularly true since the outcome measures were specifically selected to be sensitive to the effects of amalgam. Reports released as the protocol was being finalized suggested there may be low-level exposure to estrogenic-like compounds from composites, but the reports were too preliminary and came too late in the process to allow incorporation of outcome measures specifically selected to detect harmful effects of composites. Also, there would be a clear difference between treatment groups in the levels of mercury exposure, whereas the difference in exposure to composite material would be a matter of degree (making any observed treatment effect in this direction difficult to interpret).

Fourth, annual interim analyses were required. Although the dental treatments given were considered standard-of-care, from an alternative point of view we were exposing children to low levels of a substance that in higher doses has been shown to have health effects, and it was important to monitor the effects of the trial and assess each year whether the trial should continue.

Fifth, there was the question of how any adverse effects of the amalgam would be manifested among the primary outcome measures. The adverse result considered most likely was consistent but subtle effects in all or most of the outcome measures, no one of which was large enough to be statistically significant by itself. If the four outcomes were equally affected by mercury exposure and they were consistent in demonstrating small harmful effects, we would want the statistical test to be sensitive to this possibility. On the other hand, if it turned out that one of the four primary outcomes was much more sensitive to low-level mercury exposure than the other three, we would want the statistical test to be able to detect that effect. As is indicated later, these two scenarios would lead to the use of two different tests.

The final issue to be addressed in the statistical approach was to avoid unnecessary risks of obtaining false-positive findings. Since amalgam is used worldwide, is less expensive (it takes less dentist time) and is generally thought to be more durable, especially when employed under less-than-ideal working conditions (it is less technique sensitive), a false-positive finding of a harmful effect of amalgam could lead to an unnecessary ban on its use with economic and public health consequences. Of course, if there truly are harmful effects of amalgam, then we want to detect them, and the benefit of avoiding the associated health effects would likely outweigh the economic and public health consequences of a ban. However, the temptation in trying to detect a small harmful effect is to increase the size of the rejection region (significance level) and, therefore, the type I error rate. For this study, it is important to use a test procedure that is sensitive to potential harmful effects of mercury, but also to balance the need for sensitivity by maintaining a reasonable overall type I error rate.

The use of multiple outcome measures led to the adoption of an O'Brien test as a means of combining the endpoints [31]. However, the test was originally proposed for a one-time analysis at the end of a study, and its use in this study with longitudinal data and interim annual testing required an extension of the test [32]. The O'Brien-type test is particularly sensitive to possible consistent small effects in all outcome measures, but it is not sensitive to a possible effect manifested in only one outcome. To protect against that possibility, the Hotelling T-squared multivariate test was also adopted as part of the overall testing procedure. The overall significance level of the entire statistical procedure was set at 0.05. A two-sided testing procedure was adopted to allow legitimate testing for harmful effects of both restorative ma-

terials. However, unequal significance levels were used for the two sides in recognition of the fact that the study was designed, and outcome measures were selected, to be sensitive primarily to harmful effects of amalgam. The overall 0.05 significance level was divided into a level of 0.03 for an O'Brien-type test sensitive to uniform harmful effects of amalgam in all outcome measures, a level of 0.01 for the O'Brien-type test sensitive to uniform harmful effects of composite in all outcome measures, and a level of 0.01 for the Hotelling T-square test sensitive to a large effect (in either direction) in just one outcome measure. Furthermore, since the longitudinal nature of the study required interim annual testing, the overall significance level of 0.05 was spent over seven interim tests, with the overall significance level for each annual analysis given in Table 4. As is shown, the spending function we used did not distribute the alpha levels uniformly over all years. Because we wanted to quickly detect an early harmful effect (i.e., an incremental effect manifested in the first year), we spent a higher proportion of the alpha level (0.0125) in the first test. If the effect were not incremental in nature, then we assumed it would be cumulative and linear over time, and we could spend the remaining alpha equally (0.0015) over years 2 through 6, while saving the majority of the alpha (0.03) for the final analysis at year 7.

Sample size determinations

Using the statistical procedures described above, the sample size required for the study had to be determined based on the power of the procedure to detect harmful effects that might be observed. Given the number of possible scenarios, especially with four outcome measures and two statistical tests involved, we decided to focus on what we thought might be typical effects that we would want high power to detect. We looked at two scenarios: one with small but (relatively) consistent effects in all outcome measures, and the other with a pronounced effect in only one outcome measure. Scenario 1 consisted of effect sizes of 0.3 standard deviations in each of the three neurobehavioral outcome measures and an effect size of 0.15 in nerve conduction velocity. The postulated effect size of 0.3 standard deviations is abstract and somewhat arbitrary, but in the absence of any evidence as to what kind of difference between the two groups might be of concern, this effect size does have a descriptive interpretation based on a presumed normal distribution. If the population mean shifts by 0.3 standard deviations, the proportion that was originally identified as the lower 2.5% of the population distribution (and perhaps classified as "abnormally low") would increase to 5%, resulting in an approximate doubling of the "abnormally low" proportion of the population. We felt this to be a reasonably small effect that we would want to detect. Scenario 2 consisted of a larger effect (an effect size of 0.5 SD) in only one outcome measure, nerve conduction velocity, with no effect in the other outcome measures.

Table 4. Significance levels for annual analyses and total significance levels

Test component:	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total
Test for adverse effects of amalgam	0.0075	0.0009	0.0009	0.0009	0.0009	0.0009	0.018	0.03
Test for adverse effects of composite	0.0025	0.0003	0.0003	0.0003	0.0003	0.0003	0.006	0.01
Hotelling's T-squared test	0.0025	0.0003	0.0003	0.0003	0.0003	0.0003	0.006	0.01
Overall test	0.0125	0.0015	0.0015	0.0015	0.0015	0.0015	0.030	0.05

NOV-13-2002 10:34 FROM BATTELLE CHARE SEATTLE TO *64564569120222612?4 P.35/42

Exploration of power for these scenarios with varying sample sizes resulted in the conclusion that a total sample size of 400 children (200 in each group) with complete data at the end of the study would provide adequate power (greater than 97%) to detect the two scenarios. In order to account for loss to follow-up and ensure that we would achieve adequate power, we set an enrollment minimum of 450 with a target of 500. We have continued to monitor the power of the study based on our experience with recruitment and follow-up of subjects (see details on implementation below). In the competing renewal proposal recently reviewed and recommended for funding, it was proposed that the follow-up period be extended to 7 years after initial treatment to allow for sufficient power to detect scenario 2. The annual attrition rate was assumed to be 5% in the first year and 3% subsequently. The results showed that the study will have sufficient power (94%) with just a 5-year follow-up period to detect small effects that are roughly uniform across outcome measures as in scenario 1. The power to detect similar adverse effects of composite material is smaller because smaller significance levels are used for these tests, but is still adequate (87%). Adequate power (94–95%) exists with 5-year follow-up to detect a linear effect in just one outcome measure equal to 0.1 per year over 5 years. However, 5-year follow-up is inadequate to detect a linear effect in just one outcome measure equal to 0.06 per year (cumulative effect size 0.3 over 5 years or 0.42 over 7 years). The power is just 49% with 5 years of follow-up, but extension of the follow-up period to 7 years increases the power to a reasonable level of 85%.

Implementation

Enrollment commenced in February 1997, when final authorization to proceed came from our Data Safety Monitoring Board (DSMB) and NIDCR. As is shown in Fig. 2, we had projected an enrollment period of approximately 10 months (December 1997) to enroll the minimum number of 450 children. Because of a slight delay in getting started and because the enrollment rate was slightly slower than anticipated, we reached the minimum enrollment number of 450 in May 1998. However, because the goal enrollment of 500 seemed within reach, we continued enrolling until October 1998, when enrollment was stopped at 507, with 253 randomized to one treatment group and 254 to the other. As is indicated in Table 5, the 507 enrollees were obtained from a pool of 845 students in the appropriate age range who were approached about the study. Of those contacted, 647 (76%) provided consent and were screened. Among those screened and declared ineligible, most either had previous exposure to amalgam or did not have at least one carious lesion on posterior permanent teeth. Implementation of enrollment and follow-up also raised design issues that had to be addressed.

Ethical issues in informed consent

Since participants in the study are minors, consent had to be obtained from parents or guardians for their participation. The parental consent form was reviewed and approved by Institutional Review Boards (IRBs) at the University of Washington and the University of Lisbon. However, the issue was raised as to whether we also were required to obtain the assent of the child. The technical answer was that we were not required to obtain assent from the children because the treatments being provided in both groups were considered standard-of-care, not experimental. However, we decided that it would likely lead to better coopera-

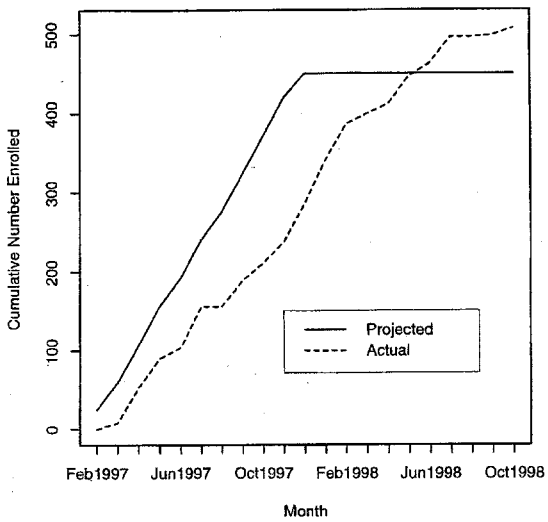

Fig. 2. Recruitment by time period.

tion by the children if we included them in the consent process, so we also asked for their written assent.

An issue raised by the DSMB about the informed consent process concerned the 20% of the children in the schools who were wards of the state and who lived in Casa Pia housing. For those children, the director of the Casa Pia school system was their legal guardian. The ethical issue was whether it was appropriate for one person, the director, to have consent responsibility for such a large group of students. One concern was whether it was a conflict of interest for the senior administrator of the school system to make such a decision, given that the school system was responsible for the general welfare of these children and that there could be a financial benefit to the school system to have all of these children receive free dental care through participation in the study. On the other hand, access to dental care for all children in the Casa Pia school system was quite limited, regardless of whether they lived at home or at school. There was just one part-time dentist for the entire school system who only treated emergencies, and very few of the families sought or had access to dental care in private or public health settings. Thus, there seemed to be no more of an incentive for the director of Casa Pia to consent for students who were residents of Casa Pia to participate than

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Table 5. Number of children approached, consented, randomized and declared ineligible with reasons for ineligibility

		Randomized		Ineligible					
Approached	Consented and screened	Group A	Group B	IQ < 67	No caries on permanent posterior teeth	Previous exposure to amalgam	Urinary Hg >10 μg/L	Blood lead >15 μg/dL	Excluding health condition
845	647	254	253	32	38	54	5	0	2

there was for parents of individual students to consent. In both cases, participation brought with it access to dental care. A related ethical concern was whether the offer of free dental care was too great a financial incentive and constituted a form of coercion. The counter argument was that the "exposure" in the trial consisted of dental treatment, and since the targeted population was not seeking dental treatment, they probably would not have participated if the dental treatment had not been free.

When the DSMB questioned the appropriateness of one person providing consent for the many children (approximately 100) who were residents of the schools, it created an issue with the potential to affect the cooperation from the Casa Pia schools that had been (and continues to be) so important to the study. The director of Casa Pia is highly respected in the community and takes his responsibilities as legal guardian of the resident children very seriously. Addressing the DSMB concern by requiring additional consent by someone other than the director would have meant imposing a consent process different from what is legally required in Portugal; it might have been interpreted as questioning the integrity of the director, and therefore it could have caused problems. The solution, as suggested by the National Institute of Health Office of Protection from Research Risks, was to ask the IRB at the University of Lisbon to revisit the consent process for the resident Casa Pia children to determine if the provision of consent by the director met local community ethical standards. They met, reviewed the process, and confirmed its appropriateness.

Table 6. Demographic information at baseline by treatment group

	Group A		Group B	
	Number	Percent	Number	Percent
Year of birth				
1986	90	35.6	74	29.1
1987	85	33.6	93	36.6
1988	54	21.3	55	21.7
1989	24	9.5	32	12.6
Sex				
Male	135	53.4	142	55.9
Female	118	46.6	112	44.1
Race				
White	176	69.6	179	70.5
Black	75	29.6	67	26.4
Asian or other	2	0.8	8	3.2

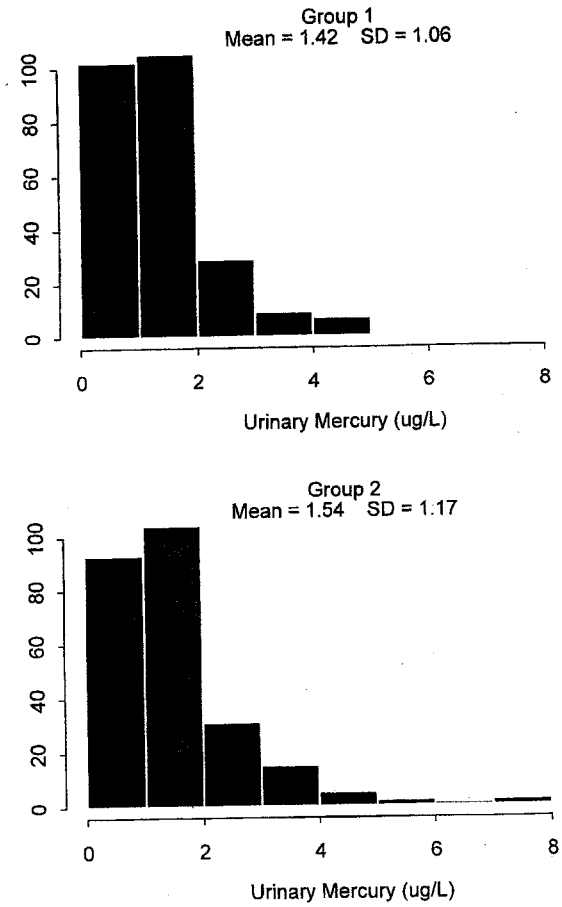

Fig. 3. Baseline urinary mercury levels by treatment group.

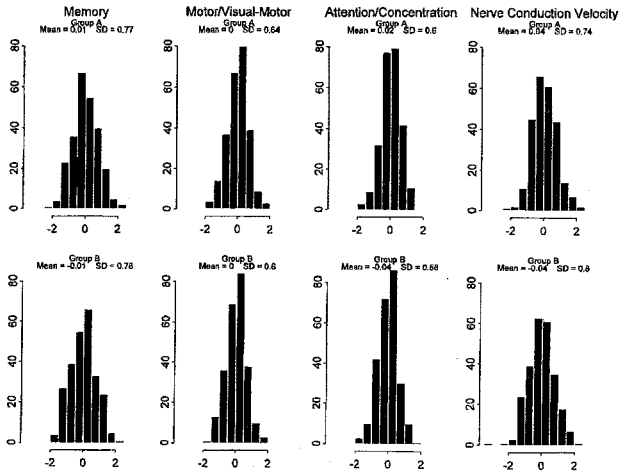

Fig. 4. Distribution by group at baseline of Z-scores for memory, motor/visual motor and attention/concentration neurobehavioral domains and nerve conduction velocities.

Sentinel health events monitoring system

While the study is designed to evaluate the safety of treatment with dental amalgam, there is no guarantee that any adverse effects will occur only among the primary or secondary outcome measures we have specified. In reviewing our follow-up on patients posttreatment, the DSMB asked us to also monitor for any unexpected medical diagnoses or health events that might have occurred during follow-up. The only mechanism initially in place to detect such occurrences was the routine questions asked by the treating dentist about any recent illnesses. Since the patients were children, that process was not thought to be sufficient to ensure that any significant illnesses would be identified. We implemented a short health history questionnaire sent to parents and guardians annually, but the DSMB thought our questions were too open ended and lacked sufficient detail, while we resisted developing a lengthy annual questionnaire to send to parents. It was questionable whether our informed consent covered administration of a subsequently developed annual questionnaire, and (more importantly) investigators from the University of Lisbon doubted we would get a good return rate from parents and thought we might run the risk of alienating them. In order to provide reasonable assurance that we could identify any serious illnesses developed by the study participants during follow-up, we instituted a multifaceted sentinel health events monitoring system. The system consists of three components. The

first is the annual short health history questionnaire sent to parents. The second is a structured set of health history questions (asking about a variety of symptoms) that a dental hygienist administers to each child at the time of the annual exam. The third component consists of consultation with teachers and school officials, including the school physician, to monitor for reported diagnoses or extended absences among study participants that could be related to illness as a means of checking the completeness of the health histories. While any report of illness identified through this system may not be completely reliable, if sufficient numbers of illnesses of any specific type are reported to be of concern, additional efforts can (and will have to) be made to get proper consent for access to medical records and appropriate confirmation.

Besides annual interim statistical analyses to compare group responses on the primary endpoints of the study and the sentinel health events monitoring system to identify unexpected medical diagnoses or events, part of the overall monitoring of the study involves identifying and assessing individual extremes in neurobehavioral performance each year to identify any children who may require referral for treatment. This process involves using the Reliable Change Index (RCI) [33,34], which takes into account the standard error of measurement as well as the correlation between performances on a test at two time points to identify children whose performance falls outside a one-sided 95% confidence interval for their predicted value. Those children identified by the RCI method as having extreme (poor) scores on several of the individual neurobehavioral tests have their overall performances and clinical records examined by the study neuropsychologist (blinded to treatment group identification) to determine if the patterns of test performances and clinical neurological exam findings indicate a diagnosis requiring referral for treatment.

Baseline characteristics

As a result of the randomization process, patients were assigned to one of two treatment groups (designated as Groups A and B or 1 and 2 to maintain blinding). As is shown in Table 6, the two groups were balanced in demographic characteristics, with approximately 54% male and 70% white in both groups, with only slight variations in year of birth. The treatment needs of the two groups at baseline were also comparable, with one group averaging 15.6 decayed surfaces (primary and permanent teeth combined) and the other 15.8 decayed surfaces. The background levels of urinary mercury in the two groups are shown in Fig. 3, with only slight group differences (one group averaging 1.42 μg of mercury per liter of urine, the other group averaging 1.54). Both group averages are at the lower end of what has been observed in populations with no known overt sources of mercury exposure.

Baseline scores for the two groups in the primary outcome measures are shown in Fig. 4. Again, the two groups are balanced, which will allow for subsequent group comparisons to be made without having to adjust for baseline differences. However, the use of regression adjustment for baseline scores (or alternatively a change score) will be considered if it provides higher precision and hence higher power.

Summary

The need to examine the safety of a treatment (dental amalgam) already widely used in children presented some unique design challenges. It required identifying a population with

extensive dental disease that could be followed up long term, determining study outcome measures in the absence of hard evidence concerning how health effects of low-level mercury exposure would be manifested, and developing statistical methods that allowed group comparisons on multiple outcome measures at multiple interim time points. The Casa Pia Study addresses those issues. Follow-up will continue until the children have been followed for 7 years after their initial treatment, which will occur in 2005.

Acknowledgments

The authors wish to acknowledge the many contributions by others on the study team to various aspects of the study design and baseline results presented here. These include: (from the University of Lisbon) Henrique Luís, Dr. Mario Bernardo, Lurdes Vaz, Helena Amaral, Dr. Isabelle Pavão, Dr. Mamede Carvalho, Goretty Ferreira, Pedro Rodrigues, Helena Nazareth, Dr. Paula Marques; (from the University of Washington) Gail Rosenbaum, Natalie Hawkins, Aimee Sparks, Dr. Jacqueline Farwell, Dr. Harvey Sarnat, Dr. Sandra Watkins, Lynne Simmonds, Dr. Glen Johnson; and (from NIDCR) Dr. Maryann Redford. This work is funded by the National Institute of Dental and Craniofacial Research Cooperative Agreement U01 DE11894.

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ADA Health Foundation Research Institute

Fan, P. L., senior director
Siew, Chakwan, senior director, Laboratories
Batchu, Hanu, assistant director, Critical Issues
Gruninger, Stephen, assistant director, Safety and Biocompatibility

The Research Institute (RI), part of the American Dental Association Health Foundation (ADAHF) and located within the ADA Division of Science, conducts applied research in response to critical and emerging issues identified by the Council on Scientific Affairs and the ADA Research Agenda in the delivery and improvement of oral health care. The RI also participates in collaborative research with the ADAHF Paffenbarger Research Center (PRC) and hosts research externs from the American Student Dental Association (ASDA) and visiting faculties from several universities. As part of its core activities, the RI reviews research proposals received by the ADAHF and acts as scientific liaison to ADAHF-funded research projects, including the Health Screening Program.

The Strategic Plan of the American Dental Association: The RI's activities are in accord with the duties of the ADAHF and the strategic plan of the ADA through research on issues that impact the oral health of the public, the health of the dental team and the practice of dentistry.

Current and ongoing research projects focus on occupational health (via the Health Screening Program), safety and effectiveness of dental therapeutics and materials, dental office wastewater, dental unit waterlines, and safety in the dental office. Findings of the RI research are reported in peer-reviewed publications, abstracts and presentations at scientific meetings. Copies of published materials are available on request.

2001 Health Screening Program: At the 2001 ADA annual session in Kansas City, a total of 821 dentists, dental hygienists and dental assistants participated in the ADAHF Health Screening Program (HSP). Dentist participation in the 2001 HSP in Kansas City increased 17.8% over the HSP held in Chicago one year earlier. There were three optional serum tests that were offered at cost to participants: (1) N-telopeptide, a marker of osteoporosis; (2) thyroid stimulating hormone (TSH), a marker for thyroid gland function; and (3) prostate specific antigen (PSA), a marker for prostate cancer in men. The other tests offered at no cost to participants are part of the RI's ongoing research into the occupational health of the dental team.

Hepatitis B and C Results. Over 90% of the dentists participating in the 2001 HSP reported they were hepatitis B vaccine recipients. Of the 645 dentists who participated in testing for hepatitis C virus (HCV) antibodies, four initially tested positive for HCV through an enzyme-linked immunosorbent assay (ELISA). Two of these four individuals were repeat positives from previous years. Following immunoblot confirmation, three were determined to be definitively positive for HCV infection and one indeterminate (i.e., a borderline positive of HCV infection). In sum, less than 1% of participants in the 2001 HSP were HCV positive, which is below the level found in the general population of the United States (1.5-2.3%, as reported by the Centers for Disease Control and Prevention). These results further corroborate a previous publication by the Council on Scientific Affairs, which indicated that the chances of HCV transmission in dental settings appear remote.

Urinary Mercury. Among the 507 dentists who participated in the 2001 HSP, the average urinary mercury level was 4.1 μg Hg/L (ppb). This level is almost identical to the urinary mercury level of the general population (about 4 μg Hg/L [ppb]), further indicating the profession's compliance with ADA-recommended mercury hygiene practices.

Oral Cancer Screening. Oral cancer screening using computer-assisted brush biopsy technology was also included in the 2001 HSP. Out of 336 participants, 29 suspected lesions from 29 participants were brush-biopsied, and one was confirmed to be "atypical" and potentially neoplastic by computer-assisted brush biopsy technology. A private oral surgeon performed a follow-up scalpel biopsy of this lesion, and it was determined to be non-cancerous. During the previous two HSPs (1999 and 2000), a total of seven individuals were identified to have "atypical" and positive lesions by computer-assisted brush biopsy technology, with three of the seven confirmed by scalpel biopsy to have pre-cancerous lesions.

Latex Hypersensitivity Screening. Allergy to latex proteins has been a significant concern for healthcare providers, particularly since the Occupational Safety and Health Administration (OSHA) mandated the use of gloves for all procedures involving contact with a patient's bodily fluids. Upon completion of testing for immediate (Type I) allergy to gloves made from natural rubber latex (NRL) by performing skin-prick tests on HSP dental professionals, a clear trend has emerged in the data. Among dental professionals tested in the HSP, there has now been a six-year downtrend in the prevalence of immediate hypersensitivity to latex proteins. After a peak prevalence in 1996 (8.5%, N=866), the prevalence of latex hypersensitivity declined in subsequent years: 1997, 7.2% (N=614); 1998, 5.5% (N=651); 1999, 4.9% (N=633); 2000, 4.3% (N=626) and 2001, 1.8% (N=440). This significant decline in NRL sensitizations is most likely due to improved manufacturing and quality control techniques, which have minimized the amount of protein in examination gloves.

EXHIBIT 4

Safety and Effectiveness of Dental Therapeutics and Materials:

Natural Rubber Latex and Gutta Percha. Recent reports suggested the possibility of immuno cross-reactivity between natural rubber latex and gutta percha proteins in endodontic points. Using an inhibition ELISA assay, the RI conducted a study to assess cross-reactivity between antigenic proteins derived from gutta percha and NRL. Aqueous protein extracts were prepared from raw gutta percha, 13 brands of gutta percha points, and NRL gloves. After incubation with NRL antibodies, none of the extracts from raw gutta percha or gutta percha points were reactive. On the other hand, similar NRL glove extracts were highly reactive. This RI study demonstrated no immunologic cross-reactivity between raw gutta percha, gutta percha points, and proteins derived from NRL gloves. Thus, exposure to gutta percha endodontic points does not appear likely to initiate immediate hypersensitivity in individuals sensitized to NRL proteins.

Fluoride in Toothpaste. The RI continues to develop laboratory evaluation methods for product effectiveness. A previously used method to measure available and total fluoride in toothpastes has limitations in evaluating fluoride in newly introduced toothpastes that contain complex and novel ingredients. To address this issue, the RI developed a new method that utilizes suppressed ion chromatography to analyze fluoride in toothpastes. This method has shown to be applicable to fluoride determinations for toothpastes with complex formulations and is being incorporated into the Council on Scientific Affairs' Acceptance Program Guidelines for Fluoride-Containing Dentifrices.

Toothbrushes. Currently the designations of toothbrushes as "soft," "medium" and "hard" are not clearly defined. The RI evaluated the applicability of a proposed international standard to define these designations based on measuring the stiffness of the bristles of toothbrushes having brush heads featuring flat surfaces. Based on the results of toothbrush bristle stiffness testing, according to the proposed international standard, most of the 77 brands of toothbrushes tested could be properly designated. As the proposed standard cannot measure accurately the stiffness of bristles in toothbrushes that are designed to have more complicated brush heads and bristle surfaces, the RI is investigating whether a modification of the proposed test could extend the applicability of the proposed international standard to the toothbrushes whose brush heads are not flat surfaces.

Curing Lights and Depth of Cure of Resin-Based Composites. Adequate curing of resin-based composites is paramount in their clinical performance. The RI evaluated the curing light intensity and the depth of cure of resin-based composites using international standards for curing light intensity and depth of cure measurements. Curing lights with an intensity of 300 mW/cm^2 appear to effectively cure most resin-based composites to 2 mm depth of cure when appropriate curing times were used. The study also suggested an in-office method dentists can use to verify the depth of cure of their resin-based composites. The results of this study were published in: Fan PL, Schumacher RM, Azzolin K, Geary R, Eichmiller FC. "Curing-light intensity and depth of cure of resin-based composites tested according to international standards." *Journal of the American Dental Association* 2002;133(4): 429-434.

Dental Unit Waterline Contamination (DUWL): In early 2001, the RI surveyed contamination of water from dental unit waterlines in volunteer dental clinics to assess the impact of improvements in current technology for the reduction of dental unit water contamination. Approximately 30 mL of water were aseptically collected from each high-speed handpiece and air/water syringe at monthly intervals for six months. The dental units were connected to a tap water supply or self-contained water reservoirs. Diligent attention to DUWL disinfection was required to achieve and maintain less than 200 CFU/mL. The majority of clinics surveyed were unsuccessful in meeting the goal of 200 CFU/mL in dental unit water. Increased efforts to motivate clinicians to retrofit older dental units to reservoir systems, along with increased awareness that treatment regimens must be strictly followed, may increase compliance in minimizing dental unit water contamination.

Safe Needle Devices and Occupational Safety in the Dental Office: In an effort to protect health care workers from percutaneous injuries in the health care environment, the Occupational Safety and Health Administration (OSHA) revised its Bloodborne Pathogens Standard in January 2001 to clarify the duty to provide engineered sharps protection to health care workers at occupational risk of exposure to bloodborne pathogens. The revised standard requires dentists to evaluate, with input from at risk employees, commercially available safety needle devices and adopt those determined to be effective.

The RI is undertaking a study to gather scientific information from practicing dentists with regard to the use of safety needles. A specific objective of this study is to provide dentists with an evaluation tool to help them judge the effectiveness of commercially available safety needle devices and, furthermore, to evaluate new devices as they are introduced in the dental marketplace. Another objective is to facilitate the development of ADA guidelines for the acceptance of safety needle devices as appropriate and effective for use in dentistry.

Amalgam in Dental Office Wastewater: The RI conducted a laboratory evaluation of 12 commercially available amalgam separators for their amalgam removal efficiency using the international standard ISO 11143. During this test, the evaluation also measured the total mercury concentrations in effluent from the amalgam separators.

Using amalgam samples containing particles between 3.15 mm to 0.001 mm as defined by ISO 11143, the RI evaluation showed that all 12 amalgam separators exceeded the ISO 11143 requirement of 95% amalgam removal efficiency. The total mercury concentrations in the effluent ranged from 10 ppb to over 30,000 ppb. The results of this laboratory evaluation are published in: Fan PL, Batchu H, Chou H-N, Gasparac W, Sandrik J, Meyer DM. "Laboratory evaluation of

amalgam separators." *Journal of the American Dental Association* 2002;133(5): 577-584.

The RI continues to assist constituent and component dental societies by providing scientific support in responding to amalgam wastewater issues, including reviewing waste management documents, research protocols and research results. The RI also assisted the constituent dental societies of California, Minnesota, Ohio, Oregon, Washington and several other states in addressing amalgam wastewater issues.

Resolutions: This report is informational in nature and no resolutions are presented.

Facts For Communicators

Waste Management

The ADA and its members are committed to public health through protection of the environment.

Several ADA councils and the American Dental Association Health Foundation study amalgam waste to help ADA members respond to regulation, coordinate scientific research on dental waste and help regulators assess this research.

- **How Amalgam Enters the Waste Stream**

  Amalgam restorations, made from an alloy of several metals including silver and mercury, are highly durable and can last 15 years or more. Filters installed in dental offices trap some amalgam particles that result from placement or removal of restorations, but small particles still may be suctioned down the dental office drain. These particles, with minute amounts of soluble products, could ultimately reach the public waste stream and mix with waste from industrial, medical and other sources.

  Studies estimate that the average dental office discharges only about 35 mg of mercury daily via dental wastewater. Almost all of the total discharge, however, is in the form of solid amalgam particles, which do not release mercury to the environment. Sources such as industry, residences and atmospheric deposition are the main contributors of mercury found in the environment.

- **Environmental Issues**

Studies by publicly operated waste treatment facilities in San Francisco and Seattle estimate that dentists' contribution of amalgam to wastewater constitutes between 6 percent and 14 percent of the total mercury load in wastewater treatment plants. Significantly, these findings are based on how much amalgam, not how much mercury, dental offices discharge. Dental offices do not discharge elemental mercury.

It is scientifically inappropriate for public treatment facilities to equate amalgam discharge with mercury discharge. To do so presumes, without scientific evidence, that a significant portion of amalgam breaks down and releases mercury during the waste treatment process. In fact, a 1996 study found that when amalgam particles were subjected to simulated wastewater treatment processes, no soluble mercury was detected, even at a concentration of one part per billion.

Non-dental sources such as air deposition are generally conceded to be by far the largest contributors of mercury to the environment. A 1997 U.S. EPA Mercury Report to Congress estimated that 0.4% of the national mercury emission is from dentistry. The presence of significant other mercury sources suggests that the regulatory focus should not be on dentistry.

- **ADA Research**

A study was conducted to determine what happens to amalgam particulate during a simulated waste treatment process. The study detected no mercury at one part per billion when amalgam particles were subjected to wastewater treatment procedures.

A preliminary study on the effects of amalgam on

aquatic life was inconclusive. Some results suggest that elements in amalgam might affect some of these life forms. However, other results show that when sediment is included in the water, as it generally is in a river, lake or ocean, amalgam particles had no effect on these aquatic life forms.

Still other results indicate harmful effects even in an amalgam-free environment. In one experiment in which sediment was mixed with sand, toxicity occurred in the amalgam-free controls, suggesting particles, per se, might influence the potential for acute effects.

Differences in composition of sediments probably affect aquatic life forms. It appears that environmental effects of amalgam, if any, are site-specific, i.e., they may vary based on composition of sediments at different locations.

- **Source Reduction**

Even though there is no evidence that amalgam poses significant environmental problems, the ADA also is researching practical ways for dentists to reduce the amount of amalgam discharge that enters the waste stream.

Several state and local dental societies have published dental office waste management practice recommendations for solid waste and wastewater.

Proposals to ban the use of amalgam because of environmental concerns would, without scientific justification, deny patients the choice of this safe, low-cost and durable filling material.

The ADA does not endorse any single pretreatment source reduction methodology. Source reduction methods should take site-specific factors into consideration.

Amalgam separators have been the most-studied source-reduction method. The level of technology in amalgam separators varies. Research is being conducted to develop appropriate evaluation methods for amalgam separators. The ADA is extensively involved in such research.

In order to assist state dental societies, the ADA has prepared information on several options for amalgam waste management. State societies can use this information to select the options that may be suitable for amalgam waste reduction programs in their areas.

See also: OSHA Compliance and Scientific Services and Resources

Revised June 2001

Page Updated: June 06, 2002

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Today's News Oct. 10, 2002

Survey data support 'best management practices' for wastewater

By Mark Berthold

Arlington, Va. — Amalgam discharge in dental wastewater has no significant impact on methylmercury levels in the environment, a new study concludes.

The September evaluation by Environ International Corp., used ADA survey data on amalgam usage and a critical review of the scientific literature — called a "materials balance approach" — to model a "typical" dental office and amount of mercury discharged.

The environmental consulting group contracted by the ADA also studied the mercury capture efficiency of sewerage treatment plants to calculate how much mercury from dental offices is likely to enter the environment and potentially be converted into methylmercury.

What Environ found is that dentists' adherence to "best management practices," such as chairside traps and vacuum filters, reduces amalgam particles in wastewater by a significant 78 percent. This amount is further reduced by the "very high mercury capture efficiency" of treatment plants, about 91.6 percent.

The result is that mercury in dental wastewater comprises less than 0.7 percent of the total amount from all industries and sources that enters the environment and might be available for conversion to methylmercury.

"Our analysis shows that, although mercury-containing dental amalgam continues to be used, dentists are not a significant contributor to organic methylmercury, primarily due to 'best management practices' at the dental chair," says Jay Vandeven of Environ.

"Mercury also is very effectively removed at treatment plants, particularly amalgam particles," he adds. "Unlike mercury from other industrial sources that is dissolved or in smaller particles, dental amalgam is managed as solid material because of its size and density and therefore, significantly less is released in the effluent that leaves the sewerage plant."

Dr. James Bramson, ADA executive director, notes, "Regulators need a scientific, objective tool for assessing dental office wastewater and evaluating regulatory alternatives. The good thing about the Environ study is that it looks at the entire issue and takes a detailed approach to assessing the concerns and putting things in the proper perspective."

"Considering the daily variation in the amount of dental amalgam discharged,

EXHIBIT 6

the differences between dental practices and the existing ADA survey data on dental offices — this approach by Environ is more accurate than previous models that attempted to assess the amount of mercury in dental wastewater," says Dr. Daniel Meyer, associate executive director of the ADA Division of Science.

"It's also important to note the distinction between dental amalgam and mercury when looking at dental wastewater and environmental issues," Dr. Meyer adds. "Amalgam is a very stable alloy that has not been demonstrated to break down in the environment unless it is incinerated or chemically processed."

Use of amalgam separators would reduce the dental contribution, from 0.7 percent to about 0.3 percent, of total mercury from all sources that enters the environment. This would not significantly impact on current levels of methylmercury in surface water or fish tissue, or on the ultimate goal of protecting human health.

"We are working to ensure that ADA policies regarding amalgam in wastewater are based on the best available, sound science," says ADA president Greg Chadwick. "That's the best way we can serve the needs of the public, our members and the patients they treat."

Document address: http://www.ada.org/members/pubs/daily/0210/1010wat.html

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Government and Advocacy

State Legislative Report

Editor's Note

Sound Byte

Amalgam Safety

Recent Developments on Amalgam in Dental Office Wastewater

Democrats Make Some Gains in 2001 - Will it Last?

State Legislative Report Archives

State Legislative Report -- December/January 2002

Recent Developments on Amalgam in Dental Office Wastewater

Dental societies in Florida and Illinois adopted guidelines in 2001 for proper disposal of scrap amalgam in dental offices. The Florida Department of Environmental Protection said dental offices that follo these guidelines for handling and recycling the mercury from dental amalgams will be considered to be "in compliance" with state environmental, biomedical, occupational health and transportation regulations.

Other active steps were taken by dental societies in Connecticut and Minnesota this past summer. The Connecticut Department of Environmental Protection and the Connecticut State Dental Associat organized a bulk mercury collection program in June that resulted in collection of 400 pounds of bulk mercury from 165 dentists who participated in the program. The Minnesota Dental Association recei a state grant to distribute a video on waste management practices tc dentists upon request. Dentists may use the video to fulfill part of the CE requirements.

The City of New York's Bureau of Environmental Protection is trying estimate the amount of mercury discharged into a local publicly own treatment facility (POTW) from various sources, including dental offic The Oregon Dental Association (ODA) cooperated with the state's Environmental Council, which is charged with developing strategies t eliminate mercury release from human activities by the year 2020. O did provide input and review of the Council's report. Oregon is one o several states that have adopted Zero Mercury Discharge Campaign

The 2001 ADA House of Delegates overwhelmingly recognized the need to assist members on the issue of dental amalgam in wastewat discharged from dental offices. The House approved Resolution 82, which sets forth a seven-part ADA Action Plan.

In essence, the Action Plan calls on the ADA to:

1. Develop model state/local response and action plans, and assist (if requested by a state) with the implementation of such plans;

2. Make available grants in matters of national significance;

3. Assess the release of mercury from dental offices, including comparison of the influent mercury content versus the effluent mercury content in dental office wastewater;

4. Evaluate cost benefit/cost effectiveness;

5. Develop and implement a national advocacy initiative;

6. Implement educational activities; and,

7. Ensure that appropriate regulatory or independent standard-setting organizations develop scientifically sound methods of measuring the effectiveness of amalgam reduction technology, including accurate cost estimates of installation, use and maintenance.

Document Posted: January 04, 2002
Page Updated: January 04, 2002
Document address: http://www.ada.org/members/pubs/stateleg/0201/slr-03.html

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JADA Association Report
July 1999

Dental Mercury Hygiene Recommendations

ADA Council on Scientific Affairs

The following recommendations, adopted in October 19 by the ADA Council on Scientific Affairs, are provided to update mercury hygiene recommendations published by former ADA Council on Dental Materials, Instruments an Equipment in 1991. They are intended to provide guidan to dental offices in adopting an appropriate mercury hygi program. They are not intended to establish a standard care or to set requirements that must be followed in all cases.

1. Train all personnel involved in the handling of mercur dental amalgam regarding the potential hazard of mercu vapor and the necessity of observing good mercury hygi practices.

2. Make personnel aware of the potential sources of mercury vapor in the dental operatory—that is, spills; op storage of amalgam scrap; open storage of used capsul trituration of amalgam; placement, polishing or removal amalgam; heating of amalgam-contaminated instrument leaky capsules; and leaky bulk mercury dispensers. Personnel also should be knowledgeable about the prop handling of amalgam waste and be aware of environmer issues. Some state dental societies have published wast management recommendations applicable to their state

3. Work in well-ventilated spaces, with fresh air exchang and outside exhaust. If the spaces are air-conditioned, a conditioning filters should be replaced periodically.

4. Periodically check the dental operatory atmosphere fc mercury vapor. Monitoring should be considered in case

EXHIBIT 8

mercury spill or suspected spill, or when there is a reasonable concern about the concentration of mercury vapor in the operatory. Dosimeters may be used for monitoring. Mercury vapor analyzers (that is, hand-held monitors often used by industrial hygienists), which prov rapid readout, also are appropriate, especially for rapid assessment after a spill or cleanup. The current limit for mercury vapor established by the Occupational Safety a Health Administration is 50 micrograms/cubic meter (tim weighted average) in any eight-hour work shift over a 40 hour workweek.[a]

5. Use proper work area design to facilitate spill contamination and cleanup. Floor covering should be nonabsorbent, seamless and easy to clean.

6. Use only precapsulated alloys; discontinue the use of mercury and bulk alloy.

7. Use an amalgamator with a completely enclosed arm.

8. Use care in handling amalgam. Avoid skin contact wit mercury or freshly mixed amalgam.

9. If possible, recap single-use capsules from precapsul alloy after use. Properly dispose of them according to applicable waste disposal laws.

10. Use high-volume evacuation when finishing or remo amalgam. Evacuation systems should have traps or filte Check and clean or replace traps and filters periodically remove waste amalgam (including contact amalgam) fro the waste stream.

11. Salvage and store all scrap amalgam (that is, noncontact amalgam remaining after a procedure) in a tightly closed container, either dry or under radiographic fixer solution. Amalgam scrap should not be stored in wa If the scrap is stored dry, mercury vapor can escape into room air when the container is opened. If the scrap is st under radiographic fixer solution, special disposal of the may be necessary. Note: Some recyclers will accept onl

scrap amalgam that is dry.[b]

12. Where feasible, recycle amalgam scrap and waste amalgam. Otherwise, dispose of amalgam scrap and wa amalgam in accordance with applicable laws. When choosing a recycling company, it is important to check th the company has obtained all required government perm and has not been the subject of a state or federal enforcement action. Because of the nature of environme laws, the generator of the waste (for instance, the dental office) may be held legally responsible if it is improperly handled by others further down the waste stream. Dentis would be wise to check with their state or local dental society about the laws that apply to recycling and to requ documentation from the recycling company that the scra waste has been handled properly.

13. Dispose of mercury-contaminated items in sealed ba according to applicable regulations. Consult the state or local dental society about the regulations that apply in th area. Do not dispose in regulated (medical) waste containers or bags or along with waste that will be incinerated.[c]

14. Clean up spilled mercury properly using trap bottles, tapes or freshly mixed amalgam to pick up droplets, or u commercial cleanup kits. Do not use a household vacuu cleaner.[d]

15. Remove professional clothing before leaving the workplace.

Footnotes

a. Mercury vapor is odorless and can only be detectec using a mercury analyzer or a dosimeter. Monitorin the dental office could provide information on merc vapor concentration and determine whether the practice of dental mercury hygiene needs to be reviewed and revised. The Council recommendatio do not include personal monitoring through urinary

mercury analysis, which yields information on recer exposure to mercury vapor. The American Dental Association Health Foundation includes urinary mercury testing as part of its Health Screening Program, which is conducted during the ADA's Ann Session. The Health Screening Program is free to participants, and data collected by the Health Screening Program provided the basis for some of t Council's mercury hygiene recommendations. In rec years, the mean urinary mercury level in dentists ha been declining steadily and is approaching the leve the general population.

b. Amalgam scrap (non-contact amalgam) could be recycled. The recommendation to store amalgam s in a tightly closed container is aimed at minimizing t amount of mercury vapor emitted from freshly mixe amalgam to the dental operatory. However, the am of mercury vapor emitted from amalgam scrap is nc well quantified. Storage under photographic fixer solution further reduces the potential for mercury va emission as the fixer solution reacts with mercury tc form nonvolatile mercury compounds. However, the fixer solution could then contain trace levels of merc and may create a disposal problem. Preliminary investigation has shown that storing amalgam scrap may not contribute significant amounts of mercury vapor to the dental operatory atmosphere. Dry stora of amalgam scrap may also make it easier to send t recycling.

c. Mercury vapor would be released when contaminat waste is incinerated. Several state and local dental societies included this recommendation in their bes management practices (BMP) for dental office wast

d. The rotating brush of a household vacuum cleaner would disperse smaller droplets of spilled mercury t other parts of the floor.

Address reprint requests to the ADA Council on Scientifi Affairs, 211 E. Chicago Ave., Chicago, Ill. 60611.

Document Posted: July 1999
Page Updated: March 14, 2002
Document address:
http://www.ada.org/members/pubs/jada/reports/mercury.

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Dental Society Resources

- Tripartite Grassroots Membership Initiative
- Communications
- Dental Executive Staff & Leaders
- Membership Recruitment and Retention
- New Dentist
- State Government Affairs Leader and Staff
- Tripartite System Users
- Allied Dental Recruitment

Dental Society Resources

ADA Response -- Dentist the Menace? The Uncontrolled Release of Dental Mercury

The ADA and state dental associations need not apologize when it comes to the environment. The dental community cares deeply about all matters affecting public health. Our record speaks for itself. First and foremost, the ADA is an organization whose mission is to protect the public health. Second, the ADA is a science-based organization and makes thoughtful decisions based on sound science. Finally, the 140,000 ADA member dentists, their hundreds of thousands of caring employees, and the many ADA and state and local dental society employees are highly conscious of environmental issues, not only in the interest of their patients but also their families, loved ones and future generations.

Download the complete document about dental amalgam and dental office wastewater in either Microsoft word or Adobe PDF format.

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Back to top

Page Updated: June 12, 2002

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ADA RESPONSE: ***"Dentist the Menace? The Uncontrolled Release of Dental Mercury"***

The ADA and state dental associations need not apologize when it comes to the environment. The dental community cares deeply about all matters affecting public health. Our record speaks for itself. First and foremost, the ADA is an organization whose mission is to protect the public health. Second, the ADA is a science-based organization and makes thoughtful decisions based on sound science. Finally, the 140,000 ADA member dentists, their hundreds of thousands of caring employees, and the many ADA and state and local dental society employees are highly conscious of environmental issues, not only in the interest of their patients but also their families, loved ones and future generations.

Again, the record speaks for itself. Dental associations have taken the following actions:

- Encouraged recycling of dental amalgam since the 1980s.
- Urged appropriate handling of dental amalgam in the dental office since the 1980s, including recommending that dentists eliminate use of bulk dental mercury and bulk amalgam alloy and use only precapsulated amalgam alloy.
- Encouraged manufacturers of dental amalgam to continue to improve this restorative material and ensure safe handling of all of the component parts (silver, nickel, tin, mercury), to include establishing recycling programs for used amalgam capsules.
- Conducted laboratory research on the efficacy of amalgam separators.
- Encouraged clinical research on the efficacy of amalgam separators
- Encouraged development of new and improved restorative materials.
- Led the way in the development of composite resin restorative materials.
- Supported sound science.

While it is difficult to counter all the erroneous information in the report, the following inaccuracies stand out.

Dental Office Single Largest Wastewater Contributor

Assertion: By far the largest single contributor of mercury to wastewater is dental offices.

Response: Dental offices do not discharge mercury into wastewater. No one disputes that dental offices are sources of amalgam discharge, but charges regarding dental office contribution of mercury, which remains tightly bound in the amalgam mixture, are unfounded. The vast majority of mercury in surface water is from atmospheric sources, not direct discharge. For example, the Environmental Protection Agency calculated that 99% of mercury entering the Savannah River in Georgia was from atmospheric sources. Dental offices' relative contribution of "total mercury" (in the form of amalgam) to wastewater depend on other sources (industrial, residential) of discharge to a particular wastewater treatment plant and vary based on local conditions. Estimates of dental office contribution to "total mercury" in wastewater vary widely. San Francisco and Seattle estimated such contributions at 8-14% but did not report estimates of

EXHIBIT 10

contribution from other sources. The dental community welcomes the opportunity to do its fair share in reducing levels of mercury in the environment.

Assertion: Today, dentists are the third largest user of mercury in the United States, consuming over 20% of the estimated 200 metric tons used in 2001–or over 40 metric tons of mercury–with most eventually released into the environment.

Response: The issue is not how much mercury is used in amalgam. Little of that mercury is released into the environment. When amalgam is discharged, it is in the form of solid amalgam (silver, tin, copper and mercury), not elemental mercury. In addition, use of mercury for dental amalgam is decreasing, and the report's extrapolation of statistics is specious. The Bureau of Mines estimate cited in the report shows a decrease from 44 metric tons in 1990 to 31 metric tons in 1996. An ADA survey (ADA News, June 3, 2002) shows that the number of amalgam restorations in 1999 was 58% less than in 1990 so the amount of mercury used for amalgam is considerably less than the 44 metric tons cited in the report.

Toxicity of Mercury

Assertion: Mercury is a persistent, bioaccumautltive toxin that poses a risk to human health, wildlife and the environment.

Response: It is important to distinguish dental amalgam, a solid intermetallic compound of mercury, silver, tin and copper from other forms of mercury, such as elemental mercury (liquid/vapor) and methylmercury. The report's description of the effects of mercury is not applicable to dental amalgam. Governmental agencies responsible for protecting the public's health agree that dental amalgam is a safe restorative material (USPHS, FDA, WHO, NIDCR).

Assertion: In water and soil, mercury is transformed into its most toxic form, methyl mercury, by the natural biochemical process of methylation.

Response: The transformation of mercury into methylmercury is not an automatic process, and not all mercury that exists in the environment is converted to methylmercury. The methylation process needs suitable environmental conditions and the presence of necessary microorganisms for methylation to occur.

Why Call Them Silver Fillings?

Assertion: The ADA, state dental associations and their members consistently refer to amalgams as "silver fillings," even though, on average, the silver actually comprises only 25 percent of an amalgam filling.

Response: This restorative material is referred to by different names by the ADA, academicians, researchers and others. No one name is used consistently, but "dental amalgam" is probably the most common. "Silver fillings" is a common way of distinguishing dental amalgam by appearance from "white fillings" (composite resin) or "gold fillings" (gold).

Dental Industry Wary of Change to Composites

Assertion: Potentially higher costs, especially in the case of gold or gold alloys, and the possibility of other problems such as shorter lifespan—as some believe is the case with composites—make the dental industry wary of accepting responsibility for the transition away from mercury amalgams and for reducing their mercury releases.

Response: Dentistry has no ulterior motive for including amalgam as an option among restorative materials for patients and dentists. It would be very much in the financial interests of dentistry to eliminate use of amalgam, a relatively inexpensive, durable restorative material, in favor of materials that cost more. After all, the costs would be borne by patients and their insurers. The dental profession and dental associations have been strong proponents of new and better dental restorative materials and have supported research, development and improvement of composite materials for many years. In fact, the ADA has been the primary sponsor of research into alternatives to dental amalgam. But if dental amalgam were banned, the cost of dental care could be expected to rise, and access to care by the low-income would suffer.

Environmentally Responsible Dentists

Assertion: Environmentally responsible dental clinics reduce use of mercury where feasible, employ best management practices and operate amalgam separators to get the highest capture rates of dental mercury.

Response: Dentists are reducing the use of amalgam (ADA News June 2, 2002). The most appropriate restorative material, whether resin-based composites, cast alloys or amalgam, is selected depending on the need of the patient. The ADA periodically provides guidance to dentists in the choice of restorative material. Examples are the ADA publications, "Choosing Intracoronal Restorative Materials" (JADA 1994; 125:102-103) and "ADA Chart of Dental Materials" (ADA News, March 18, 2002).

The ADA and state and local dental societies have cooperated fully with governmental agencies in developing best management practice guidelines for individual dentists to follow. The ADA supports measures to increase dentists' awareness of environmental requirements and is developing a national action plan to improve dentists' understanding of environmental issues and environmentally responsible practices.

Use of Dental Amalgam to Remain Stable

Assertion: Current projections anticipate that dental amalgam use is expected to remain relatively stable, with perhaps a gradual decrease, in the coming years. (Table on page 3 of *Dentist the Menace: The Uncontrolled Release of Dental Mercury.)*

Response: The use of dental amalgam is decreasing. An ADA survey (ADA News, June 3, 2002) shows that the number of amalgam restorations in 1999 is 58% less than in 1990. It is important to note that the table uses two sources of estimated mercury use. The estimated usage for 1985 to 1996 is from a Bureau of Mines Report. The 2001 estimated usage is an article in

Chemical and Engineering News, 2001. The 2001 estimate of 44 metric tons of mercury for dental use is inexplicably the same amount estimated by the Bureau of Mines for 1990. Using ADA survey findings that the number of amalgam restorations in 1999 was 58 percent less than in 1990, the amount of mercury used in dentistry for 1999 is estimated to be 18.5 metric tons (42% of 44 metric tons). The amount for 2001 would be even less than that for 1999.

ADA Continues to Recommend Dental Amalgam

***Assertion*:** In spite of the existence of increasingly attractive non-mercury fillings, the ADA continues to recommend the use of amalgam.

***Response*:** The ADA does not recommend any one restorative material. The ADA believes that patients, in consultation with their dentists, should have a full range of treatment options, including filling materials. Decisions on what is most clinically appropriate should be made by the patient and the dentist. Dental amalgam is but one of many dental filling materials that the ADA evaluates to help dentists and their patients choose safe and effective treatments.

Dental Mercury Disposal Routes

Assertion: It is estimated that when an amalgam is prepared, 10 percent is left over and is often simply discarded.

Response: The ADA, in its dental mercury hygiene recommendations published since the 1980s, recommends proper storage of amalgam scrap for recycling. Amalgam scrap, the unused amalgam prepared for fillings, has intrinsic value and is often recycled. Several companies (e.g., Doral, Garfield) offer recycling of amalgam scrap.

"Discharge of Dental Mercury to Waste Water Systems" Table

The estimates are based on amalgam in wastewater measured as "total mercury." Dental offices do not discharge mercury. Furthermore, some of the estimates contradict other reports for the same city. For example, a Seattle King County study (Dental Office Waste Stream Characterization Study 1991) reported "about 14 percent of the mercury loading to the Metro sewerage system appears to come from dental offices." A Massachusetts Water Resources Authority (MWRA) presentation (Mercury in Dental Facilities, Massachusetts Water Resources Authority September, 1997; Mercury in the Environment: Proceedings of a Specialty Conference September 15-17, 1999) stated "MWRA believes that its high-end estimate is improbable, but is confident that the low-end, rounded down to 10%, is a reasonable minimum estimate. This estimate is consistent with findings of other studies: studies estimated dentists' contributions to the total mercury load at 8-13% in San Francisco, 14% in Seattle and 26% in Duluth."

Solid Waste

Assertion: Mercury-bearing scrap amalgam is often discarded into the trash and leaves the dental office by solid waste hauler and is either landfilled or incinerated.

Response: The ADA has recommended recycling of amalgam scrap since the 1980s. In a study subjecting amalgam scrap to the EPA's TCLP test, the concentration of mercury and silver in the extracts does not exceed the EPA's maximum allowable concentrations. It was concluded that amalgam scrap is not a hazardous solid waste. (Reference 73 in the report. It should include the citation as Environmental hazard evaluation of amalgam scrap. Dent Mater 1992; 8:359-361).

Dentist Can Remove, Recycle Mercury for $50.00 A Month

Assertion: The change required in dental office practices is relatively straightforward and inexpensive. *For example, it costs less than $50.00 a month, slightly less than the cost of a single filling, for a dentist in the Massachusetts Dental Society to remove and recycle mercury from amalgams.*

Response: This estimate of cost is unfounded. The Massachusetts Dental Society has no such estimate of the costs as quoted. The ADA is preparing an estimate of the cost of various dental amalgam waste disposal and recycling options to assess what best management practices are appropriate. This estimate should be available soon.

Few Dentists Reduce Use and Release of Mercury

Assertion: However, only a small percentage of dentists nationwide have taken the steps necessary to reduce use and release of this dangerous toxin [mercury].

Response: As the knowledge base increases, an increasing number of state and local dental societies have adopted waste management guidelines and have urged their members to follow best management practices. In the past few years, state and local dental societies in as many as 20 states have developed programs to reduce the discharge of dental amalgam. These voluntary activities have been favorably received by environmental regulators and widely publicized through their networks to regulators in other areas of the country and the U. S. Environmental Protection Agency. These activities include:

- Development of guidelines/recommendations for managing waste in dental offices, also known as Best Management Practices, often as joint endeavors with environmental regulators;
- Distribution of pamphlets, brochures and newsletters on waste management;
- Education and training programs or workshops for dentists;
- Presentations and other exchanges of information between dental societies and environmental regulators (e.g., inviting regulators to speak at dental society meetings);
- Bulk recycling programs. State and local governments were asked to provide funding and other assistance to develop recycling collection sites. Bulk recycling programs have been adopted in places such as Michigan; Duluth, MN; Ohio; Oregon and Wisconsin; and
- Scrap amalgam recycling.

ADA, State Dental Societies Oppose Mercury Reduction Efforts

Assertion: The American Dental Association (ADA) and many state dental associations have refrained from promoting, and even opposed, mercury reduction efforts. The ADA refuses to encourage its members to assume reasonability for curtailing dental mercury pollution, opting instead to obstruct initiatives at the state and local level.

Response: The ADA has not obstructed and does not obstruct initiatives at the state and local level. In fact, the ADA serves as a clearinghouse for information for state dental societies seeking information and advice on environmental issues. ADA staff routinely encourage state dental associations and their lobbyists to work cooperatively with state and local environmental regulators in developing effective programs to reduce discharge of dental amalgam into the waste stream. The ADA has distributed copies of best waste management practices developed by numerous dental societies to other states seeking ADA advice in an effort to encourage them to take similar action. The ADA has encouraged state dental societies in the Great Lakes states to attend the Great Lakes Dental Mercury Reduction Project. This project resulted in the development of waste management guidelines to reduce amalgam discharge and encourage recycling of unused or scrap amalgam. These guidelines have been well received by environmental regulators. They have been adopted by state dental societies in the region and served as a model for guidelines developed in states in other regions of the country.

Collection of Excess Elemental Mercury

Assertion: While some states and locales have hosted "clean sweeps" to collect excess elemental mercury from dentists, quantities collected so far suggest it is likely that large quantities of elemental dental mercury remain uncollected and represent a significant risk of being mismanaged or improperly disposed.

Response: The ADA encourages state and local dental societies to institute bulk recycling collection programs. Such programs are periodically conducted in numerous states. In addition, the ADA encourages dental societies to work with environmental regulators to identify amalgam and silver waste recyclers in their geographic regions so they can inform their members

ADA, State Dental Societies Undermine Efforts to Control Mercury Discharges

Assertion: All of the contentions, arguments, and positions by the ADA and state dental societies are designed to undermine and discourage legislative and regulatory efforts to control mercury discharge limits for the dental industry, even though scientifically the positions are largely unfounded.

Response: The ADA and its state dental societies welcome legislative or regulatory attempts to protect the environment that are based on sound science. The ADA has worked with numerous state dental societies seeking assistance to further that goal. The ADA does, however, oppose efforts to restrict dentists and patients from making an informed choice to use dental amalgam as one of several acceptable types of dental restorative materials found to be safe by virtually all national and international health organizations.

Voluntary and Mandatory Initiatives Most Successful for Dentists to Reduce Pollution

Assertion: A combination of voluntary and mandatory initiatives has been most successful in convincing dentists to take the necessary steps to reduce their mercury pollution.

Response: *S*trictly voluntary initiatives implemented by dental societies in other states have made significant strides in reducing the amount of dental amalgam in wastewater.

ADA Advocating for FDA to Preempt State Legislation

Assertion: Consistent with its position, the ADA is now advocating for the Food and Drug Administration to effectively preempt significant legislative advances made at the state level.

Response: This is not true, nor does the cited action have anything to do with environmental controls. The fact is that the FDA has proposed tightening its regulation of amalgam-related medical devices by grouping them all in the same regulatory category (Class II) and adopting a special guidance on **labeling**. The ADA supports this effort. Congress, through the Medical Device Amendments of 1976 to the Food, Drug and Cosmetics Act, clearly communicated its intent to allow the FDA to preempt state laws that conflict with federal requirements for medical devices. That's all we're asking the FDA to do.

ADA Presents Conflicting and Contradictory Statements About Amalgam

Assertion: The ADA presents conflicting and often contradictory statements about the nature of amalgams, at times claiming that their members make only a "small contribution to mercury in dental wastewater," but other times remaining completely silent on the question of environmental impacts, such as in its "Statement on Dental Amalgam."

Response: The example given in no way supports the claim that the ADA presents conflicting and contradictory statements. Failing to speak to environmental issues in the cited document is not a conflict or contradiction. The ADA *Statement on Dental Amalgam* addresses issues of patient safety and effectiveness, not environmental issues. Nothing in the ADA *Statement* conflicts with or contradicts data on the contribution of dental offices to mercury in wastewater.

The author's purpose in making this statement is called into question by the deceptive quote attributed to the ADA. The full quote is, "The American Dental Association continues to help its members reduce the profession's small contribution to mercury in dental wastewater to address this very important health and environmental issue." This quote is taken from a story on an ADA study evaluating amalgam separators, the first such study done in the United States. A sidebar to the story describes the seven-part ADA wastewater action plan. The author writes a lengthy report focusing on the ADA and completely ignores one of the Association's most recent and significant actions.

Final ADA Comment

Among the groups involved in this publication are some reputable organizations dedicated to the public health and environment. We call on these organizations to carefully examine this document, noting its deceptive use of citations, sloppy statistics and overall lack of scientific merit and to publicly disassociate themselves from this low caliber of workmanship. Documents of this sort create heat but not light and are unlikely to contribute anything worthwhile to an important public issue.

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The ADA

Dental Society Resources

Resources for State Government Affairs Leaders and Staff

- Services
- Lobbying
- Medicaid
- Amalgam Safety
- Associated Medical Costs
- Legislative & Regulatory Issues (**Note:** You will leave this section of ADA.org)

Additional Resources
Local, State, National, & International Organizations Directory

E-mail Resources for State Government Affairs Leaders and Staff

Amalgam Safety

The safety of dental amalgam as a restorative material is called into question when amalgam opponents try to:

- persuade legislators or regulators to restrict or ban the use of dental amalgams, especially in pregnant women and children;
- require a special written informed consent prior to placement of amalgams; or
- attempt to prevent dental boards from disciplining dentists who urge non-allergic patients to remove serviceable amalgams.

Some or all of these issues have arisen in at least a dozen states. There was a significant increase in legislative activity by amalgam opponents in 2002, fueled by the introduction of environmental bills aimed at reducing or eliminating the use of mercury-added products. In some states, amendments to ban placement of amalgams were tacked on to pending environmental legislation.

If you haven't experienced this issue, you should be aware that amalgam opponents will claim that amalgams are a public health risk and that amalgams have been banned in many countries. Both statements can be rebutted. For more information call Department of State Government Affairs at extension 2525.

Also for further reference see:

Facts for Communicators on Amalgam an ADA document available online, summarizes positions world health organizations on the safety of dental amalgam fillings.

American Dental Association
Department of State Government Affairs
February 14, 2002

Page Updated: June 07, 2002

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Silver Dental Fillings Are Still a Safe Option

For more than 150 years, silver fillings - dental amalgams - have bee a reliable option in tooth restoration. From time to time, some concer has been expressed about the safety of silver fillings because they contain mercury. However, when mercury is used in dental amalgam chemically binds to the other metals being used (silver, copper, or tin and becomes a biologically inactive substance.

Small quantities of mercury can be found throughout the body. We ar exposed to mercury through drinking water and some foods, especial certain seafood, and through the air we breathe. Eventually, the body rids itself of mercury through the urine, but there is always a low level of mercury present in our bodies.

While minute amounts of mercury vapor may be released from a silve filling under the pressure of chewing or grinding, there is no scientific evidence that such low-level exposure is harmful.

Dental amalgam has been the subject of many scientific studies and there is no scientific evidence supporting a link between silver fillings and systemic diseases or chronic illnesses. No studies have demonstrated that the small contribution of mercury from dental filling to the overall mercury level in the body causes a toxic reaction, excep in the very rare case of an allergic reaction.

Dental amalgam has not been banned in the United States or any other country. A few countries have suggested limiting the use of amalgam restorations in some patients (for example, young children, pregnant women or those who have kidney disease). Several nations report declining use of amalgam. These decreases are attributed to improvements in preventive dentistry, the introduction of more durabl tooth-colored restoratives, and environmental concerns.

Agencies within the U.S. Public Health Service - including the Nation Institutes of Health, Food and Drug Administration and the Centers fc Disease Control and Prevention - have reviewed data on the safety o silver fillings. Based on the available research, these groups conclud that dental amalgam causes no demonstrated clinical harm and that removal of dental amalgam fillings will not prevent adverse health effects or reverse the course of existing diseases. The World Health Organization, American Association for Dental Research and the Environmental Protection Agency have reached similar conclusions.

If you have questions or concerns about this or other oral health

EXHIBIT 12

issues, talk to your dentist.

This dental health column is brought to you by your local dental society and the American Dental Association.

Download this article (in Microsoft Word): fillings.doc.

Page Posted: December 27, 2000
Page Updated: July 29, 2002

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ATSDR

MERCURY
CAS # 7439-97-6

Agency for Toxic Substances and Disease Registry ToxFAQs April 1999

This fact sheet answers the most frequently asked health questions (FAQs) about mercury. For more information, call the ATSDR Information Center at 1-888-422-8737. This fact sheet is one in a series of summaries about hazardous substances and their health effects. It's important you understand this information because this substance may harm you. The effects of exposure to any hazardous substance depend on the dose, the duration, how you are exposed, personal traits and habits, and whether other chemicals are present.

HIGHLIGHTS: Exposure to mercury occurs from breathing contaminated air, ingesting contaminated water and food, and having dental and medical treatments. Mercury, at high levels, may damage the brain, kidneys, and developing fetus. This chemical has been found in at least 714 of 1,467 National Priorities List sites identified by the Environmental Protection Agency.

What is mercury?
(Pronounced mŭr'kyə-rē)

Mercury is a naturally occurring metal which has several forms. The metallic mercury is a shiny, silver-white, odorless liquid. If heated, it is a colorless, odorless gas.

Mercury combines with other elements, such as chlorine, sulfur, or oxygen, to form inorganic mercury compounds or "salts," which are usually white powders or crystals. Mercury also combines with carbon to make organic mercury compounds. The most common one, methylmercury, is produced mainly by microscopic organisms in the water and soil. More mercury in the environment can increase the amounts of methylmercury that these small organisms make.

Metallic mercury is used to produce chlorine gas and caustic soda, and is also used in thermometers, dental fillings, and batteries. Mercury salts are sometimes used in skin lightening creams and as antiseptic creams and ointments.

What happens to mercury when it enters the environment?

- Inorganic mercury (metallic mercury and inorganic mercury compounds) enters the air from mining ore deposits, burning coal and waste, and from manufacturing plants.
- It enters the water or soil from natural deposits, disposal of wastes, and volcanic activity.
- Methylmercury may be formed in water and soil by small organisms called bacteria.
- Methylmercury builds up in the tissues of fish. Larger and older fish tend to have the highest levels of mercury.

How might I be exposed to mercury?

- Eating fish or shellfish contaminated with methylmercury.
- Breathing vapors in air from spills, incinerators, and industries that burn mercury-containing fuels.
- Release of mercury from dental work and medical treatments.
- Breathing contaminated workplace air or skin contact during use in the workplace (dental, health services, chemical, and other industries that use mercury).
- Practicing rituals that include mercury.

How can mercury affect my health?

The nervous system is very sensitive to all forms of mercury. Methylmercury and metallic mercury vapors are more harmful than other forms, because more mercury in these forms reaches the brain. Exposure to high levels of metallic, inorganic, or organic mercury can permanently damage the brain, kidneys, and developing fetus. Effects on brain functioning may result in irritability, shyness, tremors, changes in vision or hearing, and memory problems.

Short-term exposure to high levels of metallic mercury vapors may cause effects including lung damage, nausea,

EXHIBIT 13

vomiting, diarrhea, increases in blood pressure or heart rate, skin rashes, and eye irritation.

How likely is mercury to cause cancer?

There are inadequate human cancer data available for all forms of mercury. Mercuric chloride has caused increases in several types of tumors in rats and mice, and methylmercury has caused kidney tumors in male mice. The EPA has determined that mercuric chloride and methylmercury are possible human carcinogens.

How can mercury affect children?

Very young children are more sensitive to mercury than adults. Mercury in the mother's body passes to the fetus and may accumulate there. It can also can pass to a nursing infant through breast milk. However, the benefits of breast feeding may be greater than the possible adverse effects of mercury in breast milk.

Mercury's harmful effects that may be passed from the mother to the fetus include brain damage, mental retardation, incoordination, blindness, seizures, and inability to speak. Children poisoned by mercury may develop problems of their nervous and digestive systems, and kidney damage.

How can families reduce the risk of exposure to mercury?

Carefully handle and dispose of products that contain mercury, such as thermometers or fluorescent light bulbs. Do not vacuum up spilled mercury, because it will vaporize and increase exposure. If a large amount of mercury has been spilled, contact your health department. Teach children not to play with shiny, silver liquids.

Properly dispose of older medicines that contain mercury. Keep all mercury-containing medicines away from children.

Pregnant women and children should keep away from rooms where liquid mercury has been used.

Learn about wildlife and fish advisories in your area from your public health or natural resources department.

Is there a medical test to show whether I've been exposed to mercury?

Tests are available to measure mercury levels in the body. Blood or urine samples are used to test for exposure to metallic mercury and to inorganic forms of mercury. Mercury in whole blood or in scalp hair is measured to determine exposure to methylmercury. Your doctor can take samples and send them to a testing laboratory.

Has the federal government made recommendations to protect human health?

The EPA has set a limit of 2 parts of mercury per billion parts of drinking water (2 ppb).

The Food and Drug Administration (FDA) has set a maximum permissible level of 1 part of methylmercury in a million parts of seafood (1 ppm).

The Occupational Safety and Health Administration (OSHA) has set limits of 0.1 milligram of organic mercury per cubic meter of workplace air (0.1 mg/m^3) and 0.05 mg/m^3 of metallic mercury vapor for 8-hour shifts and 40-hour work weeks.

Source of Information

Agency for Toxic Substances and Disease Registry (ATSDR). 1999. Toxicological profile for mercury. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Animal testing is sometimes necessary to find out how toxic substances might harm people and how to treat people who have been exposed. Laws today protect the welfare of research animals and scientists must follow strict guidelines.

Where can I get more information? For more information, contact the Agency for Toxic Substances and Disease Registry, Division of Toxicology, 1600 Clifton Road NE, Mailstop E-29, Atlanta, GA 30333. Phone: 1-888-422-8737, FAX: 404-639-6359. ToxFAQs Internet address via WWW is http://www.atsdr.cdc.gov/toxfaq.html ATSDR can tell you where to find occupational and environmental health clinics. Their specialists can recognize, evaluate, and treat illnesses resulting from exposure to hazardous substances. You can also contact your community or state health or environmental quality department if you have any more questions or concerns.

ATSDR
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

CONTENTS

What is the CERCLA List
CERCLA Substance List
Contact Information

Prior Year CERCLA Lists

1999 CERCLA Priority List
1997 CERCLA Priority List

ATSDR RESOURCES

ToxFAQs™ Info
Public Health Statements
Toxicological Profiles
Completed Exposure Path
vision of Toxicology

2001 CERCLA Priority List of Hazardous Substances

What is the CERCLA List?

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 104 (i), as amended by the Superfund Amendments and Reauthorization Act (SARA), requires ATSDR and the EPA to prepare a list, in order of priority, of substances that are most commonly found at facilities on the National Priorities List (NPL) and which are determined to pose the most significant potential threat to human health due to their known or suspected toxicity and potential for human exposure at these NPL sites. CERCLA also requires this list to be revised periodically to reflect additional information on hazardous substances.

This CERCLA priority list is revised and published on a 2-year basis, with a yearly informal review and revision. Each substance on the CERCLA Priority List of Hazardous Substances is a candidate to become the subject of a toxicological profile prepared by ATSDR and subsequently a candidate for the identification of priority data needs. This priority list is based on an algorithm that utilizes the following three components: frequency of occurrence at NPL sites, toxicity, and potential for human exposure to the substances found at NPL sites. This algorithm utilizes data from ATSDR's HazDat database, which contains information from ATSDR's public health assessments and health consultations.

It should be noted that this priority list is not a list of "most toxic" substances, but rather a prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at NPL sites.

Thus, it is possible for substances with low toxicity but high NPL frequency of occurrence and exposure to be on this priority list. The objective of this priority list is to rank substances across all NPL hazardous waste sites to provide guidance in selecting which substances will be the subject of toxicological profiles prepared by ATSDR.

There is a Support Document to the CERCLA Priority List of Hazardous Substances that describes in detail how the list is developed. To receive a copy of the support document, send an e-mail to the ATSDR Information Center at: ATSDRIC@cdc.gov or send a written request to

ATSDR Information Center

EXHIBIT 14

Division of Toxicology
1600 Clifton Rd NE, Mail Stop E-29
Atlanta, GA 30333

Related information:

The ATSDR Division of Toxicology has prepared several sets of publications that provide answers to many health concerns that are voiced by community groups and give general information on various properties of each of these substances. Those publications are listed and may be accessed online at the following links:

- **ATSDR ToxFAQs™ Sheets**
- **ATSDR Public Health Statements**
- **ATSDR Toxicological Profiles**

You may also access the previous lists online:

- **CERCLA Priority List of Hazardous Substances for 1999**
- **CERCLA Priority List of Hazardous Substances for 1997**

Contact information:

Further information can be obtained by contacting the ATSDR Information Center at:

Agency for Toxic Substances and Disease Registry
Division of Toxicology
1600 Clifton Road NE, Mailstop E-29
Atlanta, GA 30333
Phone: 1-888-422-8737
Fax: 1-404-498-0057
E-mail: ATSDRIC@cdc.gov.

2001 CERCLA Priority List Hazardous Substances

2001 RANK	SUBSTANCE NAME	TOTAL POINTS	1999 RANK	CAS No.
1	ARSENIC	1653.61	1	007440-38-2
2	LEAD	1528.01	2	007439-92-1
3	MERCURY	1503.32	3	007439-97-6
4	VINYL CHLORIDE	1388.65	4	000075-01-4
5	POLYCHLORINATED BIPHENYLS	1364.35	6	001336-36-3
6	BENZENE	1356.41	5	000071-43-2
7	CADMIUM	1319.78	7	007440-43-9
8	BENZO(A)PYRENE	1303.14	8	000050-32-8
9	POLYCYCLIC AROMATIC HYDROCARBONS	1300.73	9	130498-29-2

10	BENZO(B)FLUORANTHENE	1271.94	10	000205-99-2
11	CHLOROFORM	1234.42	11	000067-66-3
12	DDT, P,P'-	1190.24	12	000050-29-3
13	AROCLOR 1254	1178.24	14	011097-69-1
14	AROCLOR 1260	1175.08	13	011096-82-5
15	TRICHLOROETHYLENE	1160.49	15	000079-01-6
16	DIBENZO(A,H)ANTHRACENE	1159.41	17	000053-70-3
17	DIELDRIN	1148.51	18	000060-57-1
18	CHROMIUM, HEXAVALENT	1147.80	16	018540-29-9
19	CHLORDANE	1131.11	22	000057-74-9
20	HEXACHLOROBUTADIENE	1130.07	19	000087-68-3
21	DDE, P,P'-	1129.31	20	000072-55-9
22	COAL TAR CREOSOTE	1124.54	21	008001-58-9
23	ALDRIN	1120.21	24	000309-00-2
24	PHOSPHORUS, WHITE	1116.30	29	007723-14-0
25	BENZIDINE	1114.32	23	000092-87-5
26	DDD, P,P'-	1113.74	27	000072-54-8
27	AROCLOR 1248	1106.62	25	012672-29-6
28	CYANIDE	1099.94	26	000057-12-5
29	AROCLOR 1242	1092.58	28	053469-21-9
30	HEPTACHLOR	1085.76	30	000076-44-8
31	TOXAPHENE	1082.49	32	008001-35-2
32	TETRACHLOROETHYLENE	1081.45	31	000127-18-4
33	HEXACHLOROCYCLOHEXANE, GAMMA-	1081.27	33	000058-89-9
34	BENZO(A)ANTHRACENE	1062.54	35	000056-55-3
35	HEXACHLOROCYCLOHEXANE, BETA-	1061.60	34	000319-85-7
36	1,2-DIBROMOETHANE	1058.09	36	000106-93-4
37	DISULFOTON	1053.72	37	000298-04-4
38	BERYLLIUM	1044.18	39	007440-41-7
39	HEXACHLOROCYCLOHEXANE, DELTA-	1039.19	40	000319-86-8
40	ENDRIN	1038.83	38	000072-20-8
41	1,2-DIBROMO-3-CHLOROPROPANE	1032.99	43	000096-12-8
42	HEPTACHLOR EPOXIDE	1026.85	47	001024-57-3
43	PENTACHLOROPHENOL	1024.18	44	000087-86-5
44	CARBON TETRACHLORIDE	1020.59	46	000056-23-5
45	ENDOSULFAN, ALPHA	1016.38	55	000959-98-8
46	AROCLOR 1221	1015.56	41	011104-28-2
47	DI-N-BUTYL PHTHALATE	1015.43	42	000084-74-2
48	AROCLOR 1016	1014.94	45	012674-11-2
49	COBALT	1012.27	49	007440-48-4
50	DDT, O,P'-	1011.55	51	000789-02-6
51	CIS-CHLORDANE	1011.29	60	005103-71-9
52	ENDOSULFAN SULFATE	1006.01	50	001031-07-8
53	NICKEL	1005.34	52	007440-02-0
54	ENDOSULFAN	1004.00	56	000115-29-7
55	3,3'-DICHLOROBENZIDINE	1003.98	53	000091-94-1
56	XYLENES, TOTAL	1003.91	48	001330-20-7

57	TRANS-CHLORDANE	999.67	66	005103-74-2
58	METHOXYCHLOR	998.82	76	000072-43-5
59	DIBROMOCHLOROPROPANE	993.50	54	067708-83-2
60	BENZO(K)FLUORANTHENE	985.64	57	000207-08-9
61	AROCLOR	984.93	58	012767-79-2
62	ENDRIN KETONE	980.70	59	053494-70-5
63	ENDOSULFAN, BETA	975.42	64	033213-65-9
64	2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN	964.52	67	001746-01-6
65	CHROMIUM(VI) OXIDE	964.00	163	001333-82-0
66	METHANE	961.42	65	000074-82-8
67	AROCLOR 1232	956.41	63	011141-16-5
68	TOLUENE	954.93	62	000108-88-3
69	ENDRIN ALDEHYDE	954.04	69	007421-93-4
70	BENZOFLUORANTHENE	947.43	68	056832-73-6
71	2-HEXANONE	944.69	61	000591-78-6
72	ACROLEIN	938.18	211	000107-02-8
73	ZINC	932.44	70	007440-66-6
74	DIMETHYLARSINIC ACID	929.43	71	000075-60-5
75	DI(2-ETHYLHEXYL)PHTHALATE	921.55	72	000117-81-7
76	CHROMIUM	911.63	73	007440-47-3
77	NAPHTHALENE	899.35	75	000091-20-3
78	METHYLENE CHLORIDE	891.98	74	000075-09-2
79	1,1-DICHLOROETHENE	887.05	77	000075-35-4
80	AROCLOR 1240	886.38	78	071328-89-7
81	2,4,6-TRINITROTOLUENE	870.31	82	000118-96-7
82	1,2-DICHLOROETHANE	867.95	80	000107-06-2
83	2,4-DINITROPHENOL	865.19	81	000051-28-5
84	BROMODICHLOROETHANE	864.22	225	000683-53-4
85	BIS(2-CHLOROETHYL) ETHER	862.39	79	000111-44-4
86	HYDRAZINE	858.99	220	000302-01-2
87	2,4,6-TRICHLOROPHENOL	854.60	83	000088-06-2
88	THIOCYANATE	844.50	89	000302-04-5
89	ASBESTOS	843.64	90	001332-21-4
90	1,1,1-TRICHLOROETHANE	842.06	86	000071-55-6
91	ETHYLBENZENE	841.37	87	000100-41-4
92	CYCLOTRIMETHYLENETRINITRAMINE (RDX)	837.73	85	000121-82-4
93	4,6-DINITRO-O-CRESOL	836.37	91	000534-52-1
94	URANIUM	835.16	92	007440-61-1
95	RADIUM-226	833.49	94	013982-63-3
96	CHLORINE	831.39	84	007782-50-5
97	ETHION	830.34	96	000563-12-2
98	RADIUM	829.29	93	007440-14-4
99	THORIUM	825.64	97	007440-29-1
100	HEXACHLOROBENZENE	825.21	95	000118-74-1
101	2,4-DINITROTOLUENE	824.99	100	000121-14-2
102	BARIUM	819.77	99	007440-39-3
103	1,1,2,2-TETRACHLOROETHANE	817.79	88	000079-34-5

104	RADON	817.53	102	010043-92-2
105	CHLOROBENZENE	816.86	98	000108-90-7
106	FLUORANTHENE	816.71	101	000206-44-0
107	RADIUM-228	815.52	103	015262-20-1
108	THORIUM-230	815.18	104	014269-63-7
109	URANIUM-235	814.18	108	015117-96-1
110	HEXACHLOROCYCLOHEXANE, ALPHA-	813.67	114	000319-84-6
111	1,3,5-TRINITROBENZENE	813.67	107	000099-35-4
112	N-NITROSODI-N-PROPYLAMINE	813.52	112	000621-64-7
113	URANIUM-234	812.94	110	013966-29-5
114	DIAZINON	812.27	105	000333-41-5
115	THORIUM-228	809.96	111	014274-82-9
116	RADON-222	809.92	116	014859-67-7
117	CHRYSENE	807.53	115	000218-01-9
118	STRONTIUM-90	807.17	125	010098-97-2
119	CHRYSOTILE ASBESTOS	806.97	118	012001-29-5
120	METHYLMERCURY	806.94	127	022967-92-6
121	POLONIUM-210	806.74	117	013981-52-7
122	COAL TARS	806.47	121	008007-45-2
123	PLUTONIUM-239	806.20	130	015117-48-3
124	PLUTONIUM-238	806.00	122	013981-16-3
125	CHLORPYRIFOS	805.50	128	002921-88-2
126	LEAD-210	805.23	129	014255-04-0
127	AMERICIUM-241	804.96	132	086954-36-1
128	THORON (RADON-220)	804.93	123	022481-48-7
129	COPPER	804.32	124	007440-50-8
130	IODINE-131	803.72	133	010043-66-0
131	PLUTONIUM	803.49	131	007440-07-5
132	NEPTUNIUM-237	802.95	NEW	013994-20-2
133	AMOSITE ASBESTOS	802.75	134	012172-73-5
134	GUTHION	802.48	134	000086-50-0
135	CHLORDECONE	801.74	138	000143-50-0
135	PLUTONIUM-240	801.74	138	014119-33-6
135	TRIBUTYLTIN	801.74	138	000688-73-3
138	MANGANESE	801.62	141	007439-96-5
139	HYDROGEN CYANIDE	799.57	NEW	000074-90-8
140	S,S,S-TRIBUTYL PHOSPHOROTRITHIOATE	795.72	142	000078-48-8
141	BROMINE	787.92	106	007726-95-6
142	POLYBROMINATED BIPHENYLS	787.62	144	067774-32-7
143	DICOFOL	786.09	145	000115-32-2
144	SELENIUM	785.29	143	007782-49-2
145	PARATHION	783.64	146	000056-38-2
146	HEXACHLOROCYCLOHEXANE, TECHNICAL	775.72	147	000608-73-1
147	PENTACHLOROBENZENE	772.32	148	000608-93-5
148	1,2,3-TRICHLOROBENZENE	771.72	190	000087-61-6
149	TRICHLOROFLUOROETHANE	770.06	149	027154-33-2
150	TREFLAN (TRIFLURALIN)	769.22	150	001582-09-8

151	4,4'-METHYLENEBIS(2-CHLOROANILINE)	766.34	151	000101-14-4
152	DDD, O,P'-	763.14	153	000053-19-0
153	HEXACHLORODIBENZO-P-DIOXIN	761.61	154	034465-46-8
154	HEPTACHLORODIBENZO-P-DIOXIN	755.72	155	037871-00-4
155	2-METHYLNAPHTHALENE	752.62	156	000091-57-6
156	1,1-DICHLOROETHANE	749.54	152	000075-34-3
157	1,1,2-TRICHLOROETHANE	744.26	157	000079-00-5
158	ACENAPHTHENE	743.38	159	000083-32-9
159	1,2,3,4,6,7,8,9-OCTACHLORODIBENZOFURAN	743.07	160	039001-02-0
160	AMMONIA	741.26	158	007664-41-7
161	1,4-DICHLOROBENZENE	726.92	167	000106-46-7
162	PHENOL	721.78	161	000108-95-2
163	HEPTACHLORODIBENZOFURAN	721.77	165	038998-75-3
164	TRICHLOROETHANE	719.49	162	025323-89-1
165	HEXACHLOROCYCLOPENTADIENE	717.01	166	000077-47-4
166	1,2-DIPHENYLHYDRAZINE	716.60	168	000122-66-7
167	1,2-DICHLOROETHENE, TRANS-	712.02	164	000156-60-5
168	TETRACHLOROBIPHENYL	711.16	230	026914-33-0
169	CRESOL, PARA-	706.70	169	000106-44-5
170	OXYCHLORDANE	705.39	172	027304-13-8
171	2,3,4,7,8-PENTACHLORODIBENZOFURAN	704.56	173	057117-31-4
172	HEXACHLORODIBENZOFURAN	703.92	176	055684-94-1
173	PALLADIUM	703.50	238	007440-05-3
174	CARBON DISULFIDE	703.06	183	000075-15-0
175	GAMMA-CHLORDENE	702.19	NEW	056641-38-4
176	AMERICIUM	701.69	179	007440-35-9
177	DIBENZOFURAN	701.07	186	000132-64-9
178	1,2-DICHLOROBENZENE	700.98	170	000095-50-1
179	TETRACHLOROPHENOL	700.59	182	025167-83-3
180	INDENO(1,2,3-CD)PYRENE	700.29	185	000193-39-5
181	ACETONE	696.98	175	000067-64-1
182	CHLOROETHANE	693.20	184	000075-00-3
183	P-XYLENE	687.06	187	000106-42-3
184	2,4-DIMETHYLPHENOL	685.59	188	000105-67-9
185	AROCLOR 1268	684.85	189	011100-14-4
186	ALUMINUM	682.13	193	007429-90-5
187	HYDROGEN SULFIDE	680.14	192	007783-06-4
188	PENTACHLORODIBENZOFURAN	678.52	191	030402-15-4
189	TETRACHLOROETHANE	671.79	194	025322-20-7
190	CHLOROMETHANE	668.35	199	000074-87-3
191	BIS(2-METHOXYETHYL) PHTHALATE	665.55	NEW	034006-76-3
192	BUTYL BENZYL PHTHALATE	663.28	198	000085-68-7
193	1,2,4-TRICHLOROBENZENE	660.89	196	000120-82-1
194	CRESOL, ORTHO-	659.45	195	000095-48-7
195	1,3-BUTADIENE	657.68	NEW	000106-99-0
196	HEXACHLOROETHANE	654.96	197	000067-72-1
197	VANADIUM	649.51	200	007440-62-2

198	CARBON MONOXIDE	646.60	NEW	000630-08-0
199	TETRACHLORODIBENZO-P-DIOXIN	643.71	202	041903-57-5
200	1,3-DICHLOROBENZENE	643.68	201	000541-73-1
201	PENTACHLORODIBENZO-P-DIOXIN	632.83	205	036088-22-9
202	1,2-DICHLOROETHYLENE	630.18	209	000540-59-0
203	2,3,7,8-TETRACHLORODIBENZOFURAN	628.94	206	051207-31-9
204	2-BUTANONE	626.20	203	000078-93-3
205	N-NITROSODIPHENYLAMINE	625.83	204	000086-30-6
206	2,4-DICHLOROPHENOL	621.20	208	000120-83-2
207	SILVER	620.74	207	007440-22-4
208	BROMOFORM	616.59	210	000075-25-2
209	CESIUM-137	611.77	113	010045-97-3
210	2,4,5-TRICHLOROPHENOL	611.57	213	000095-95-4
211	CHROMIUM TRIOXIDE	611.30	212	007738-94-5
212	NITRITE	609.07	222	014797-65-0
213	DINITROTOLUENE	608.01	NEW	025321-14-6
214	NONACHLOR, TRANS-	607.78	214	039765-80-5
214	POTASSIUM-40	607.78	120	013966-00-2
216	NITRATE	606.61	217	014797-55-8
217	THORIUM-227	605.70	119	015623-47-9
218	COAL TAR PITCH	605.53	215	065996-93-2
219	PHENANTHRENE	605.08	216	000085-01-8
220	ARSENIC TRIOXIDE	604.53	218	001327-53-3
221	NONACHLOR, CIS-	604.26	219	005103-73-1
222	ANTIMONY	603.97	251	007440-36-0
223	ARSENIC ACID	603.52	223	007778-39-4
224	PHORATE	603.25	224	000298-02-2
225	DIMETHOATE	602.75	225	000060-51-5
226	ACTINIUM-227	602.63	NEW	014952-40-0
226	STROBANE	602.63	227	008001-50-1
228	4-AMINOBIPHENYL	602.57	230	000092-67-1
228	BENZOPYRENE	602.57	177	073467-76-2
228	PYRETHRUM	602.57	230	008003-34-7
231	ARSINE	602.52	229	007784-42-1
232	NALED	602.48	228	000300-76-5
233	DIBENZOFURANS, CHLORINATED	602.25	233	042934-53-2
233	ETHOPROP	602.25	233	013194-48-4
233	NITROGEN DIOXIDE	602.25	233	010102-44-0
236	CARBOPHENOTHION	602.01	236	000786-19-6
237	DICHLORVOS	601.74	238	000062-73-7
237	N-NITROSODIMETHYLAMINE	601.74	257	000062-75-9
237	OZONE	601.74	238	010028-15-6
240	ALPHA CHLORDENE	601.51	NEW	056534-02-2
240	CALCIUM ARSENATE	601.51	241	007778-44-1
240	MERCURIC CHLORIDE	601.51	241	007487-94-7
240	URANIUM-233	601.51	241	013968-55-3
244	CRESOLS	597.22	252	001319-77-3

245	FORMALDEHYDE	592.62	256	000050-00-0
246	2,4-D ACID	588.18	250	000094-75-7
247	2-CHLOROPHENOL	587.29	254	000095-57-8
248	HYDROGEN FLUORIDE	586.28	NEW	007664-39-3
249	PYRENE	584.37	253	000129-00-0
250	CHLORODIBROMOMETHANE	582.14	258	000124-48-1
251	DICHLOROBENZENE	578.15	255	025321-22-6
252	BUTYLATE	576.19	259	002008-41-5
253	DICHLOROETHANE	575.51	260	001300-21-6
254	ETHYL ETHER	571.38	264	000060-29-7
255	DIMETHYL FORMAMIDE	571.30	262	000068-12-2
256	4-NITROPHENOL	568.53	265	000100-02-7
257	1,3-DICHLOROPROPENE, CIS-	563.86	263	010061-01-5
258	TRICHLOROBENZENE	557.08	267	012002-48-1
259	1,3-DICHLOROPROPENE, TRANS-	554.10	266	010061-02-6
260	PHOSPHINE	553.29	NEW	007803-51-2
261	FLUORIDE	546.26	268	016984-48-8
262	METHYL PARATHION	545.94	271	000298-00-0
263	2,6-DINITROTOLUENE	543.95	270	000606-20-2
264	METHYL ISOBUTYL KETONE	536.33	272	000108-10-1
265	STYRENE	534.84	274	000100-42-5
266	CARBAZOLE	534.34	NEW	000086-74-8
267	OCTACHLORODIBENZO-P-DIOXIN	533.72	273	003268-87-9
268	1,2-DICHLOROETHENE, CIS-	532.02	NEW	000156-59-2
269	CARBARYL	531.41	NEW	000063-25-2
270	FLUORENE	530.87	275	000086-73-7
271	1,2,3,4,6,7,8-HEPTACHLORODIBENZO-P-DIOXIN	529.06	NEW	035822-46-9
272	1-METHYLNAPHTHALENE	528.79	NEW	000090-12-0
273	MALATHION	526.46	NEW	000121-75-5
274	1,3-DINITROBENZENE	526.02	261	000099-65-0
275	1,4-DIOXANE	525.25	NEW	000123-91-1

Back to top of this page

RELATED RESOURCES
ToxFAQs™
Minimal Risk Levels
Tox Profile Info
Division of Toxicology
CONTENTS
1.1 What is mercury?
1.2 What happens to mercury when it enters the environment?
1.3 How might I be exposed to mercury?
1.4 How can mercury enter and leave my body?
1.5 How can mercury affect my health?
1.6 How can mercury affect children?
1.7 How can families reduce the risk of exposure to mercury?
1.8 Is there a medical test to determine whether I have been exposed to mercury?
1.9 What recommendations has the federal government made to protect human health?
1.10 Where can I get more information?
References

Public Health Statement for

Mercury

CAS# 7439-97-6

March 1999

This Public Health Statement is the summary chapter from the Toxicological Profile for Mercury. It is one in a series of Public Health Statements about hazardous substances and their health effects. A shorter version, the ToxFAQs™, is also available. This information is important because this substance may harm you. The effects of exposure to any hazardous substance depend on the dose, the duration, how you are exposed, personal traits and habits, and whether other chemicals are present. For more information, you may call the ATSDR Information Center at 1-888-422-8737.

This public health statement tells you about mercury and the effects of exposure.

The Environmental Protection Agency (EPA) identifies the most serious hazardous waste sites in the nation. These sites make up the National Priorities List (NPL) and are the sites targeted for long-term federal cleanup activities. Mercury has been found in at least 714 of the 1,467 current or former NPL sites. However, the total number of NPL sites evaluated for this substance is not known. As more sites are evaluated, the sites at which mercury is found may increase. This information is important because exposure to this substance may harm you and because these sites may be sources of exposure.

When a substance is released from a large area, such as an industrial plant, or from a container, such as a drum or bottle, it enters the environment. This release does not always lead to exposure. You are exposed to a substance only when you come in contact with it. You may be exposed by breathing, eating, or drinking the substance or by skin contact.

If you are exposed to mercury, many factors determine whether you'll be harmed. These factors include the dose (how much), the duration (how long), and how you come in contact with it. You must also consider the other chemicals to which you're exposed, as well as your age, sex, diet, family traits, lifestyle, and state of health.

EXHIBIT 15

1.1 What is mercury?

Mercury occurs naturally in the environment and exists in several forms. These forms can be organized under three headings: metallic mercury (also known as elemental mercury), inorganic mercury, and organic mercury. Metallic mercury is a shiny, silver-white metal that is a liquid at room temperature. Metallic mercury is the elemental or pure form of mercury (i.e., it is not combined with other elements). Metallic mercury metal is the familiar liquid metal used in thermometers and some electrical switches. At room temperature, some of the metallic mercury will evaporate and form mercury vapors. Mercury vapors are colorless and odorless. The higher the temperature, the more vapors will be released from liquid metallic mercury. Some people who have breathed mercury vapors report a metallic taste in their mouths. Metallic mercury has been found at 714 hazardous waste sites nationwide.

Inorganic mercury compounds occur when mercury combines with elements such as chlorine, sulfur, or oxygen. These mercury compounds are also called mercury salts. Most inorganic mercury compounds are white powders or crystals, except for mercuric sulfide (also known as cinnabar) which is red and turns black after exposure to light.

When mercury combines with carbon, the compounds formed are called "organic" mercury compounds or organomercurials. There is a potentially large number of organic mercury compounds; however, by far the most common organic mercury compound in the environment is methylmercury (also known as monomethylmercury). In the past, an organic mercury compound called phenylmercury was used in some commercial products. Another organic mercury compound called dimethylmercury is also used in small amounts as a reference standard for some chemical tests. Dimethylmercury is the only organic mercury compound that has been identified at hazardous waste sites. It was only found in extremely small amounts at two hazardous waste sites nationwide, but it is very harmful to people and animals. Like the inorganic mercury compounds, both methylmercury and phenylmercury exist as "salts" (for example, methylmercuric chloride or phenylmercuric acetate). When pure, most forms of methylmercury and phenylmercury are white crystalline solids. Dimethylmercury, however, is a colorless liquid.

Several forms of mercury occur naturally in the environment. The most common natural forms of mercury found in the environment are metallic mercury, mercuric sulfide (cinnabar ore), mercuric chloride, and methylmercury. Some microorganisms (bacteria and fungi) and natural processes can change the mercury in the environment from one form to another. The most common organic mercury compound that microorganisms and natural processes generate from other forms is methylmercury. Methylmercury is of particular concern because it can build up in certain edible freshwater and saltwater fish and marine mammals to levels that are many times greater than levels in the surrounding water.

Mercury is mined as cinnabar ore, which contains mercuric sulfide. The metallic form is refined from mercuric sulfide ore by heating the ore to

temperatures above 1,000 degrees Fahrenheit. This vaporizes the mercury in the ore, and the vapors are then captured and cooled to form the liquid metal mercury. There are many different uses for liquid metallic mercury. It is used in producing of chlorine gas and caustic soda, and in extracting gold from ore or articles that contain gold. It is also used in thermometers, barometers, batteries, and electrical switches. Silver-colored dental fillings typically contain about 50% metallic mercury. Metallic mercury is still used in some herbal or religious remedies in Latin America and Asia, and in rituals or spiritual practices in some Latin American and Caribbean religions such as Voodoo, Santeria, and Espiritismo. These uses may pose a health risk from exposure to mercury both for the user and for others who may be exposed to mercury vapors in contaminated air.

Some inorganic mercury compounds are used as fungicides. Inorganic salts of mercury, including ammoniated mercuric chloride and mercuric iodide, have been used in skin-lightening creams. Mercuric chloride is a topical antiseptic or disinfectant agent. In the past, mercurous chloride was widely used in medicinal products including laxatives, worming medications, and teething powders. It has since been replaced by safer and more effective agents. Other chemicals containing mercury are still used as antibacterials. These products include mercurochrome (contains a small amount of mercury, 2%), and thimerosal and phenylmercuric nitrate, which are used in small amounts as preservatives in some prescription and over-the-counter medicines. Mercuric sulfide and mercuric oxide may be used to color paints, and mercuric sulfide is one of the red coloring agents used in tattoo dyes.

Methylmercury is produced primarily by microorganisms (bacteria and fungi) in the environment, rather than by human activity. Until the 1970s, methylmercury and ethylmercury compounds were used to protect seed grains from fungal infections. Once the adverse health effects of methylmercury were known, the use of methymercury and ethylmercury as fungicides was banned. Up until 1991, phenylmercuric compounds were used as antifungal agents in both interior and exterior paints, but this use was also banned because mercury vapors were released from these paints.

1.2 What happens to mercury when it enters the environment?

Mercury is a naturally occurring metal found throughout the environment. Mercury enters the environment as the result of the normal breakdown of minerals in rocks and soil from exposure to wind and water, and from volcanic activity. Mercury releases from natural sources have remained relatively constant in recent history, resulting in a steady rise in environmental mercury. Human activities since the start of the industrial age (e.g., mining, burning of fossil fuels) have resulted in additional release of mercury to the environment. Estimates of the total annual mercury releases that result from human activities range from one-third to two-thirds of the total mercury releases. A major uncertainty in these estimates is the amount of mercury that is released from water and soils that were previously contaminated by human activities as opposed to new natural releases. The levels of mercury in the atmosphere (i.e., the air you breathe in the general environment) are very, very low and do not pose a health risk; however, the steady release

of mercury has resulted in current levels that are three to six times higher than the estimated levels in the preindustrial era atmosphere.

Approximately 80% of the mercury released from human activities is elemental mercury released to the air, primarily from fossil fuel combustion, mining, and smelting, and from solid waste incineration. About 15% of the total is released to the soil from fertilizers, fungicides, and municipal solid waste (for example, from waste that contains discarded batteries, electrical switches, or thermometers). An additional 5% is released from industrial wastewater to water in the environment.

With the exception of mercury ore deposits, the amount of mercury that naturally exists in any one place is usually very low. In contrast, the amount of mercury that may be found in soil at a particular hazardous waste site because of human activity can be high (over 200,000 times natural levels). The mercury in air, water, and soil at hazardous waste sites may come from both natural sources and human activity.

Most of the mercury found in the environment is in the form of metallic mercury and inorganic mercury compounds. Metallic and inorganic mercury enters the air from mining deposits of ores that contain mercury, from the emissions of coal-fired power plants, from burning municipal and medical waste, from the production of cement, and from uncontrolled releases in factories that use mercury. Metallic mercury is a liquid at room temperature, but some of the metal will evaporate into the air and can be carried long distances. In air, the mercury vapor can be changed into other forms of mercury, and can be further transported to water or soil in rain or snow. Inorganic mercury may also enter water or soil from the weathering of rocks that contain mercury, from factories or water treatment facilities that release water contaminated with mercury, and from incineration of municipal garbage that contains mercury (for example, in thermometers, electrical switches, fluorescent light bulbs, or batteries that have been thrown away). Inorganic or organic compounds of mercury may be released to the water or soil if mercury-containing fungicides are used.

Microorganisms (bacteria, phytoplankton in the ocean, and fungi) convert inorganic mercury to methylmercury. Methylmercury released from microorganisms can enter the water or soil and remain there for a long time, particularly if the methylmercury becomes attached to small particles in the soil or water. Mercury usually stays on the surface of sediments or soil and does not move through the soil to underground water. If mercury enters the water in any form, it is likely to settle to the bottom where it can remain for a long time.

Mercury can enter and accumulate in the food chain. The form of mercury that accumulates in the food chain is methylmercury. Inorganic mercury does not accumulate up the food chain to any extent. When small fish eat the methylmercury in food, it goes into their tissues. When larger fish eat smaller fish or other organisms that contain methylmercury, most of the methylmercury originally present in the small fish will then be stored in the bodies of the larger fish. As a result, the larger and older fish living in contaminated waters build up the highest amounts of methylmercury in their bodies. Saltwater fish (especially sharks and swordfish) that live a long time and can grow to a

very large size tend to have the highest levels of mercury in their bodies. Plants (such as corn, wheat, and peas) have very low levels of mercury, even if grown in soils containing mercury at significantly higher than background levels. Mushrooms, however, can accumulate high levels if grown in contaminated soils.

1.3 How might I be exposed to mercury?

Because mercury occurs naturally in the environment, everyone is exposed to very low levels of mercury in air, water, and food. Between 10 and 20 nanograms of mercury per cubic meter (ng/m^3) of air have been measured in urban outdoor air. These levels are hundreds of times lower than levels still considered to be "safe" to breathe. Background levels in nonurban settings are even lower, generally about 6 $ng/^{m3}$ or less. Mercury levels in surface water are generally less than 5 parts of mercury per trillion parts of water (5 ppt, or 5 ng per liter of water), about a thousand times lower than "safe" drinking water standards. Normal soil levels range from 20 to 625 parts of mercury per billion parts of soil (20–625 ppb; or 20,000–625,000 ng per kilogram of soil). A part per billion is one thousand times bigger than a part per trillion.

A potential source of exposure to metallic mercury for the general population is mercury released from dental amalgam fillings. An amalgam is a mixture of metals. The amalgam used in silver-colored dental fillings contains approximately 50% metallic mercury, 35% silver, 9% tin, 6% copper, and trace amounts of zinc. When the amalgam is first mixed, it is a soft paste which is inserted into the tooth surface. It hardens within 30 minutes. Once the amalgam is hard, the mercury is bound within the amalgam, but very small amounts are slowly released from the surface of the filling due to corrosion or chewing or grinding motions. Part of the mercury at the surface of the filling may enter the air as mercury vapor or be dissolved in the saliva. The total amount of mercury released from dental amalgam depends upon the total number of fillings and surface areas of each filling, the chewing and eating habits of the person, and other chemical conditions in the mouth. Estimates of the amount of mercury released from dental amalgams range from 3 to 17 micrograms per day (μg/day). The mercury from dental amalgam may contribute from 0 to more than 75% of your total daily mercury exposure, depending on the number of amalgam fillings you have, the amount of fish consumed, the levels of mercury (mostly as methylmercury) in those fish, and exposure from other less common sources such as mercury spills, religious practices, or herbal remedies that contain mercury. However, it should be kept in mind that exposure to very small amounts of mercury, such as that from dental amalgam fillings, does not necessarily pose a health risk.

Whether the levels of exposure to mercury vapor from dental amalgam are sufficiently high to cause adverse health effects, and exactly what those effects are, continues to be researched and debated by scientists and health officials. U.S. government summaries on the effects of dental amalgam conclude that there is no apparent health hazard to the general population, but that further study is needed to determine the possibility of more subtle behavioral or immune system effects, and to determine the levels of exposure that may lead to adverse effects in sensitive populations. Sensitive populations may include pregnant women,

children under the age of 6 (especially up to the age of 3), people with impaired kidney function, and people with hypersensitive immune responses to metals. If you belong to this group, you should discuss your medical condition with your dentist prior to any dental restoration work. Removal of dental amalgams in people who have no indication of adverse effects is not recommended and can put the person at greater risk, if performed improperly. Chelation therapy (used to remove metals from the body tissues) itself presents some health risks, and should be considered only when a licensed occupational or environmental health physician determines it necessary to reduce immediate and significant health risks due to high levels of mercury in the body.

Some religions have practices that may include the use of metallic mercury. Examples of these religions include Santeria (a Cuban-based religion whose followers worship both African deities and Catholic saints), Voodoo (a Haitian-based set of beliefs and rituals), Palo Mayombe (a secret form of ancestor worship practiced mainly in the Caribbean), and Espiritismo (a spiritual belief system native to Puerto Rico). Not all people who observe these religions use mercury, but when mercury is used in religious, ethnic, or ritualistic practices, exposure to mercury may occur both at the time of the practice and afterwards from contaminated indoor air. Metallic mercury is sold under the name "azogue" (pronounced ah-SEW-gay) in stores called "botanicas." Botanicas are common in Hispanic and Haitian communities, where azogue may be sold as an herbal remedy or for spiritual practices. The metallic mercury is often sold in capsules or in glass containers. It may be placed in a sealed pouch to be worn on a necklace or in a pocket, or it may be sprinkled in the home or car. Some people may mix azogue in bath water or perfume, or place azogue in devotional candles. Because metallic mercury evaporates into the air, these practices may put anyone breathing the air in the room at risk of exposure to mercury. The longer people breathe the contaminated air, the greater their risk will be. The use of metallic mercury in a home or an apartment not only threatens the health of the people who live there now, but also threatens the health of future residents who may unknowingly be exposed to further release of mercury vapors from contaminated floors or walls.

Metallic mercury is used in a variety of household products and industrial items, including thermostats, fluorescent light bulbs, barometers, glass thermometers, and some blood pressure devices. The mercury in these devices is contained in glass or metal, and generally does not pose a risk unless the item is damaged or broken, and mercury vapors are released. Spills of metallic mercury from broken thermometers or damaged electrical switches in the home may result in exposure to mercury vapors in indoor air. You must be careful when you handle and dispose of all items in the home that contain metallic mercury.

Very small amounts of metallic mercury (for example, a few drops) can raise air concentrations of mercury to levels that may be harmful to health. The longer people breathe the contaminated air, the greater the risk to their health. Metallic mercury and its vapors are extremely difficult to remove from clothes, furniture, carpet, floors, walls, and other such items. If these items are not properly cleaned, the mercury

can remain for months or years, and continue to be a source of exposure.

It is possible for you to be exposed to metallic mercury vapors from breathing contaminated air around hazardous waste sites, waste incinerators, or power plants that burn mercury-containing fuels (such as coal or other fossil fuels), but most outdoor air is not likely to contain levels that would be harmful. Exposure to mercury compounds at hazardous waste sites is much more likely to occur from handling contaminated soil (i.e., children playing in or eating contaminated surface soil), drinking well-water, or eating fish from contaminated waters near those sites. Not all hazardous sites contain mercury, and not all waste sites that do contain mercury have releases of mercury to the air, water, or surface soils.

You can be exposed to mercury vapors from the use of fungicides that contain mercury. Excess use of these products may result in higher-than-average exposures. You may also be exposed to mercury from swallowing or applying to your skin outdated medicinal products (laxatives, worming medications, and teething powders) that contain mercurous chloride. Exposure may also occur from the improper or excessive use of other chemicals containing mercury, such as skin-lightening creams and some topical antiseptic or disinfectant agents (mercurochrome and thimerosal).

Workers are mostly exposed from breathing air that contains mercury vapors, but may also be exposed to other inorganic mercury compounds in the workplace. Occupations that have a greater potential for mercury exposure include manufacturers of electrical equipment or automotive parts that contain mercury, chemical processing plants that use mercury, metal processing, construction where building parts contain mercury (e.g., electrical switches, thermometers), and the medical professions (medical, dental, or other health services) where equipment may contain mercury (e.g., some devices that measure blood pressure contain liquid mercury). Dentists and their assistants may be exposed to metallic mercury from breathing in mercury vapor released from amalgam fillings and to a much lesser extent from skin contact with amalgam restorations. Family members of workers who have been exposed to mercury may also be exposed to mercury if the worker's clothes are contaminated with mercury particles or liquid.

Some people may be exposed to higher levels of mercury in the form of methylmercury if they have a diet high in fish, shellfish, or marine mammals (whales, seals, dolphins, and walruses) that come from mercury-contaminated waters. Methylmercury accumulates up the food chain, so that fish at the top of the food chain will have the most mercury in their flesh. Of these fish, the largest (i.e., the oldest) fish will have the highest levels. The Food and Drug Administration (FDA) estimates that most people are exposed, on average, to about 50 ng of mercury per kilogram of body weight per day (50 ng/kg/day) in the food they eat. This is about 3.5 micrograms (μg) of mercury per day for an adult of average weight. This level is not thought to result in any harmful effects. A large part of this mercury is in the form of methylmercury and probably comes from eating fish. Commercial fish sold through interstate commerce that are found to have levels of methylmercury

above an "action level" of 1 ppm (established by the FDA) cannot be sold to the public. This level itself is below a level associated with adverse effects. However, if you fish in contaminated waters and eat the fish you catch, you may be exposed to higher levels of mercury. Public health advisories are issued by state and federal authorities for local waters that are thought to be contaminated with mercury. These advisories can help noncommercial (sport and subsistence) fishermen and their families to avoid eating fish contaminated with mercury. Foods other than fish that may contain higher than average levels of mercury include wild game, such as wild birds and mammals (bear) that eat large amounts of contaminated fish. People in the most northern climates may be exposed to high levels of mercury from eating meat or fat from marine mammals including whales, dolphins, walruses, and seals. These marine mammals are at or near the top of their marine food chain. Plants contain very little methylmercury or other forms of mercury. Mushrooms grown in mercury-contaminated soil may contain levels of mercury that could pose some risk to health, if large amounts were eaten.

1.4 How can mercury enter and leave my body?

A person can be exposed to mercury from breathing in contaminated air, from swallowing or eating contaminated water or food, or from having skin contact with mercury. Not all forms of mercury easily enter your body, even if they come in contact with it; so it is important to know which form of mercury you have been exposed to, and by which route (air, food, or skin).

When you swallow small amounts of metallic mercury, for example, from a broken oral thermometer, virtually none (less than 0.01%) of the mercury will enter your body through the stomach or intestines, unless they are diseased. Even when a larger amount of metal mercury (a half of a tablespoon, about 204 grams) was swallowed by one person, very little entered the body. When you breathe in mercury vapors, however, most (about 80%) of the mercury enters your bloodstream directly from your lungs, and then rapidly goes to other parts of your body, including the brain and kidneys. Once in your body, metallic mercury can stay for weeks or months. When metallic mercury enters the brain, it is readily converted to an inorganic form and is "trapped" in the brain for a long time. Metallic mercury in the blood of a pregnant woman can enter her developing child. Most of the metallic mercury will accumulate in your kidneys, but some metallic mercury can also accumulate in the brain. Most of the metallic mercury absorbed into the body eventually leaves in the urine and feces, while smaller amounts leave the body in the exhaled breath.

Inorganic mercury compounds like mercurous chloride and mercuric chloride are white powders and do not generally vaporize at room temperatures like elemental mercury will. If they are inhaled, they are not expected to enter your body as easily as inhaled metallic mercury vapor. When inorganic mercury compounds are swallowed, generally less than 10% is absorbed through the intestinal tract; however, up to 40% may enter the body through the stomach and intestines in some instances. Some inorganic mercury can enter your body through the skin, but only a small amount will pass through your skin compared to

the amount that gets into your body from swallowing inorganic mercury.

Once inorganic mercury enters the body and gets into the bloodstream, it moves to many different tissues. Inorganic mercury leaves your body in the urine or feces over a period of several weeks or months. A small amount of the inorganic mercury can be changed in your body to metallic mercury and leave in the breath as a mercury vapor. Inorganic mercury accumulates mostly in the kidneys and does not enter the brain as easily as metallic mercury. Inorganic mercury compounds also do not move as easily from the blood of a pregnant woman to her developing child. In a nursing woman, some of the inorganic mercury in her body will pass into her breast milk.

Methylmercury is the form of mercury most easily absorbed through the gastrointestinal tract (about 95% absorbed). After you eat fish or other foods that are contaminated with methylmercury, the methylmercury enters your bloodstream easily and goes rapidly to other parts of your body. Only small amounts of methylmercury enter the bloodstream directly through the skin, but other forms of organic mercury (in particular dimethylmercury) can rapidly enter the body through the skin. Organic mercury compounds may evaporate slowly at room temperature and may enter your body easily if you breathe in the vapors. Once organic mercury is in the bloodstream, it moves easily to most tissues and readily enters the brain. Methylmercury that is in the blood of a pregnant woman will easily move into the blood of the developing child and then into the child's brain and other tissues. Like metallic mercury, methylmercury can be changed by your body to inorganic mercury. When this happens in the brain, the mercury can remain there for a long time. When methylmercury does leave your body after you have been exposed, it leaves slowly over a period of several months, mostly as inorganic mercury in the feces. As with inorganic mercury, some of the methylmercury in a nursing woman's body will pass into her breast milk.

1.5 How can mercury affect my health?

The nervous system is very sensitive to mercury. In poisoning incidents that occurred in other countries, some people who ate fish contaminated with large amounts of methylmercury or seed grains treated with methylmercury or other organic mercury compounds developed permanent damage to the brain and kidneys. Permanent damage to the brain has also been shown to occur from exposure to sufficiently high levels of metallic mercury. Whether exposure to inorganic mercury results in brain or nerve damage is not as certain, since it does not easily pass from the blood into the brain.

Metallic mercury vapors or organic mercury may affect many different areas of the brain and their associated functions, resulting in a variety of symptoms. These include personality changes (irritability, shyness, nervousness), tremors, changes in vision (constriction (or narrowing) of the visual field), deafness, muscle incoordination, loss of sensation, and difficulties with memory.

Different forms of mercury have different effects on the nervous system, because they do not all move through the body in the same way. When

metallic mercury vapors are inhaled, they readily enter the bloodstream and are carried throughout the body and can move into the brain. Breathing in or swallowing large amounts of methylmercury also results in some of the mercury moving into the brain and affecting the nervous system. Inorganic mercury salts, such as mercuric chloride, do not enter the brain as readily as methylmercury or metallic mercury vapor.

The kidneys are also sensitive to the effects of mercury, because mercury accumulates in the kidneys and causes higher exposures to these tissues, and thus more damage. All forms of mercury can cause kidney damage if large enough amounts enter the body. If the damage caused by the mercury is not too great, the kidneys are likely to recover once the body clears itself of the contamination.

Short-term exposure (hours) to high levels of metallic mercury vapor in the air can damage the lining of the mouth and irritate the lungs and airways, causing tightness of the chest, a burning sensation in the lungs, and coughing. Other effects from exposure to mercury vapor include nausea, vomiting, diarrhea, increases in blood pressure or heart rate, skin rashes, and eye irritation. Damage to the lining of the mouth and lungs can also occur from exposure to lower levels of mercury vapor over longer periods (for example, in some occupations where workers were exposed to mercury for many years). Levels of metallic mercury in workplace air are generally much greater than the levels normally encountered by the general population. Current levels of mercury in workplace air are low, due to increased awareness of mercury's toxic effects. Because of the reduction in the allowable amount of mercury in workplace air, fewer workers are expected to have symptoms of mercury toxicity. Most studies of humans who breathed metallic mercury for a long time indicate that mercury from this type of exposure does not affect the ability to have children. Studies in workers exposed to metallic mercury vapors have also not shown any mercury-related increase in cancer. Skin contact with metallic mercury has been shown to cause an allergic reaction (skin rashes) in some people.

In addition to effects on the kidneys, inorganic mercury can damage the stomach and intestines, producing symptoms of nausea, diarrhea, or severe ulcers if swallowed in large amounts. Effects on the heart have also been observed in children after they accidentally swallowed mercuric chloride. Symptoms included rapid heart rate and increased blood pressure. There is little information on the effects in humans from long-term, low-level exposure to inorganic mercury.

To protect the public from the harmful effects of toxic chemicals and to find ways to treat people who have been harmed, scientists use many tests.

One way to see if a chemical will hurt people is to learn how the chemical is absorbed, used, and released by the body; for some chemicals, animal testing may be necessary. Animal testing may also be used to identify health effects such as cancer or birth defects. Without laboratory animals, scientists would lose a basic method to get information needed to make wise decisions to protect public health. Scientists have the responsibility to treat research animals with care and compassion. Laws today protect the welfare of research animals, and

scientists must comply with strict animal care guidelines.

Studies using animals indicate that long-term oral exposure to inorganic mercury salts causes kidney damage, effects on blood pressure and heart rate, and effects on the stomach. Study results also suggest that reactions involving the immune system may occur in sensitive populations after swallowing inorganic mercury salts. Some animal studies report that nervous system damage occurs after long-term exposure to high levels of inorganic mercury. Short-term, high-level exposure of laboratory animals to inorganic mercury has been shown to affect the developing fetus and may cause termination of the pregnancy.

Animals exposed orally to long-term, high levels of methylmercury or phenylmercury in laboratory studies experienced damage to the kidneys, stomach, and large intestine; changes in blood pressure and heart rate; adverse effects on the developing fetus, sperm, and male reproductive organs; and increases in the number of spontaneous abortions and stillbirths. Adverse effects on the nervous system of animals occur at lower doses than do harmful effects to most other systems of the body. This difference indicates that the nervous system is more sensitive to methylmercury toxicity than are other organs in the body. Animal studies also provide evidence of damage to the nervous system from exposure to methylmercury during development, and evidence suggests that the effects worsen with age, even after the exposure stops.

Some rat and mice strains that are susceptible to autoimmune responses develop kidney damage as a result of an immune response when exposed to relatively low levels of mercury vapor or mercury chloride.

Animals given inorganic mercury salts by mouth for most of their lifetime had increases in some kinds of tumors at the highest dose tested. Rats and mice that received organic mercury (methylmercury or phenylmercury) in their drinking water or feed for most of their lives had an increased incidence of cancer of the kidney, but this affected only the males that received the highest amount of mercury given (not the females). Since the high doses caused severe damage to the kidneys prior to the cancer, these animal studies provide only limited information about whether mercury causes cancer in humans. As a result, the Department of Health and Human Services (DHHS) and the International Agency for Research on Cancer (IARC) have not classified mercury as to its human carcinogenicity. The Environmental Protection Agency has determined that mercury chloride and methylmercury are possible human carcinogens.

1.6 How can mercury affect children?

This section discusses potential health effects from exposures during the period from conception to maturity at 18 years of age in humans. Potential effects on children resulting from exposures of the parents are also considered.

Children are at risk of being exposed to metallic mercury that is not safely contained, to mercury that may be brought home on work clothes or tools, or to methylmercury-contaminated foods. Methylmercury eaten or swallowed by a pregnant woman or metallic mercury that enters her

body from breathing contaminated air can also pass into the developing child. Inorganic mercury and methylmercury can also pass from a mother's body into breast milk and into a nursing infant. The amount of mercury in the milk will vary, depending on the degree of exposure and the amount of mercury that enter the nursing woman's body. There are significant benefits to breast feeding, so any concern that a nursing woman may have about mercury levels in her breast milk should be discussed with her doctor. Methylmercury can also accumulate in an unborn baby's blood to a concentration higher than the concentration in the mother.

For similar exposure routes and forms of mercury, the harmful health effects seen in children are similar to the effects seen in adults. High exposure to mercury vapor causes lung, stomach, and intestinal damage and death due to respiratory failure in severe cases. These effects are similar to those seen in adult groups exposed to inhaled metallic mercury vapors at work.

Children who had been exposed to excessive amounts of mercurous chloride tablets for worms or mercurous chloride-containing powders for teething discomfort had increased heart rates and elevated blood pressure. Abnormal heart rhythms were also seen in children who had eaten grains contaminated with very high levels of methylmercury.

Other symptoms of poisonings in children who were treated with mercurous chloride for constipation, worms, or teething discomfort included swollen red gums, excessive salivation, weight loss, diarrhea and/or abdominal pain, and muscle twitching or cramping in the legs and/or arms. Kidney damage is very common after exposure to toxic levels of inorganic mercury. Metallic mercury or methylmercury that enters the body can also be converted to inorganic mercury and result in kidney damage.

Children who breathe metallic/elemental mercury vapors, eat foods or other substances containing phenylmercury or inorganic mercury salts, or use mercury-containing skin ointments for an extended period may develop a disorder known as acrodynia, or pink disease. Acrodynia can result in severe leg cramps; irritability; and abnormal redness of the skin, followed by peeling of the hands, nose, and soles of the feet. Itching, swelling, fever, fast heart rate, elevated blood pressure, excessive salivation or sweating, rashes, fretfulness, sleeplessness, and/or weakness may also be present. It was once believed that this syndrome occurred only in children, but recent reported cases in teenagers and adults have shown that they can also develop acrodynia.

In critical periods of development before they are born, and in the early months after birth, children and fetuses are particularly sensitive to the harmful effects of metallic mercury and methylmercury on the nervous system. Harmful developmental effects may occur when a pregnant woman is exposed to metallic mercury and some of the mercury is transferred into her developing child. Thus, women who are normally exposed to mercury vapors in the workplace (such as those working in thermometer/barometer or fluorescent light manufacturing or the chlor-alkali industry) should take measures to avoid mercury vapor exposures during pregnancy. Exposures to mercury vapors are relatively rare

outside of the workplace, unless metallic mercury is present in the home.

As with mercury vapors, exposure to methylmercury is more dangerous for young children than for adults, because more methylmercury easily passes into the developing brain of young children and may interfere with the development process.

Methylmercury is the form of mercury most commonly associated with a risk for developmental effects. Exposure can come from foods contaminated with mercury on the surface (for example, from seed grain treated with methylmercury to kill fungus) or from foods that contain toxic levels of methylmercury (as in some fish, wild game, and marine mammals). Mothers who are exposed to methylmercury and breast-feed their infant may also expose the child through the milk. The effects on the infant may be subtle or more pronounced, depending on the amount to which the fetus or young child was exposed. In cases in which the exposure was relatively small, some effects might not be apparent, such as small decreases in IQ or effects on the brain that may only be determined by the use of very sensitive neuropsychological testing. In instances in which the exposure is great, the effects may be more serious. In some such cases of mercury exposure involving serious exposure to the developing fetus, the effects are delayed. In such cases, the infant may be born apparently normal, but later show effects that may range from the infant being slower to reach developmental milestones, such as the age of first walking and talking, to more severe effects including brain damage with mental retardation, incoordination, and inability to move. Other severe effects observed in children whose mothers were exposed to very toxic levels of mercury during pregnancy include eventual blindness, involuntary muscle contractions and seizures, muscle weakness, and inability to speak. It is important to remember, however, that the severity of these effects depends upon the level of mercury exposure and the length of exposure. The very severe effects just mentioned were reported in large-scale poisoning instances in which pregnant and nursing women were exposed to extremely high levels of methylmercury in contaminated grain used to make bread (in Iraq) or seafood (in Japan) sold to the general population.

Researchers are currently studying the potential for less serious developmental effects, including effects on a child's behavior and ability to learn, think, and solve problems that may result from eating lower levels of methylmercury in foods. A main source of exposure to methylmercury for the pregnant woman and the young child is from eating fish. Most fish purchased in the market in the United States do not have mercury levels that pose a risk to anyone, including pregnant women. Since mercury accumulates in the muscles of fish, larger fish that feed on smaller fish and live for long periods usually have larger concentrations of methylmercury than fish that feed on plants. For example, shark and swordfish normally contain the highest levels of mercury out of all ocean fish. Scientists have an ongoing debate about the value of fish in the diet versus any risk from increased exposure of pregnant women to methylmercury that may be in the fish. The safety of most fish sold commercially in the United States is regulated by the FDA. These fish pose no health risk to those who purchase and eat them. Only fish or wildlife containing relatively high levels of

methylmercury are of concern.

1.7 How can families reduce the risk of exposure to mercury?

If your doctor finds that you have been exposed to significant amounts of mercury, ask whether your children might also be exposed. Your doctor might need to ask your state health department to investigate.

Children may be exposed to metallic mercury if they play with it. Metallic mercury is a heavy, shiny, silver liquid. When metallic mercury is spilled, it forms little balls or beads. Children are sometimes exposed to metallic mercury when they find it in abandoned warehouses or closed factories, and then play with it or pass it around to friends. Children have also taken metallic mercury from school chemistry and physics labs. Broken thermometers and some electrical switches are other sources of metallic mercury. Sometimes children find containers of metallic mercury that were improperly disposed of, or adults may bring home metallic mercury from work, not knowing that it is dangerous.

To protect your children from metallic mercury, teach them not to play with shiny, silver liquids. Schoolteachers (particularly science teachers) and school staff need to know about students' fascination with metallic mercury. Teachers and school staff should teach children about the dangers of getting sick from playing with mercury, and they should keep metallic mercury in a safe and secured area (such as a closed container in a locked storage room) so that children do not have access to it without the supervision of a teacher. Metallic mercury evaporates slowly, and if it is not stored in a closed container, children may breathe toxic mercury vapors.

In the past, mercurous chloride was widely used in medicinal products such as laxatives, worming medications, and teething powders. These older medicines should be properly disposed of and replaced with safer and more effective medicines. Other chemicals containing mercury, such as mercurochrome and thimerosal (sold as Merthiolate and other brands), are still used as antiseptics or as preservatives in eye drops, eye ointments, nasal sprays, and vaccines. Some skin-lightening creams contain ammoniated mercuric chloride and mercuric iodide. These and all other mercury-containing medicines should be kept safely out of the reach of children to prevent an accidental poisoning. Nonmedicinal products, including some fungicides that contain mercury compounds and paints that contain mercuric sulfide or mercuric oxide, should also be safely stored out of the reach of children.

You should check to see if any medicines or herbal remedies that you or your child use contain mercury. Some traditional Chinese and Hispanic remedies for stomach disorders (for example, herbal balls) contain mercury, and if you give these remedies to your children, you may harm them. If you are pregnant or nursing a baby and you use mercury-containing ethnic or herbal remedies, you could pass some of the mercury to your unborn child or nursing infant.

If you use metallic mercury or azogue in religious practices, you may expose your children or unborn child to mercury or contaminate your

home. Such practices in which mercury containing substances have traditionally been used include Santeria (a Cuban-based religion whose followers worship both African deities and Catholic saints), Voodoo (a Haitian-based set of beliefs and rituals), Palo Mayombe (a secret form of ancestor worship practiced mainly in the Caribbean), or Espiritismo (a spiritual belief system native to Puerto Rico).

Metallic mercury is used in a variety of household products and industrial items, including thermostats, fluorescent light bulbs, barometers, glass thermometers, and some blood pressure measuring devices. You must be careful when you handle and dispose of all items in the home that contain metallic mercury.

If small amounts of mercury are spilled, be very careful cleaning it up. Do not try to vacuum spilled metallic mercury. Using a vacuum cleaner to clean up the mercury causes the mercury to evaporate into the air, creating greater health risks. Trying to vacuum spilled metallic mercury also contaminates the vacuum cleaner. Also, take care not to step on the mercury and track it into other areas of the home. Metallic mercury vapors are very toxic and have no odor. Do not remain unnecessarily in that room, and try not to let metallic mercury contact your eyes, skin, or clothing. If you think you have been exposed directly to metallic mercury, wash yourself thoroughly and discard contaminated clothing by placing them in a sealed plastic bag. Perhaps the most important thing to remember if you break a household thermometer is do not panic. The amount of mercury contained in an oral thermometer is small and does not present an immediate threat to human health. However, if it is not properly cleaned up and disposed of, it may present a health risk over time, particularly to infants, toddlers, and pregnant women.

If a thermometer breaks on a counter top or uncarpeted floor, remove children from the area. Mercury is not absorbent, so do not try to wipe or blot it up with a cloth or paper towel; that will only spread the mercury and break it up into smaller beads, making it more difficult to find and remove. Instead, clean up the beads of metallic mercury by using one sheet of paper to carefully roll them onto a second sheet of paper, or by sucking very small beads of mercury into an eye dropper. After picking up the metallic mercury in this manner, put it into a plastic bag or airtight container. The paper and eye dropper should also be bagged in a zip-lock plastic container. All plastic bags used in the cleanup should then be taken outside of the house or apartment and disposed of properly, according to instructions provided by your local health department or environmental officials. Try to ventilate the room with outside air, and close the room off from the rest of the home. Use fans (that direct the air to the outside and away from the inside of the house) for a minimum of one hour to speed the ventilation.

If a thermometer breaks and the liquid/metallic mercury spills onto a carpeted floor, try to collect the mercury beads in the manner described in the above paragraph. Depending on the cut or pile of the carpeting, however, it may not be possible to collect all of the spilled mercury. Regardless, do not vacuum. Instead, call your local (county, city, or state) health department and tell them of your situation. (You may also call the Agency for Toxic Substances and Disease Registry [ATSDR] toll-free at 1-888-42-ATSDR [1-888-422-8737] to obtain additional

guidance, if local assistance cannot be obtained.)

If larger amounts of metallic mercury are found (for example, a jar of liquid mercury), it should be contained in an airtight container, and you should call your local health department for instructions on how to safely dispose of it. If the mercury is in an open container or the container does not have a lid, place a piece of plastic wrap around the top of the container to prevent vapors from escaping; then wash your hands thoroughly. If a larger amount is spilled, leave the area and contact your local health department and fire department. Do not simply throw metallic mercury away, but instead seek professional help.

ATSDR and EPA strongly recommend against the use of metallic (liquid) mercury that is not properly enclosed in glass, as it is in thermometers. This form of mercury should not be used or stored in homes, automobiles, day-care centers, schools, offices, or other public buildings. If you notice a child with metallic mercury on his or her clothing, skin, or hair, call the fire department and let them know that the child needs to be decontaminated.

Metallic or inorganic mercury can be carried into the home from a workers' contaminated clothing and shoes. Increased exposure to mercury has been reported in children of workers who are exposed to mercury at work, and increased levels of mercury were measured in places where work clothes were stored and in some washing machines. The children most likely to be exposed to risky levels of mercury are those whose parents work in facilities that use mercury (for example, a scientific glassware manufacturing plant or a chlor-alkali chemical plant), but where no protective uniforms or footgear are used. In some reported cases in which children were exposed in this way, protective clothing was used in the workplace by the parent, but work gloves, clothes, and boots, which were contaminated with mercury, were taken home, thus exposing family members. If you have questions or concerns about exposure to mercury at work, you have a right to obtain information from your employer about your safety and health on the job without fear of punishment. The Occupational Safety and Health Administration (OSHA) requires employers to provide Material Safety Data Sheets (MSDSs) for many of the chemicals used at the workplace. Information on these sheets should include chemical names and hazardous ingredients, important properties (such as fire and explosion data), potential health effects, how you get the chemical(s) in your body, how to properly handle the materials, and what to do in an emergency. Your occupational health and safety officer at work can and should tell you whether chemicals you work with are dangerous and likely to be carried home on your clothes, body, or tools, and whether you should be showering and changing clothes before you leave work, storing your street clothes in a separate area of the workplace, or laundering your work clothes at home separately from other clothes.

ADA has an issue with this,

Your employer is legally responsible for providing a safe workplace and should freely answer your questions about hazardous chemicals. Your OSHA-approved state occupational safety and health program or OSHA can also answer any further questions you might have, and help your employer identify and correct problems with hazardous substances. If you would like to make a formal complaint about health hazards in your

workplace, your OSHA-approved state occupational safety and health program or OSHA office will listen to your complaint and inspect your workplace when necessary.

One way in which people are routinely exposed to extremely small amounts of mercury is through the gradual (but extremely slow) wearing-away process of dental amalgam fillings, which contain approximately 50% mercury. The amount of mercury to which a person might be exposed from dental amalgams would depend on the number of amalgams present and other factors. The Centers for Disease Control and Prevention (CDC) has determined that dental amalgam fillings do not pose a health risk, although they do account for some mercury exposure to those having such fillings. People who frequently grind their teeth or often chew gum can add to the small amount of mercury normally released from those fillings over time. If you are pregnant, the decision of whether to have dental amalgam or a non-mercury material used for fillings, or whether existing amalgam fillings should be repaired or replaced during pregnancy, should be made in consultation with your dentist. The practice of having all your dental amalgam fillings replaced with non-mercury filling materials just to remove the possibility of mercury exposure is not recommended by ATSDR. In fact, the removal of the mercury amalgam fillings would actually expose the patient to a greater amount of mercury for a while. Other sources of mercury may increase your overall exposure, such as the amount of fish consumed per week, especially if caught in local waters contaminated with mercury or of certain species known to be higher in mercury content (shark and swordfish), or an exposure to mercury from a nearby hazardous waste site or incinerator.

You or your children may be exposed to methylmercury when eating certain types of fish caught from contaminated waters, or when eating certain types of wildlife from mercury contaminated areas. Most states, Native American tribes, and U.S. Territories have issued fish and/or wildlife advisories to warn people about methylmercury contaminated fish and/or wildlife. Most of the methylmercury advisories relate to specific types of freshwater or saltwater fish or shellfish, or freshwater turtles. Each state, Native American tribe, or U.S. Territory sets its own criteria for issuing fish and wildlife advisories. A fish or wildlife advisory will specify which bodies of water or hunting areas have restrictions. The advisory will tell you what types and sizes of fish or game are of concern. The advisory may completely ban eating fish or tell you to limit your meals of a certain type of fish. For example, an advisory may tell you to eat a certain type of fish no more than once a month; or an advisory may tell you to eat only certain parts of fish or game, or how to prepare it to decrease your exposure to methylmercury. The fish or wildlife advisory may be stricter to protect pregnant women, nursing women, and young children. To reduce your children's exposure to methylmercury, you should follow the instructions recommended in the fish or wildlife advisories. Information on Fish and Wildlife Advisories in your state is available from your state public health or natural resources department. Signs may also be posted in certain fishing and hunting areas with information about contaminated fish or wildlife.

FDA currently advises that pregnant women and women of childbearing

age who may become pregnant limit their consumption of shark and swordfish to no more that one meal per month. This advice is given because methylmercury levels are relatively high in these fish species. Women of childbearing age are included in this advice because dietary practices immediately before the pregnancy could have a direct bearing on fetal exposure during pregnancy, particularly during the earlier months of pregnancy.

FDA further advises that persons other than pregnant women and women of childbearing age in the general population limit their regular consumption of shark and swordfish (which typically contains methylmercury around 1 ppm) to about 7 ounces per week (about one serving) to stay below the acceptable daily intake for methylmercury. For fish species with methylmercury levels averaging 0.5 ppm, regular consumption should be limited to 14 ounces per week. Recreational and subsistence fishers who eat larger amounts of fish than the general population and routinely fish the same waterbodies may have a higher exposure to methylmercury if these waters are contaminated. People who consume greater than 100 grams of fish (approximately 3.5 ounces) every day are considered high-end consumers. This is over 10 times more than the amount of fish consumed by members of the general population (6.5 g/day). No consumption advice is necessary for the top ten seafood species that make up about 80% of the seafood sold in the United States: canned tuna, shrimp, pollock, salmon, cod, catfish, clams, flatfish, crabs, and scallops. The methylmercury in these species is generally less than 0.2 ppm, and few people eat more than the suggested weekly limit of fish (i.e., 2.2 pounds).

If you are concerned about a mercury exposure or think that you or your child are experiencing the adverse effects of mercury, you should consult with a doctor or public health official who is familiar with the health effects of mercury.

1.8 Is there a medical test to determine whether I have been exposed to mercury?

There are reliable and accurate ways to measure mercury levels in the body. These tests all involve taking blood, urine, or hair samples, and must be performed in a doctor's office or in a health clinic. Nursing women may have their breast milk tested for mercury levels, if any of the other samples tested are found to contain significant amounts of mercury. Most of these tests, however, do not determine the form of mercury to which you were exposed. Mercury levels found in blood, urine, breast milk, or hair may be used to determine if adverse health effects are likely to occur. Mercury in urine is used to test for exposure to metallic mercury vapor and to inorganic forms of mercury. Measurement of mercury in whole blood or scalp hair is used to monitor exposure to methylmercury. Urine is not useful for determining whether exposure has occurred to methylmercury. Levels found in blood, urine, and hair may be used together to predict possible health effects that may be caused by the different forms of mercury.

Blood and urine levels are used as markers to determine whether someone has been exposed to mercury. They are used to determine whether exposure to mercury has occurred and to give a rough idea of

the extent of exposure, but they do not tell exactly how much exposure has occurred. Except for methylmercury exposures, blood is considered useful if samples are taken within a few days of exposure. This is because most forms of mercury in the blood decrease by one-half every three days if exposure has been stopped. Thus, mercury levels in the blood provide more useful information after recent exposures than after long-term exposures. Several months after an exposure, mercury levels in the blood and urine are much lower. Hair, which is considered useful only for exposures to methylmercury, can be used to show exposures that occurred many months ago, or even more than a year ago if the hair is long enough and careful testing methods are used. After short-term exposures to metallic mercury, mercury vapor can be detected in the breath, but this occurs to a significant extent only within a few days after exposure, and is not a method normally used to determine if mercury exposure has occurred.

1.9 What recommendations has the federal government made to protect human health?

The federal government develops regulations and recommendations to protect public health. Regulations can be enforced by law. Federal agencies that develop regulations for toxic substances include the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA). Recommendations, on the other hand, provide valuable guidelines to protect public health, but cannot be enforced by law. Federal organizations that develop recommendations for toxic substances include the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH).

Regulations and recommendations can be expressed in not-to-exceed levels in air, water, soil, or food that are usually based on levels that affect animals; then they are adjusted to help protect people. Sometimes these not-to-exceed levels differ among federal organizations because of different exposure times (an 8-hour workday or a 24-hour day), the use of different animal studies, or other factors.

Recommendations and regulations are also periodically updated as more information becomes available. For the most current information, check with the federal agency or organization that provides it for the substance in which you are interested. Some regulations and recommendations for mercury include the following:

EPA and FDA have set a limit of 2 parts inorganic mercury per billion (ppb) parts of water in drinking water. EPA is in the process of revising the Water Quality Criteria for mercury. EPA currently recommends that the level of inorganic mercury in rivers, lakes, and streams be no more than 144 parts mercury per trillion (ppt) parts of water to protect human health (1 ppt is a thousand times less than 1 part per billion, or ppb). EPA has determined that a daily exposure (for an adult of average weight) to inorganic mercury in drinking water at a level up to 2 ppb is not likely to cause any significant adverse health effects. FDA has set a maximum permissible level of 1 part of methylmercury in a million parts (ppm) of seafood products sold through interstate commerce (1 ppm is a

thousand times more than 1 ppb). FDA may seize shipments of fish and shellfish containing more than 1 ppm of methylmercury, and may seize treated seed grain containing more than 1 ppm of mercury.

OSHA regulates levels of mercury in the workplace. It has set limits of 0.1 milligrams of mercury per cubic meter of air (mg/m^3) for organic mercury and 0.05 mg/m^3 for metallic mercury vapor in workplace air to protect workers during an 8-hour shift and a 40-hour work week. NIOSH recommends that the amount of metallic mercury vapor in workplace air be limited to an average level of 0.05 mg/m^3 during a 10-hour work shift.

1.10 Where can I get more information?

If you have any more questions or concerns, please contact your community or state health or environmental quality department or

Agency for Toxic Substances and Disease Registry
Division of Toxicology
1600 Clifton Road NE, Mailstop E-29
Atlanta, GA 30333

* Information line and technical assistance

Phone: 888-422-8737
FAX: (404)498-0057

ATSDR can also tell you the location of occupational and environmental health clinics. These clinics specialize in recognizing, evaluating, and treating illnesses resulting from exposure to hazardous substances.

* To order toxicological profiles, contact

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Phone: 800-553-6847 or 703-605-6000

References

Agency for Toxic Substances and Disease Registry (ATSDR). 1999. Toxicological profile for mercury. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

DENTAL CAULK | New Products | Caulk Special Promotions | Guest Book | MSDS & DFU Information | Product Profiles | News, Events & Announcements | E-Mail

DIRECTIONS FOR USE

Dispersalloy®

Tablets and Powder

A dispensed phase admix amalgam, containing lathe-cut particles and silver/copper eutectic spheres. Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist. For dental use only.

Composition

	Powder (for 100g.)	Tablets
Silver	69.5 g	.270 g
Tin	17.7 g	.069 g
Copper	11.8 g	.046 g
Zinc	1.0 g	.004 g

Indication for use

ipersalloy® should be used in stress bearing restorations (Class 1 and 2), when other restorative materials or restoration techniques are not indicated.

Contraindication

The use of amalgam is contraindicated;

- In proximal or occlusal contact to dissimilar metal restorations.
- In patients with severe renal deficiency.
- In patients with known allergies to amalgam.
- For retrograde or endodontic filling.
- As a filling material for cast crown.
- In children 6 and under.
- In expectant mothers.

Side Effects/Warning

Prior to use, read the MSDS information and product instructions for this item.

Exposure to mercury may cause irritation to skin, eyes, respiratory tract and mucous membrane. In individual cases, hypersensitivity reactions, allergies, or electrochemically caused local reactions have been observed. Due to electrochemical processes, the *lichen planus* of the mucosa may develop.

Mercury may also be a skin sensitizer, pulmonary sensitizer, nephrotoxin and neurotoxin.

ter placement or removal of amalgam restorations, there is a temporary increase of the mercury ncentration in the blood and urine.

Mercury expressed during condensation and unset amalgam may cause amalgamation or galvanic effect if in contact with other metal restorations. If symptoms persist, the amalgam should be replaced by a different material.

EXHIBIT 10

- Removal of clinically acceptable amalgam restorations should be avoided to minimize mercury exposure, especially in expectant mothers.

Precautions

- The number of amalgam restorations for one patient should be kept to a minimum.
- Inhalation of mercury vapor by dental staff may be avoided by proper handling of the amalgam, the use of masks, along with adequate ventilation.
- Avoid contact with skin and wear safety glasses and gloves.
- Store amalgam scrap in well sealed containers. Regulations for disposal must be observed.
  DISPERSALLOY® CONTAINS ZINC; THE AMALGAM MADE THEREFROM MAY SHOW EXCESSIVE EXPANSION IF MOISTURE IS INTRODUCED DURING MIXING, CONDENSING AND COMPACTING.

Proportions

As with all alloys, the ratio mercury to alloy is important. A 1:1 mercury/alloy ratio is recommended. When using either Dispersalloy ® Tablets or Powder, we recommend using an automatic powder and mercury proportioner. It will automatically and precisely dispense measured amounts of mercury and alloy. Refer to the instructions provided by the proportioner manufacturer.

Step-By-Step Instructions

1. Trituration

Trituration speed and time are important factors in the handling properties of any amalgam. Use Caulk reusable capsule and pestle for best results. The chart that follows provides guidelines in determining amalgamator trituration time and speed setting for Dispersalloy ® Powder and Tablets:

TRITURATION TIME RANGE - SECONDS					
Tablets		Fast Set		Regular Set	
Amalgamator	**Setting**	**1 Tablet**	**2 Tablets**	**1 Tablet**	**2 Tablets**
Caulk ProMix	Turtle	14±3	14±3	14±3	12±3
Caulk Vari-Mix II M	M2	14±3	14±3	14±3	12±3
Caulk Vari-Mix III	M2	14±3	14±3	14±3	12±3
ESPE CapMix	--	5±1	4±1	NR	NR
Wig-L-Bug DS80	High	13±2	13±2	13±2	9±2
Wig-L-Bug MSD	3800	16±3	16±3	14±3	12±3
ADEC	5	14±3	14±3	14±3	12±3
Silimat	4200	5±1	5±1	NR	NR
Silimat Plus	P-2 Slow	8±2	6±2	6±2	NR

Dear Sir.

Good friends have informed me of the Hearings on 14. Nov. and that written contributions are wellcome during the next 2 weeks to be sent to your address. I should like to contribute to your fight against amalgam.

I hold a M.Sc. in Chemistry and due to severe diseases from amalgam in the near family I have intensively studied its attack on our body, i.e. what is going on within the single cells when they are being damaged.

The reason for the scientific disagreement between on one side ADA and FDA and on the other side all those who are suffering is easy to demonstarte: **FDA and ADA neglect the Laws of Nature. They rely on inaccurate medical statistics which further are built on wrong and misunderstood methods**. A mighty scientific blunder. The political disagreement is wellknown and outside this letter.

The Laws of Nature are described in Chemistry and Physics, e.g. those of gravity and electricity, in the astronomy a.s.o. and all of them are eternal and of the same validity to the phenomina, we observe inside and outside our body. Thus findings according to these laws as described below are indisputable.

In the medical world they showed their superiority when 10.000 malformed babies were born by mothers having been subscribed thalidomide forty years ago, in the catastrophe of Minimata and now in the catastrophe of amalgam and Hg-containing vaccines.

Recently I was invited to present a paper at the International Medical Conference of Health-Trends 2002 in Copenhagen. I.a. Professors Boyd Haley, Samuel Epstein and Lester Packer also presented their contribution to the theme: "Healthy Ageing in a Polluted Future". My paper is printed below. As I, due to lack of time for presentation, had to give priority, the list of symptoms and diseases could not be included and they are printed at the end. I can also refer to the peer-reviewed US-medical journal, Clinical Practice of Alternative Medicine, Vol 2 No. 3, 2001 pg. 181-87, The Journal of the Am College for Advancement in Medicine.

I hope you will find the information of interest. Questions, comments and criticism are

wellcome.
You may distribute it wherever you think it suits the purpose to get rid of amalgams.

Kind regards,

Poul Møller, 21 B Augustenborggade, 11th floor, DK-8000 Aarhus C, Denmark

HEALTH-TRENDS 2002. Sunday, Sept 1, 8,30 a.m.

Mercury, Ageing and the next Generation.

Introduction. The Number of chronically sick and mentally retarded children accelerate much. The authotirities do not and will not consider, that the Laws of Nature are ruling Hg in the body. 1958-62 they demonstrated their superiority similarly, as 10.000 malformed children without arms or legs were born worldwide by mothers prescribed thalidomide, or in the Minamata case.
However, our government admits: Inorganic Hg is neurotoxic, organic Hg strongly neurotoxic creating extensive damages to the CNS and peripheral nerves. But these severe chronic toxicities cannot be compared to the minimal amounts released from fillings and stored in the organism.
Norway advises against amalgam, because more Hg is released than one thinks. It correlates with the amounts in the brains of dead people, in the fetus and in breast milk. The Danes know, that Hg in the fetus and infant correlates with the Number of fillings, but it has never been proven dangerous! They use wrong methods.
Combining these confessions we are close to the end of the fight: Amalgams ARE poisoning the patients.

The Chemical Impact of Mercury on the Body. Some people do not suffer much from their amalgams; and others are severely hit, about 20%. Yesterday we heard Prof Boyd Haley speaking of the genetic differences.
Healthy people are in balance, chemically. Hundreds of biochemical papers reveal that people with chronic diseases respond positively to antioxidants, i.e. they are in a chronic oxidative imbalance, caused by free radicals, very aggressive particles demolishing what they happen to hit.
Nothing is by far so active as Hg in highly toxic quantities inside all cells, 24 hrs. a day, life long. The release from a filling starts as soon as it has been placed and reaches maximum in two days. It is enhanced by hot and acidic food, bruxism, chewing gum, polishing and gold, creating an electric current. After the systematization of amalgam in the last mid-century people got 12-14 fillings on average. They have 10 grams Hg placed 2 inches below the brain with open access for its vapours along the smelling nerve. Toxicity is counted in micrograms, g.
Controlled fillings lost 50% Hg in 5 yrs. i.e. >1,300 g/day. More than 3 grams are still in the body equal to 120 m. Hg-atoms in each of our 75 trillions of cells.
Three chemical reactions are of importance:
1) Hg recycles quickly between its 2 valencies. One radical is created in each cycle, so the effect is multiplied. For comparison we have 3.000 m. DNA´s per cell. The recycling is similar of that of hemoglobin as the colour of the blood changes from pink to dark red, back to pink a.s.o.
2) Further Hg combines avidly with sulphur. Our proteins are built up from 20 amino acids.

Two are fundamentally different; cysteine and methionine, containing SH-groups. Cysteine is often placed in active sites in enzymes, in some hormones, in DNA and in our most important antioxidant, glutathione. The attack on exactly these sites is simply a tragedy.
3) Like most other organisms we convert Hg bacterially into organic Hg. We do it in the mouth and the GI tract. Being soluble in lipids it penetrates all otherwise protecting membranes. We have no barriers at all: Cell membranes are penetrated as well as the blood/brain and the blood/

2

retina barriers, the placenta and mammary glands. Organic Hg is one of the worst environmental
threats. It accumulates in the food chain.
Already 1975 Dr. B Weiss, Univ. of Rochester, N.Y. wrote: "Metals such as mercury and lead have been recognized for many years as CNS poisons. Their presence may pose hazards difficult to specify because the changes in function, even by relatively low, but chronic levels may unfold only gradually and subtly in ways that current methods are unprepared to evaluate. Organic Hg displays an extraordinary affinity for the CNS, it kills nervous tissue. It must be assumed that once distinct neurological signs appear, widespread damage to the brain has occurred".
HgS-compounds and organic Hg are those finally stored. They are extremely insoluble in water. We have no enzymes to change that. The half-time in the CNS is therefore long, above 25 years. When cells die, they stay and enter a neighbour cell to continue destruction. The other amalgam metals, copper, silver and tin behave similarly, organic tin is related to TBT used in boat paintings to kill adsorbing algae, bivalves etc.

Mercury and Health. We can now conclude that chronic toxicity is the major cause of chronic diseases in people having too little genetic resistance to heavy metals. These diseases having a common chemical origin, also have a common chemical cure.
To-day's medical science has achieved marvellous results in fighting infectious diseases and in surgery. Chronic diseases lag behind. The Establishment does not understand the Laws of Nature, as universities do not teach them. Clinical methods do not fit: Amalgam is claimed safe because no systemic toxic effects are found in blood and urine. They are for transport, not for storage of toxic Hg, that has long been stuck to the organs. The toxicity is claimed "neutralised", when Hg fixes in the final filling. Both statements are scientific blunders. Finally amalgam has a character of a taboo and authorities are unwilling to consider the risk.
Normally medical science requires fully controlled experiments. In modern times amalgam is the largest uncontrolled experiment. To observe what happens to a cohort of humans, the now middle-aged, left to go through life with potentially intolerable mercury-leaking implants in their mouths with open access to the brain. Authorities do not worry about people getting sick, how they are helped, some of their diseases are not even accepted. The result is a vast waste of ressources: Wrong diagnoses, treatment and medication of "non-diagnosable" diseases. Depression and anxiety are most frequent symptoms. Unnecessary operat-ions are reported, biochemists are ignored, and very costly medical research show modest results. It looks as if drug companies are searching for drugs, that can compensate for Hg-toxicity without knowing of it. Stem cell research is highest fashion. How much are they polluted?
Dr. Hal Huggins, US-dentist is the most experienced one in replacement of amalgams according to his "protocol" including adjustment of food and food supplements before and after to rebuild the defence of the body. Having helped more than 2,000 patients he tells in his book: Uninformed Consent, 1999, that i.a. leukemia, epilepsy and fibromyalgia have disappeared, and hypertension and hypercholesterolemia have been normalised.

The Influence on Psychical Ageing. Dr. Weiss quantified the long-term toxicity of organic Hg
by comparing biological age with functional capacity of the brain. "Taking 25 years of age as the

3

100% baseline, the next 45 years show about 20% decline of functional capacity". The normal rate of cell loss was 0.5 % p.a. If that is enhanced with 20, 100 or 200 %, a 40 year old person gets a functional brain age of 46, 56 and 95 years respectively. Due to the long span of time even moderate increases have great effect. "Estimates are conservative; exposures begin *in utero,* not at the age of 25".
It seems evident that all three chemical processes accelerate the ageing process. Large excesses of free radicals demolish any compound hit, essential cysteine containing compounds are blocked and the cell killing s by organic Hg put brakes on the steady renewal of cells. All of them promote age-degenerative diseases.
Also some of the "non-diagnosable" symptoms add to feeling older, e.g. depression, migraine, tremor, chronic fatigue, loss of memory, lack of concentration and visual disorders.

The Damage to the Next Generation. The blood of the umbilical cord and breast milk contain up to 8 times as much organic Hg as the mother´s blood. Dr. Vimy, Univ. of Calgary, used radio-active Hg for these analyses. The blood has a constant Hg-concentration over time. The supply of the poison is therefore proportional to the amount of blood entering the embryo, the fetus, and the amount of milk during the nursing period, i.e. the first 15 months of the small creature. The load will have to be considered per unit of weight. At start it is very high due to the small weight.
The proliferation period of the neurons is complete at mid-gestation. Then the intense interact-ions start and continue to the age of 2 years. Cell dividings on the way to 100 bn neurons and as many glial cells may be interrupted by the organic Hg. The poison is supplied just during brain formation and never more, if the child do not get any fillings. Disturbances at any stage may cause persisting intellectual and/or behavioural impairments to the incomplete brain.
The brain is metabolically very active accounting for some 25% of the body´s metabolic rate at rest. Its unsaturated lipids, EPA and DHA take about 60% by weight.It is therefore specially susceptible to attack from free radicals.
These days we experience mental retardation as reduced IQ, demand for social assistance and special education at schools, DAMP-children, autism, ciabetes-2 at school age, hyperactivity, violence and criminality. These phenomena escalate because a so called "high copper amalgam" was introduced to children in the 70´s. It is easier to handle, but deteriorates 50 x faster. The girls have now reached fertile age and transfer their Hg to the next generation.
The same effects were observed from leaded petrol in large cities in the US, UK, on the conti-nent and in developing countries. The chemistries of lead and mercury are identical.

Conclusion. It is even worse. Contemporarily with these escalating problems in the young end, the old, the filling generation, who got victims of the systematization in the mid-1900´s, show escalating age-degenerative chronic diseases. In a few years both these disasters.which had been preventable, will reach a level, which societies have neither capacity nor knowledge to handle. At present they take up some 50% of the total public cost of care in this country Alone the special education is a little less than 1 bn . Add to that the sufferings of the patients and their families.

We must act now to remove the hatched area in this fig. showing the potential of well-being. THE END.

From an unpublished paper:

4. Symptoms and diseases

All the above-mentioned facts make amalgam-Hg by far the most dangerous cause of heavy oxidative stress. Mental symptoms occur such as:
depression anxiety shyness headache
visual disorders suicidal thoughts irritability nervousness
loss of memory lack of concentration fatigue muscle and joint pains
tremor vertigo numbness tingling of lips and fingers
cold extremities.
Physicians assuming amalgam safe, might easily fail to associate the symptoms with the presence of dental amalgam. Patients then risk being considered hypochondriacs. They are not, they are suffering from Hg toxicity.
Diseases pointed out by biochemists to be connected with oxidative stress are i.a.
senile dementia Parkinson´s and Alzheimer´s dz. MS and ALS,
schizophrenia fibromyalgia epilepsy migraine
tinnitus chronic fatigue atherosclerosis cancer (22)
osteoporosis some rheumatic dz some allergies - asthma and psoriasis
age-related eye diseases, cataract, AMD reduced quality of sperm. (1) - (7).
The CNS is severely influenced and the associated diseases, that normally take many years to develop, are explained by biochemistry. They arise, when our defence systems no longer resist the attack.
A genetic relationship has been discovered as regards apo-lipoproteins E (30). ApoE2, 3 and 4 have two, one and zero cysteine-SH-groups in substitution for arginine groups without S. The protection from the ApoE´s against AD increases with the number of SH-groups as shown by the age of AD onset. In the US some 12% in the best group show an age of onset above 90 years, 65% in the interval 80 - 90 and 24% between 70 and 80 years. This finding has been proposed as a method for large scale genotype screening of those potentially at a higher risk of mercury poisoning (31), where a physician and a dentist sum up their more detailed experience. The physician (MEG of New Zealand) has started the screening of those getting 16 fillings on the average in the 1950s to 1970s in the socialized school dental care program. He wrote: "These 500,000 of a population of 3.5 m. now the middle-aged who have effectively been an uncontrolled experiment that has never previously been done, namely to observe what happens to a cohort of humans left to go through life with a potentially intolerable amount of mercury-leaking implants in their mouths". 180 patients have been tested so far. "We are facing a 100.000 new AD cases, a horrendous scenario that could be totally pre-empted once MDs are instructed to look at teeth, doing ApoE genotyping, then getting the amalgam out with the help of competently trained dentists. All this will take a decade to establish, so we have to act NOW". (Godfrey ME, personal communication).

To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform, regarding the November 14, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science. [web outline: http://www.house.gov/reform/pr.02.11.13.htm]

Please enter my remarks about the dangers of mercury in dental amalgam, and my request to Disband the American Dental Association. I am a health care professional who helped many people in their struggles with health conditions related to mercury. All of them had dental fillings, and all problems dated after amalgam mercury fillings were placed.

Some of the people I have encountered over my years in health care, including those seen by other practitioners [dental, medical, naturopathic, chiropractic, acupuncture], were severely ill and several died of complications due to debilitation from mercury according to our clinical judgement.

I have seen major improvement in several patients who had their dental mercury removed and replaced with non-metal materials. Because this letter is in accord with the expected content of other Dental Amalgam Mercury Syndrome group members' letters, I will not attempt to recreate the list of the many concerns we have shared with each other over the years. Research is needed, money needs to be spent on this, but the ADA does not do this and then complains there is not research. We practitioners are left with minimal research and are doing the best we can with the limited freedom allowed us to help the suffering public.

I hope someone will read this email and attached document from dental professional literature. The attached document is basic proof of the extreme maltreatment the American public has suffered from the American Dental Association.

The ADA has systematically ignored and occasionally destroyed scientific evidence of the dangers of mercury in dentistry. I personally visited the excellent clinic that Dr. Hal Huggins (DDS, MS) set up in Colorado Springs to remove mercury in a safe way, and to help people rebuild their bodies that had been so brutally affected by mercury; he was attacked in dastardly fashion and his practice closed and he now practices in another country; he has proof of documents in the ADA library being destroyed; his own research that showed nerve breakdown in the brain fluids appearing after mercury fillings were placed was desecrated and shut down but not before he captured the data of mercury's damage to brain structure. Dr. Huggins spoke of damaging research literature he found in the ADA library that mysteriously later disappeared. In the last decades powerful scientific evidence of mercury's destruction of nerve tissue and other correlations with he! alth problems has continued to accrue.

The attached document was published in 1883. It shows scientific studies revealing death of test animals after exposure to mercury dental fillings. This research was published over a century ago, but the ADA ignores it when it says there has been no research showing dental mercury is deadly.

12/16/2002

I and many of the public feel that there is no sincere protection of the public by the ADA from mercury (and other conditions not related to this hearing on mercury), and that this hearing is being seriously underattended and ignored.

I submit this letter to:
1) support the outlawing of dental mercury, and,
2) request that the ADA, American Dental Association, be disbanded and a new association allowed to form composed of dentists and medical researchers who honestly look at the danger the ADA poses to health due to their approval of dental mercury.

I will close now while I can remain moderately civil toward these underhanded, untrustworthy self-interested trade guild manipulators--the ADA. Please outlaw dental mercury, and consider disbanding the ADA.

Ralph Wilson, N.D.

For submission to the Congressional Record, November 14, 2002, Hearing on Mercury in Dental Amalgam: An Examination of the Science.

To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

Dear Sir,
it is well known that dental amalgams (DA) corrode and are subject to wear. The desperate efforts of the compromized dental representants to deny the tendency to deterioration and consecutive mercury release have been many. In Sweden, perhaps the most active pro-amalgam advocates have been Maud Bergman, University of Umeå, and Per-Olof Glantz, University of Malmö. In 1982, these professors have been commisioned by the Swedish Social Welfare Board to conduct a review of the risks of dental amalgam fillings deteriorating, releasing mercury, and causing the danger to health.
They reported (literal translation): *"In our opinion, the available scientific literature does not contain any scientifically confirmed results, which would indicate a clinical systematic deterioration of silver amalgam fillings."*
This formal report, among others, was clearly untruth and fraud in both science and clinical medicine, threatening the health of millions of people. You find enough references in the literature list in my publications, attached to this mail.
I mention this just to show, that the DA-issue is not only a scientific one, not only about bringing a clear-cut evidence of the danger of implanted heavy metals.

The material aspects in the Dental Amalgam Issue can be used for evaluation of the mercury exposure in dental patients. This possibility of the mercury exposure-estimate has been neglected in the debate of the exposure and of the danger of the released mercury. Logically, mercury found in blood, urine or body tissues is so far from its source, that it will not mirror the amounts the body has been *exposed* to, even more so if the excreeting function of kidneys had been impaired by the same mercury.

Nowadays, there are two main brands of DA on the market:
a) Conventional silveramalgam
b) Modern non-gamma-2 amalgams.

Both of them deteriorate and corrode, but the noticeable features are somewhat different. I attache two figures with representative appearance of both brands, indicating release of mercury:
a) The conventional **silveramalgam in Fig. 1** shows corrosion after several years of exposure in vivo. On the polished section through the filling, a dark surface layer has been converted (corroded) to corrosion products, free of mercury. Often, there is no lack of the bulk material, visible to bare eye, but in the Scanning Electrone Microscope (SEM) both the morphology and decreased mercury content can be documented. Not difficult at all, but still kept as secret as possible by the dental profession.

b) The **non-gamma-2 amalgams** (with increased copper contents) after slight abrasion are shown in

Fig.2. Here, the special feature is excretion of tiny mercury rich globules (white dots). The excretion occurs irrespective the age of the specimen. It is not an attribute of the vacuum in the SEM, as exactly same phenomenon has been observed in optical microscope at ambient conditions. More than 20 abrasions have been made with the same results.

Counting the globules per surface unit renders it possible to calculate the released mercury, and thus *exposure*. It makes about 20 micrograms per abrasion from 1 cm2, which gives ca **200 micrograms** after one chewing event, in an average patient with 10 cm2 of amalgam surface.
This is 8 times the occupational limit of 25 micrograms Hg a day.

I wish to add, that I have been chronically poisoned by DA-mercury and got my health back only after removal of the DA-fillings. My case is described in the reference nr. 1 in the attached list of publications. 19 years later I feel more healthy than ever and must only confirm my previous conclusion, that the amalgam therapy markedly disturbed my health and the quality of my life during many years. Moreover, it had been the most serious health problem in my life.

Sincerely yours

Jaro Pleva, PhD
jaro.pleva@glocalnet.net
Phone & Fax +46 563 22032

Attachments:
Fig. 1
Fig. 2
List of Publications. The review (6) is recommended as overall review of the issue without bias.

PS: Unfortunately I have had problems to send the micrographs with this e-mail. I will try again, otherwise I can send them by normal mail, if desired.

LIST OF PUBLICATIONS OF JAROSLAV PLEVA, PhD.

Lakheden 20, S-68392 HAGFORS, SWEDEN
e-mail: jaro.pleva@glocalnet.net

PUBLICATIONS ON DENTAL AMALGAM AND MERCURY POISONING

1. Pleva J, Mercury poisoning from dental amalgam. **J.Orthomol.Psychiat.** 12(1983) 184-193 (Writers own case description).
2. Pleva J, Corrosion and mercury release from dental amalgam. **J.Orthomol.Med.** 4(1989)141-158.
3. Pleva J, Corrosion of dental amalgam. **Mater.Perf.** 29(1990)60; dtto30(Jan.1991)6,7,82.
4. Hanson M, Pleva J, The dental amalgam issue. A review. **Experientia** 47(1991)9-22.
5. Pleva J, Mercury from dental amalgams: Exposure and effects. **Int.J. of Risk & Safety in Medicine** 3(1992)1-22.
6. Pleva J, Dental mercury-a public health hazard. **Rev. Environ.Health** 10, No1(1994)1-27.
7. Redhe O, Pleva J, Recovery from amyotrophic lateral sclerosis and from allergy after removal of dental amalgam fillings. **Int.J.Risk & Safety in Medicine** 4(1994)229-236.
8. Pleva J, Are Promoters of Dental Amalgam Poisoned by Mercury? **J.Orthomol.Med.** 9(1994)75-78.
9. Pleva J, Mercury release from dental amalgams. In: **Status Quo and Perspectives of Amalgam and Other Dental Materials,** Internat. Symp. Proceedings, Ed. L.T.Friberg & G.N.Schrauzer, Georg Thieme Verlag, Stuttgart, 1995, p.21-31.

PUBLICATIONS ON MATERIAL PROPERTIES OF STAINLESS STEELS AND ALUMINIUM

10. Pleva J, Nordin S, Properties of different MMA-welds on modified type 329 ferritic-austenitic stainless steel. Conf. Proc. **Duplex Stainless Steels**, Ed.R.A.Lula, ASM 1983; Oct. 25-28, 1982, p.603, St.Louis, Missouri, USA.
11. Pleva J, Evaluation of welding methods and filler metals for duplex stainless steels. In: Proc. **Stainless Steels '84**, Göteborg, Sweden, Sept. 3-4, 1984, p.343ff.
12. Pleva J, Korrosionsfeste stickstofflegierte Stähle - Eigenschaften und Erfahrungen. In: **Ergebnisse der Werkstoff-Forschung, Band 4**: Stickstofflegierte Stähle, S. 153. Herausg. M.O.Speidel und P.J.Uggowitzer, ETH-Zürich, Schweiz, 1991.
13. Pleva J, Advanced stainless steels for building applications. In: Conf.Proc. **Stainless Steels '91**, June 10-13, Chiba, Japan, p. 359-366.
14. Pleva J, Corrosion in pulp and paper industry - failures and remedies (in swedish). Swedish Corrosion Inst., **Bull. nr. 93**, 1982, 63 pages.
15. Pleva J, Liljas M, Stenvall P, Stiller K, Precipitation hardening of a new duplex stainless steel. In: Conf. Proc. **Applications of Stainless Steels '92**, Stockholm, Sweden, 9-11 June 1992.
16. Pleva J, Untersuchungen über die ungleichmässige Korrosion von Aluminium und Al-Cu- Legierungen (Investigations on the localized corrosion of aluminum and Al-Cu-alloys). **PhD-Thesis**, Friedrich-Alexander-Universität Erlangen-Nürnberg, Germany, 1976.

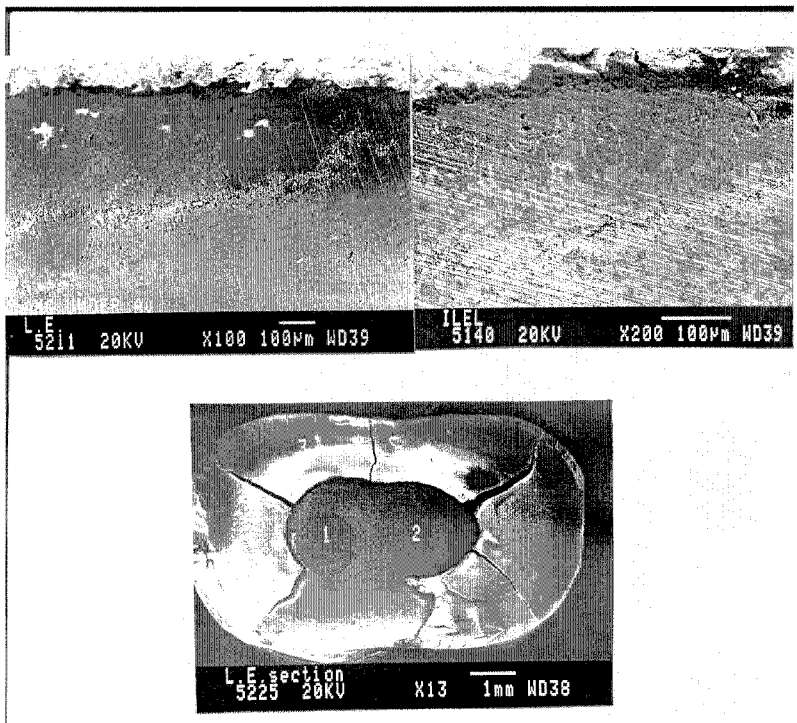

Fig.1: Conventional silveramalgam (nr.5211 and 5140) sections showing surface layers (dark) converted to mercury free corrosion products.
The micrograph below (5225) shows section through a tooth filled with silveramalgam (1 and 2). The increasing volume of the corrosion products cracked the tooth at several locations.

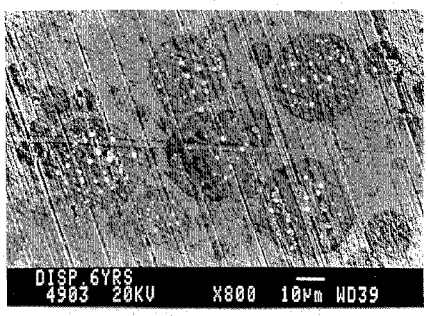

Fig.2: Modern non-gamma-2 amalgam: Excretion of mercury rich globules after every of 20 slight abrasions of Dispersalloy, 6 years after condensation by a dentist. (J.Pleva)

Chairman Dan Burton, Rep. Diane Watson, and Members of the committee on government reform:

I have been a general practice physician for over 29 years. Initially I had been neutral regarding the amalgam issue. However, over time my clinical experience has convinced me of the validity of mercury's harmful effects. One of the chief difficulties in recognizing its harmful effects is the problem of communication, or more correctly, the LACK of communication.

For example, if somebody experiences an adverse effect, especially a systemic effect, after having a dentist place some fillings in their mouth, they will not normally return to the dentist to complain about that, but instead, will go to their local physician. And how often will their physician ask them about how long it has been since they went to their dentist, and what he did to them?

Because of the lack of communication between dentists and physicians, because physicians tend to assume that dental treatments have nothing to do with human health, that dentists treat only teeth, and not human bodies, and because the public is not aware of the potential for significant systemic health effects from dental materials, these adverse reactions are not being accurately recognized and reported.

In addition, of course, many of the systemic effects of amalgam fillings take time to develop, similar to the effects of cigarette smoking. One doesn't get lung cancer after smoking 1 cigarette. One does not usually get lung cancer after smoking 1 pack a day for one year. So, some of the adverse effects of amalgams in teeth are experienced only after decades of exposure.

At any rate, I, as an observant medical practitioner, am now able to recognize adverse health effects of mercury in the majority of my patients. The most common symptoms are: digestive problems including GERD, thyroid disorders, headaches, depression, autoimmune disorders, essential hypertension, and reproductive problems. Some of these symptoms are the consequence of slowly accumulating mercury within the cells of the nerves to the involved organs, thus interfering with the normal pathways of communication from the brain to the rest of the body. Others are due to the damage to the organs themselves, or, in some cases, to derangements of the immune system, causing it to attack the body's own tissues. Most significantly, I have yet to see even one of my patients, of the dozens who have addressed this issue by removal of all amalgam fillings and replacement with non-metal fillings, later regret their decision. Even though it is very expensive, because the improvements they have experienced in their health have been so significant, every single one of them have been glad they took that step. I have had at least 2 patients who had been totally disabled regain their ability to

return to full-time gainful employment as a result of the replacement of their amalgam fillings.

I challenge ANYONE to show me a SINGLE person with a documented diagnosis of multiple sclerosis who has NEVER had an amalgam filling! In my opinion, mercury (whether in dental fillings or vaccines and other injectables) should be classed as a hazardous material, and should be reserved for use in mechanical equipment and non-biological systems only.

PLEASE do everything in your power to abolish the use of mercury in dental fillings as soon as possible.

Sincerely, Jon R. Mundall, M.D.

Dear Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform:

I am a disabled dentist due to a 3/4 pound spill of mercury in shag carpeting below my operating chair. Although I had gone to my physician
with many health complaints, he failed to properly diagnose me. It was not until Dr. Louis Chang, a toxicologist from the University of
Arkansas, documented my case that I had a credible diagnosis. I had a worker's compensation case on disability from mercury exposure in
practice. Although I had one of the world's leading toxicologists, I still lost the case. This is to point out how difficult it is to prove and diagnose mercury toxicity. You can always have someone on the other side who wants to confound the issue because mercury toxicity is such an
insidious poison. By the way, months later, the judge admitted he probably made a mistake in my case but it was too late.

The problem with this whole issue of the safety of mercury amalgam fillings is that there is no test for sub acute chronic mercury toxicity.

I am highly respectful of the ADA as a professional organization. Unfortunately, their position on the safety of dental amalgam is flawed. I read an article in an ADA newsletter that compared the stability of dental amalgam with that of oxygen in a stable water molecule. They said that free oxygen is an explosive element but people don't explode when they drink water. There is a big difference with amalgam. Amalgam is not a stable chemical molecule. It is an amalgamation of mercury, silver, tin, and usually zinc. It is a fact that mercury does escape from this mixture upon pressure of chewing and heat. Even the smallest amount of mercury is toxic. The ADA's response to this is that it is too little to cause health problems. On personal communication with the ADA, they reject the idea that with low exposure mercury can accumulate in certain individuals over a period of time. This accumulation may take place until a threshold is reach where clinical symptoms manifest itself. The individual response to mercury is greatly varied and sensitization to mercury can occur which can increase the toxic effect of exposure.

Amalgam is not really that stable. When amalgam was first used over 150 years ago, it was a combination of mercury and silver. It was so unstable that it would expand and

fracture teeth. The present alloy of silver, tin, and zinc are combined in such a way that the expansive and contractual forces are balanced which just give the appearance of amalgam stability.

Since the time I became disabled from mercury toxicity, I spoke to over 100 people with symptoms like mine. My exposure from mercury was from a spill of mercury in shag carpeting which is a known hazard. Even then, the average physician did not properly treat or diagnose me. It took years to prove what happened to me. The difficulty in definitively diagnosing amalgam toxicity is so much more difficult than a large mercury spill. If a clear diagnosis of amalgam toxicity existed, there would be no controversy since the ADA states that no one has ever been poisoned with amalgam.

I feel that many people are suffering due to this insidious poison. It is inhumane to allow this to go on because of lack of medical knowledge in this field to definitively diagnose this disease. The FDA would not be able to introduce amalgam as a dental filling material today. Scientific testing would not prove the safety of amalgam. To rely on the statement that dental amalgam has been used for over a 150 years without any adverse effects is unscientific.

There should at least be informed consent by the dental patient receiving this toxic substance in their mouth. Over the counter products that contain themerosal have a warning on their label that a person with a sensitivity to themerosal (mercury compound) should not use the product. Should not a dental patient have the same warning to a material implanted in their body which remains in place for many years? A person exposed to a thimerosal containing product have limited short exposure.

Please take this issue seriously. There are too many people who have already suffered with the insidious symptoms of this poison.

I hope that I can contribute to the public welfare. My life and dental career have been devastated by this insidious poison. If I can make a difference, perhaps my suffering will not have been in vain.

Respectfully submitted,

Stuart Scheckner, DMD

For Submission to the Congressional Record, November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science

To; Chairman Dan Burton, Rep. Diane Watson and members of the Committee on Government Reform

From: Oregon Doctors of Chiropractic (ODOC), Ann Durrant, D.C. President and John F. Schmidt, D.C. Vice President, both chairpersons of the Public Health Committee

November 18, 2002

ODOC's Public Health Committee has made an extensive review of the scientific information available on the issue of Dental Mercury Amalgam. There is no doubt as to the fact that mercury is a powerful neurotoxin, an inhibitor of immune system function and that it compromises proper function of human hormonal balance. Mercury is a major contributing factor to diagnosable disease states indentified by a multitude of medical researchers. It is therefore logically a causative factor in weakened immune systems and compromised neurological functions which have not yet manifested as a diagnosable condition. We will refer to this state of reduced health as Subclinical Immune and Neurological Dysfunction (SIND).

We are gravely concerned that a state of reduced health and vitality as a result of SIND is occuring in the American people who have Dental Mercury Amalgams. Our review of the literature conclusively demonstrates that Amalgams "leak" mercury and that mercury from those amalgams is the single greatest source of this powerful toxin in those with even a minimal amalgam placement. (1,2)

The reduced vitality of the American people compromises their ability to thrive and prosper. It also causes an economic burden to our health care system. This is particularly discernable by providers such as ourselves since many of the patients we see with SIND have not yet reached and in fact are trying to avoid full blown disease states. Until these peoples' conditions are deteriorated by improper amalgam removal their condition is not medically diagnosable, thus their plight is not recognized in any epidemiological study. Patients who then seek traditional medical care after worsening become a factor in the multitude of studies already supplied to you by scientific experts showing evidence of

those disease states and their relation to mercury amalgams.

Evaluation of health concerns should not only be a function of published research but also of clinical observation by those of us who see people every day who are "sick" but not yet diagnosable and are suffering from SIND. SIND is often labeled as "Fibromyalgia", "Compromised Immune System", "Chronic Fatigue Syndrome", "Depression" or some other vague description which all mean that the person is expressing a reduced state of vitality. People with SIND often have a history of dental mercury amalgam removal just prior to the onset of their chronic symptom pattern. They are also unaware of the close correlation in timming until asked and usually are not asked unless the clinician has been made aware of the dental mercury amalgam connection. This onset is caused by the massive mercury burden on the Neuro-immune-hormonal system as a result of removing the amalgam containing mercury in a clinical setting offering less than optimum protection to! mercury vapor and particulate matter. In addition to the obvious assimilation into the body through both the lungs and digestive tract, Mercury from amalgam removal disrupts neurological function via "Retrograde Axonal Transport" via the Trigemminal or Fifth Cranial Nerve and the Hypoglossal or Twelfth Cranial Nerve. (3,4)

We support and encourage further investigation by the House Committee on Government Reform into this issue and we support the passage of H. R. 4163. However, we have grave concerns regarding the aftermath of increasing public awareness of not only the dangers of mercury amalgam placement, but continuing to have it in your mouth. As awareness increases people will want it removed. In most cases it will be removed wrong without appropriate protective protocols.

It is imperative that anyone removing mercury understands and uses safety protocols to avoid triggering SIND or full blown diagnosable conditions such as multiple sclerosis and Alzheirmers. Public awareness of the truth about amalgams, followed by hasty decisions of millions of people to have removal by dental personnel **not** adequatedly trained in protection protocols will create an economic health care burden that this country ill afford.

Every week we see patients who want to have Mercury Amalgams removed. The momentum for change is inevitable, "mercury free" is the "in thing" and the question is no longer "if", but "when" America will no longer be placing this neurotoxic metal in the mouths of our citizenry without informed consent, and within three inches of our brainstems.

We respectfully request that you consider an amendment with language protecting Americans from inappropriate removal. Please also consider mandating insurance coverage allowing for safe removal protocols for Total Dental Revision **without interference from third party payors.** To do anything less will create long term economic health impacts far exceeding the initial cost of appropriate removal with complete protection from mercury vapor, particulate matter and resulting disruption of the bodies nervous system function. Those same insurance carriers will experience long term savings in

the improved health of their insureds since Total Dental Revision with complete protection, "sequential removal", and replacement only with bio-compatible materials has been shown to alleviate conditions now costing the health care system billions of dollars. (5,6)

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November 18, 2002

Dear Chairman Dan Burton, Representative Diane Watson, and Committee on Government Reform:

Re: Hearing on Mercury in Dental Amalgam
(for submission to Congressional record)

It's time to putting an end to placing mercury into our teeth. According to the EPA mercury is classified as a bioaccumulative toxic substance. OSHA has strict regulations about how the dentist is to handle it before placement and how he/she is to dispose of removed teeth containing it. Technology, the Jerome meter for example, now exists with which one can see the mercury vapor escaping into the mouth from the surface of the tooth. (I'm including a fact sheet about mercury) According to the EPA and the American Toxic Substance Disease Registry, mercury is among the top 3 toxic substances adversely affecting large numbers of people (Toxicological Profile of Mercury, 1999, by US Public Health Service).

My own experience of losing symptoms after removal of dental amalgam, beginning immediately after removal, is not unusual. The mixture of dissimilar metals creates a "battery effect", so when the parts of the "battery" are removed the horrible symptoms stop. In my case I changed

from	to
not being able to stand erect	standing erect
barely able to walk	walking/running without any difficulty
frequent earaches	no earaches
burning sensations over my body	rarely have small areas of burning

to name the symptoms I most vividly recall.

Mercury poisoning occurred to me because as part of periodontal(gums) treatment corroded mercury fillings were drilled out and replaced with new mercury fillings. Some of my teeth got double/triple doses of mercury per tooth over the course of my life. Some of this was done at the Medical College of Virginia School of Dentistry between 1979-1984. Some more of the same was done between 1993 and 1995 by a dentist in private practice in Newport News. In 1997 paladium (an excellent conductor of electricity) was added in the form of a palate to hold a false tooth in place. Later when I approached the School of Dentistry with proof of mercury poisoning in my hand , many unexplained symptoms, and 16 amalgam fillings, I was told by 3 male faculty members that the test results were part of a "scam". My conventional internist (MD) here in Williamsburg, however, believed the

November 18, 2002

results indicated a serious problem. He had no comment to make about dental fillings.

I've been writing and contacting government officials for more than 2 years about this topic. MERCURY POISONING IS A HORRIBLE EXPERIENCE.. I'M VERY MUCH OPPOSED TO MY TAX MONEY BEING SPENT TO POISON THE POOR (MERCURY IS THE CHEAPEST FILLING) AND THEN TO MEDICATE THOSE WITH SYMPTOMS CAUSED BY THE POISON. The medical community for the most part is not testing to look for a buildup of any toxic metal in any patient's body. Yet the Center for Disease Control ranks toxic metals as the number one environmentalal health threat to children, and it's a high on the list for the elderly. I have collected hundreds of signatures of concerned citizens about this issue (and copied and mailed them to politicians). Mercury poisoning of patients and dentists is avoidable if we face up to the truth of how it is happening.

Sincerely,
Linda Cifelli, RN

re: BURTON COMMITTEE HEARINGS: November 14!

Dear Congressman Burton, As a concerned citizen I wish to thank you for your courage in chairing hearings on the subject of mercury amalgam fillings. I have taken the time to read the literature (about 5 pounds of it!), and find the evidence compelling that mercury is extremely dangerous and not something that we should put in the mouths of our citizens. It is obviously also dangerous to the dentists and dental technicians who are handling it. And it doesn't help our rivers or streams either! Brain damage, liver damage, immune problems, skin problems, in short, all kinds of medical difficulties. The advanced countries of Europe have made its use largely illegal. Only in America is a major dental organization fighting tooth and nail to continue its use, pressuring our government to allow its use, pressuring its members to be quiet on threat of being sued or deprived of their licenses to practice, and stacking the FDA with individuals promising to vote the party line for its use.
Thank God for your efforts in this important scientific arena, and may justice prevail. Sincerely Yours, Fred Levin, M.D.

I am a fellow of the International Academy of Oral Medicine and Toxicology (IAOMT) and past chair of its Environmental Committee. I have worked with, lectured on, and published research on the environmental effects of dental amalgam mercury. I have received several local environmental awards for these efforts. I would like to add comment to the informative testimony provided to you on November 14. I commend the committee for its openness and eagerness to fairly investigate this issue.

A few comments on the environmental issue. The spokesman for the ADA would have us believe that amalgam and mercury are two completely different issues when it comes to the mouth as well as the environment. Yes, one can say they are two different substances, but that does not negate the problem. To say that mercury does not separate from amalgam sludge in the environment is ludicrous and has already been disproven. One very clear piece of evidence follows, but first let's remember that a significant number of wastewater treatment plants across the country send their biosolids to be **incinerated**. At such incineration temperatures, virtually 100% of mercury contained in amalgam sludge will be volatalized and sent into the atmosphere as mercury vapor. Nobody with any science background at all will argue with that.

What about biosolids that are not incinerated? One study, published in the peer-reviewed *Archives of Environmental Health* (and authored, coincidentally, by myself) should lay this question to rest. A reprint of this study was sent to your staff member, John Rowe. I'd like to briefly describe one of the implications of this study. It looked at air discharged into the environment by dental offices from their vacuum pumps. *It is laden with mercury vapor.* Please bear with me a moment to understand the point. The suction tips operated by the dental assistant while procedures are underway draw up water, air, saliva, amalgam sludge, etc. from the patients' mouths. This material travels through the office plumbing to the central vacuum pump. Here, air is separated and vented to the outside while the liquid/solid material is discharged into the wastewater. This is the wastewater sludge that had been discussed as containing significant amounts of mercury.

The air that is discharged to the outside has simply been passing over this sludge in the dental office plumbing. If mercury vapor can be found in this air, then this amalgam sludge is obviously **volatalizing mercury.** The study showed a high concentration of mercury vapor in this air. The sludge in the office plumbing **is the same as the sludge discharged into the wastewater** that enters the treatment plant. In this study, no artificial heat, enzymes, agitation or anything was applied. There was simply air drawn over this sludge. Enough mercury vapor was detected that would extrapolate to about a ton of mercury vapor discharged into the atmosphere annually by the collective dental offices in the United States.

Waste amalgam sludge releases mercury. Period. Case closed. **Of course** dental offices should install mercury separators to keep this sludge out of the wastewater. I would respectfully submit that the air discharge system of dental offices should also be looked into.

Thank you for considering my remarks.

Sincerely,
Paul G. Rubin, DDS, FIAOMT

12/16/2002

I spend a majority of my time dealing with patients that are dealing with compromised immune systems primarily from Amalgam restorations. Many countries have a ban or limited use of amalgam, why not the United States? How can we justify placing this material in underpriviledged citazens and then paying for the neurological and immunological problems it causes later in their free health care?
I educate my patients about how it is not legal to buy Mercury thermometers. How other countries have reduced vaccine useage with mercury as the stabilizing agent and removed amalgams as the material of choice to repair teeth. We pride ourselves as being in the lead of healthcare and yet we are so far behind in so many areas.
My son has neurological damage both from heavy metals used in vaccines and from dental work. This is how I became an enlightened practitioner.
I have gotten my patients very interested in politics and convinced them that their vote does matter. Make the right choice and listen to the scientific information on amalgam fillings which will speak for itself.

Dr Dawn Ewing

Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform,

Studies Document that amalgam dental fillings are the largest source of both inorganic and organic mercury in most people.Peer-reviewed medical studies and thousands of clinical tests by Medical Labs have documented that:

1. The daily mercury exposure(measured in saliva and feces) for those with amalgam dental fillings is on average more than 10 times higher than those without amalgam fillings.

2. Amalgam is the largest source of mercury exposure in most people- both for inorganic and organic mercury.

3. Millions of people in the U.S. have dangerous levels of mercury exposure and millions of women of child bearing age have levels high enough to make birth defects and developmental disorders in infants likely.

Documentation:

The reference average level of mercury in feces(dry weight) for those tested at Doctors Data Lab with amalgam fillings is .26 mg/kg, compared to the reference average level for those without amalgam fillings of .02 mg/kg(10). (13 times that of the population w/o amalgam). A Swedish lab that does fecal tests for mercury had similar results(10). Government and Scientific panels have confirmed amalgam is the number one source of mercury in most people and affects millions(22,26).In a large study of a group with amalgams, a group without amalgams, and a group that had undergone amalgam replacement- using saliva mercury measurements, it was concluded that amalgam is the main source of organic mercury in most people. Those with amalgams on average had more than 4 times as much organic mercury as either group without amalgam. Those with amalgam had over 10 times the total mercury as those without(11). And mercury from fish was controlled for in the study and not a factor in these results. Mercury vapor and inorganic mercury are well documented to be methylated to methyl mercury in the mouth and intestines by bacteria,

yeast, and other methyl donors.

The saliva mercury level for those with several amalgam fillings(8 or more) was more than 10 times the level of those without amalgam fillings. 10 % of those with amalgam fillings had unstimulated mercury saliva levels of over 100 ug/L. Mercury level was proportional to the number of fillings(12,11). Three studies that looked at a population with more than 12 fillings found generally higher levels than this study, with average mercury level in unstimulated saliva of 29 ug/L [33 ug/d](13), 32.7 ug/L

[37 ug/d] (14), and 75 ug/day(15). The saliva and feces of children with amalgams have approximately 10 times the level of mercury as children without (10,16,17,26),

and much higher levels in saliva after chewing.Mercury levels in saliva and feces usually decline after amalgam replacement between 80 to 95% (10,11,18-20,26). The studies document that **amalgam is the number one source of both inorganic and organic mercury in most people**. It has been documented that inorganic mercury is methylated to methyl mercury in the mouth and intestines by bacteria, yeast, and other methyl donors(21).

Because of the extreme toxicity of mercury, the U.S. EPA drinking water standard for mercury is 2 parts per billion, which allows for not over 4 micrograms per day mercury exposure for an average adult. The U.S.EPA mercury health guideline for elemental mercury exposure(vapor) is 0.3 micrograms per cubic meter of air(0.3 ug/M3). For the average adult breathing 20 M3 of air per day, this amounts to an exposure of 6 micrograms(ug) per day. The U.S. Department of Health, Agency for Toxic Substances and Disease Registry (ASTDR) standard (MRL) -for acute inhalation exposure to mercury vapor is 0.2 micrograms Hg/M3, which translates to approx. 4 ug/day for the average adult(26).

The main reasons for the high exposure levels from mercury are the high volatility of mercury(which is vaporizing constantly at room temperature) and the galvanic currents in the mouth generated by mixed metals in an electrolyte(saliva)

(27). Metal crowns are usually placed over amalgam base which gives even more galvanic currents and mercury exposure than amalgam fillings. This is warned against by the largest amalgam manufacturer and many Government health agencies, along with other common practices regarding amalgam by dentists in the U.S. (26) Several states now require warnings to patients by dentists about the toxicity of mercury.

Studies that the Government Health Standards were based on have found adverse health effects at very low levels(22,23,26) and developmental effects on infants and children at very low levels of exposure(23,24,), along with finding that mercury vapor from a mother's fillings is readily transferred through the mother''s blood across the placenta to a fetus and also through mother's milk(24,FS 8,22) and commonly causes developmental effects(24,23).

DAMS is currently working with thousands of people in the U.S. dealing with serious health effects caused by exposure to mercury from amalgam and urges

everyone to find out more about this major problem and to get involved in resolving these health safety issues. DAMS can provide information and help to anyone who is interested or who thinks they might have health problems related to their amalgam fillings. (www.amalgam.org)

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Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

THE ENVIRONMENTAL EFFECTS OF AMALGAM FILLINGS AFFECT EVERYONE

THE FOLLOWING FINDINGS ARE DOCUMENTED IN THIS Review Paper:

1. Human excretion into sewers by those with amalgam dental fillings along with dental office amalgam waste have been documented to be the largest source of mercury into sewers.

2. All sewer plants in the U.S. have high levels of mercury(over 1000 times the EPA drinking water standard) and all sewer sludge has dangerous levels of mercury(much above the EPA/FDA action level for mercury in food).

3. Dental amalgam fillings are a major source of mercury going into rivers, lakes, and bays, both from dental offices and human wastes in home and office sewers. Dentistry is the third largest use of mercury in the U.S. using

45 tons per year most of which ends up in the environment.

4. Mercury pollution is widespread in U.S. rivers, lakes, and bays; with dangerous amounts of mercury commonly found in freshwater and saltwater fish. Over 50% of Florida's rivers and lakes have warnings regarding eating the fish and most bays. Over 20% of all U.S. lakes have fish consumption warnings and 10% of all U.S. river miles. Most Gulf Coast salt water predator fish species have high levels of mercury(above EPA/FDA warning level)

5. Mercury is the most toxic substance commonly encountered, and is adversely

affecting the health of millions of people in the U.S.

6. If sewer sludge is incinerated, most of the mercury goes into emissions.

7. Crops grown on land using sewer sludge pick up high levels of mercury.

Soil bacteria in landfills and land spread sludge areas methylate mercury to methyl mercury, which is released in methane and landfill gas in high levels.

High levels of mercury are being found in rain all over the U.S.

8. Dental Amalgam fillings are the number one source of mercury in most people and levels of mercury exposure from amalgam commonly exceeds Government Health Guidelines, with high levels in human excretion wastes documented.

9. The level of mercury in all sewer plants in the U.S. exceeds the U.S. Environmental Protection Agency(EPA's) proposed mercury limit for mercury in water due to the large amount from amalgam in sewers from dental offices, homes, and businesses.

10. Crematoria emissions commonly violate mercury air emission standards and constitute a significant source of mercury emissions due to mercury in amalgam fillings.

11. Due to the high mercury releases from dental offices, most European countries require amalgam separators in dental offices but the U.S. still has no regulations on this source of mercury. Due to the major environmental effects of mercury from amalgam fillings, plus the additional known adverse health effects, most Japanese Dental Schools no longer teach the use of mercury amalgam fillings and several other countries have voted to ban amalgam use or issued warnings regarding its use, as have several U.S. states.

Documentation:

Mercury is one of the most toxic substances commonly encountered, and according to Government agencies causes adverse health effects in large numbers of people in the U.S.[1,20] The extreme toxicity of mercury can be seen from documented effects on wildlife by very low levels of mercury exposure. The amount of mercury in the marine environment is increasing 4.8% per year, doubling every 16 years(16). Some Florida panthers that eat birds and animals that eat fish containing very low levels of mercury(about 1 part per million) have died from chronic mercury poisoning(17). Since mercury is an estrogenic chemical and reproductive toxin, the majority of the rest cannot reproduce. The average male Florida panther has higher estrogen levels than females, due to the estrogenic properties of mercury(17).Similar is true of some other animals at the top of the food chain like polar bears, beluga whales, and alligators, which are affected by mercury and other hormone disrupting chemicals. Mercury in whalemeat has been found to be high enough to cause acute toxicity from one meal. Several liver samples contained over 1000 ppm mercury, over 2000 times the Japanese health standard. Muscle samples contained 2.5 to 25 times the health standard (25). The Japanese government's limit for mercury contamination, 0.4 micrograms per gram(25).

The average amalgam filling has more than ½ gram of mercury, and has been documented to continuously leak mercury into the body of those with amalgam fillings due to the low mercury vapor pressure and galvanic current induced by mixed metals in the mouth(20). Amalgam has been well documented to be the number one source of mercury in most people(19,20) and to commonly cause serious adverse health effects(20). Amalgam has also been documented to be the largest source of methyl mercury in most people, since mercury vapor and inorganic mercury have been shown to be methylated to methyl mercury in the mouth and intestines by bacteria, yeasts and other methyl donors(20).

Because of the extreme toxicity of mercury, only ½ gram is required to contaminate the ecosystem and fish of a 10 acre lake to the extent that a health warning would be issued by the government to not eat the fish[2]. Over half the rivers and lakes along with most bays in Florida have such health warnings(3) banning or limiting eating of fish, and most other states and 4 Canadian provinces have similar health warnings(16,29). Wisconsin has fish consumption warnings for over 250 lakes and rivers(13) and Minnesota even more, as part of the total of over 50,000 such lakes with warnings(16)(over 20% of all significant U.S. lakes) and 7% of all U.S. river miles. All Great Lakes as well as many coastal bays and estuaries and large numbers of salt water fish carry similar health warnings.

Nationwide the dental industry is the third largest user of mercury, using over 45 tons of mercury per year(26), and most of this mercury eventually ends up in the environment. Amalgam from dental offices is by far the largest contributor of mercury into sewers and sewer plants(4,13b,14,26), with mercury from replaced amalgam fillings and crown bases the largest source. As much as 10% of prepared new amalgam becomes waste. This mercury also accumulates in building sewer pipes and septic tanks or drain fields where used, creating toxic liabilities. Unlike most European countries and Canada which have much more stringent regulation of mercury that requires amalgam separators in dental offices(26,28,22), the U.S. does not and most dental offices do not have them. The discharge into sewers at a dental office per dentist using amalgam without amalgam separators is between 270 and 570 milligrams per day(4,26). For the U.S. with approximately 170,000 dentists working with amalgam(26), this would be approximately 16,000 kg/yr (or slightly over 16 tons/year of mercury into sewers and thus into streams, lakes, bays,

and sewer sludge. In Canada the annual amount discharged is about 2 tons per year(28), with portions ending up in waters/fish, some in landfills and cropland, and in air emissions. The recently enacted regulations on dental office waste are expected to reduce emissions by at least 63% by 2005, compared to 2000(28).

A study in Michigan estimated that dental mercury is responsible for approximately 14 % of mercury discharged to streams(5). An EPA study(13) found that dental office waste were responsible for similar levels of mercury in lakes, bays, and streams in other areas throughout the U.S. A Canadian study found similar levels of mercury contribution from dental offices into lakes and streams, and surveys of dental office disposal practices found the majority violated disposal regulations, and dangerous levels of mercury are accumulating in pipes and septic tanks from many offices (14,21,26).

The total discharge into sewers from dental amalgam at individual homes and businesses

is almost as large as that from dental offices, since the average person with amalgam fillings excretes in body waste approx. 100 micrograms per day of mercury(6,7,8,20). This has also been confirmed by medical labs(13c), such as Doctors Data Lab in Chicago and Biospectron in Sweden, which do thousands of stool tests per year and is consistent with studies measuring levels in residental sewers by municipalities(13b). In the U.S. this would amount to approximately 7300 kilograms per year into sewers or over 8 tons per year. Thus the amount of mercury being excreted from dental amalgam is more than enough to cause dangerous levels of mercury in fish in most U.S. streams into which sewers empty. Studies by Oak Ridge National Laboratory(U.S. Dept. of Energy) and other studies have confirmed high levels of mercury in sewers and sewer sludge(22,23). According to an EPA study the majority of U.S. sewerage plants cannot meet the new EPA guideline for mercury discharge into waterways that was designed to prevent bioaccumulation in fish and wildlife due to household sewer mercury levels(15,13). Over 3 tons of mercury flows into the Chesapeake Bay annually from sewer plants, with numerous resulting fish consumption advisories for that area and similar for other areas(16). The EPA discharge rule had been reduced due to a National Academy of Sciences report of July 2000 that found that even small levels of mercury in fish result in unacceptable risks of birth defects and developmental effects in infants(18).

ORNL studies have found that crops grown on land using land spread sewer sludge pick up high levels of mercury, and soil bacteria methylate inorganic mercury into methyl mercury, which is released into the air or landfill gas at high levels(22,23). Sixty percent of the 5.6 million tons of sewage sludge generated each year are used for land application(27). Most dental amalgam waste from dental offices either goes into landfills or is incinerated(26). Much of the sewer sludge is also incinerated. Most of the mercury in materials that are incinerated goes out in the emissions, as the incinerators have no controls to remove mercury. High levels of mercury including the very toxic organic forms are being measured in rainfall throughout the U.S.(24). High levels of the extremely toxic dimethyl and methylmercury forms of mercury are being found in landfill gas coming from landfills and appear to be a source of some of this(22,24). Bacteria in landfills have been found to be methylating elemental and inorganic mercury to the organic forms. Dental amalgam waste and mercury from human sewer sludge are major sources of mercury in some landfills and sludge is also used in landspreading on farms and other areas. Health Canada has also documented similar information on mercury emissions from amalgam and sewer sludge to waterways, crops, and air(28,29).

Additionally cremation of those with amalgam fillings adds to air emissions and deposition onto land and lakes. A study in Switzerland found that in that small country, cremation released over 65 kilograms of mercury per year as emissions, often exceeding site air mercury standards(9), while another Swiss study found mercury levels during cremation of a person with amalgam fillings as high as 200 micrograms per cubic meter(considerably higher than U.S. mercury standards). The amount of mercury in the mouth of a person with fillings was on average 2.5 grams, enough to contaminate 5 ten acre lakes to the extent there would be dangerous levels in fish(2,20). A Japanese study estimated mercury emissions from a small crematorium there as 26 grams per day(10). A study in Sweden found significant occupational and environmental exposures at crematoria, and since the requirement to install selenium filters mercury emission levels in crematoria have been reduced 85%(11). For the 70% of people in Britain who die and end up with their bodies being cremated, the mercury escapes into the atmosphere and contaminates waterways, soil, wildlife and food. Crematoria now contribute 11% of all the mercury released by industry and power plants in Britain. The 440,000 people cremated in Britain every year are estimated to discharge 1300kg of mercury(12) A study of assessing hair mercury in a group of staff at some of the 238 British crematoriums found that the groups hair mercury were significantly greater than that of controls(12).

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All backup technical papers with references available free on the web page

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Available Fact Sheets from DAMS with medical study references include:

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Effects of Mercury on Infants (over 140 medical study references, most from NIH Medline)

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8. Common Exposure Levels from Amalgam Fillings and the Mechinism by which mercury causes over 30 chronic health conditions including autoimmune conditions.

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To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform, regarding the November 14, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science. [web outline: http://www.house.gov/reform/pr.02.11.13.htm]

1. Outlaw Dental Mercury.

2. Disband the American Dental Association.

Please enter my remarks about the dangers of mercury in dental amalgam, and my request to Disband the American Dental Association. I am a health care professional who helped many people in their struggles with health conditions related to mercury. All of them had dental fillings, and all problems dated after amalgam mercury fillings were placed.

Some of the people I have encountered over my years in health care, including those seen by other practitioners [dental, medical, naturopathic, chiropractic, acupuncture], were severely ill and several died of complications due to debilitation from mercury according to our clinical judgement.

I have seen major improvement in several patients who had their dental mercury removed and replaced with non-metal materials. Because this letter is in accord with the expected content of other Dental Amalgam Mercury Syndrome group members' letters, I will not attempt to recreate the list of the many concerns we have shared with each other over the years. Research is needed, money needs to be spent on this, but the ADA does not do this and then complains there is not research. We practitioners are left with minimal research and are doing the best we can with the limited freedom allowed us to help the suffering public.

I hope someone will read this email and attached document from dental professional literature. The attached document is basic proof of the extreme maltreatment the American public has suffered from the American Dental Association.

The ADA has systematically ignored and occasionally destroyed scientific evidence of the dangers of mercury in dentistry. I personally visited the excellent clinic that Dr. Hal Huggins (DDS, MS) set up in Colorado Springs to remove mercury in a safe way, and to help people rebuild their bodies that had been so brutally affected by mercury; he was attacked in dastardly fashion and his practice closed and he now practices in another country; he has proof of documents in the ADA library being destroyed; his own research that showed nerve breakdown in the brain fluids appearing after mercury fillings were placed was desecrated and shut down but not before he captured the data of mercury's damage to brain structure. Dr. Huggins spoke of damaging research literature he found in the ADA library that mysteriously later disappeared. In the last decades powerful scientific evidence of mercury's destruction of nerve tissue and other correlations with health problems has continued to!

12/16/2002

accrue.

The attached document was published in 1883. It shows scientific studies revealing death of test animals after exposure to mercury dental fillings. This research was published over a century ago, but the ADA ignores it when it says there has been no research showing dental mercury is deadly. [This is found on the internet at: http://www.web-light.nl/AMALGAM/EN/SCIENCE/amin1883.html]

I and many of the public feel that there is no sincere protection of the public by the ADA from mercury (and other conditions not related to this hearing on mercury), and that this hearing is being seriously underattended and ignored.

I submit this letter to:

1) support the outlawing of dental mercury, and,

2) request that the ADA, American Dental Association, be disbanded and a new association allowed to form composed of dentists and medical researchers who honestly look at the danger the ADA poses to health due to their approval of dental mercury.

I will close now while I can remain moderately civil toward these underhanded, untrustworthy self-interested trade guild manipulators--the ADA. Please outlaw dental mercury, and consider disbanding the ADA.

Ralph Wilson, N.D.

"Injurious effects of mercury as used in dentistry".

Talbot ES. MISSOURI DENT J, 15:124-30 (March, 1883).
[on the internet at: http://www.web-light.nl/AMALGAM/EN/SCIENCE/amin1883.html]

The subject of mercurial poisoning from the use of amalgam fillings in decayed teeth, has given rise to numberless articles, and has been a source of discussion in dental societies since its introduction into this country. Symptoms of mercurial poisoning have manifested themselves in cases where these amalgams have been employed, causing the scientific members of the profession to investigate these fillings, to determine if these symptoms are due to the mercury contained in its composition. Nor is this investigation confined to men of science; the ordinary practitioner is constantly meeting these symptoms, and by careful observation will be able to diagnose these cases when met with. I will mention two cases which have come under my notice.

January 18, 1878, Mrs. W_____, 29 years of age, had several amalgam fillings inserted by me. At that time, and for the three succeeding years, she was under a physician's treatment for antroversion of the uterus, when she was dismissed by him as cured. During this time she consulted me at intervals in regard to her teeth. For a year past she has complained of trembling at times, coldness, headache, swelling of the limbs, enlargement of the glands, and pain about the jaws, tongue swollen and sore, teeth loose and tender upon pressure, marked salivation, and a metallic taste in the mouth; appetite poor, and bowels irregular; symptoms gradually increasing until six weeks ago when she was completely prostrated, and confined to her bed part of the time. Wishing to obtain the opinion of others, I consulted three able physicians, all of whom pronounced it a case of mercurial poisoning. Four weeks ago I removed all the amalgam fillings at one sitting, and replaced them with gutta percha. A slight improvement was noticeable within a week, and a few of the symptoms disappeared. I have refilled some of the teeth with gold, hand pressure being required on account of the soreness. The metallic taste had disappeared, the tongue is normal in size, and where before she was irritable and nervous, she is now bright and cheerful, and gaining steadily in weight.

Miss M_____, a nurse, 40 years old, came to me at the suggestion of her physician, to have her teeth attended to. Soon after her recovery from diphtheric paralysis of the throat, she had a tooth filled with amalgam. She experienced a disagreeable sensation and some pain immediately after the operation. She suffered greatly from the tooth, and had an excessive flow of saliva. Her taste was impaired, and she felt a paralyzed sensation of the muscles upon that side of the mouth. In nine days she had the tooth extracted. The saliva gradually ceased flowing, but at the time of her visit to my office, four weeks after her tooth was extracted, she had not entirely recovered the normal condition of the muscles. Generally, the poisonous effects of amalgam filling do not manifest themselves immediately after the filling is inserted. Years may elapse before the symptoms indicative of mercurial poisoning, which fact but adds to the danger of this sort of stopping for the teeth. The suspicions are not aroused to the real cause of ailments, until the system becomes saturated. Occasionally other causes undermine the system, and place persons in a condition susceptible to its toxic influences.

I found the general opinion of writers on this subject to be, on the one hand, that when mercury and alloys formed a chemical union, and the hardening process took place, the mercury could not detach itself from the other metals. On the other hand, that a chemical laboratory must be set up in the mouth, and the mercury converted into some of the toxic compounds, to produce systemic effects. All experiments hitherto, so far as I know, have sought for the results by supposing that the acids of the mouth acted upon the mercury of the amalgam. These experiments were made largely, if not wholly, from a chemical standpoint, and the results in all cases were wholly insufficient to explain the cause of mercurial poisoning. These experiments were conducted out of the mouth with the different acids at all strengths and at all temperatures without finding any traces of mercury with their reagents. Other results could hardly be expected when we consider that nitric acid affects mercury only at 60 degrees Far., sulphuric acid only when heated, and hydrochloric acid has no effect upon it. Knowing that mercury gives off vapors at all temperatures, which are increased by the action of the heat, I commenced a series of experiments to ascertain to what extent this change takes place in amalgam fillings, and if it is possible for the vapor of mercury to be liberated after the chemical change or hardening process has occurred.

In conducting these experiments, I prepared the ammonio-nitrate of silver, as that is a delicate reagent, and with it wrote upon white paper. After putting the amalgam to be tested in a bottle, the strip of paper was placed across the mouth of the bottle and the stopper cemented. Should a mercurial vapor arise, the letters on the paper would become black. Leaving the bottle for ten minutes I examined it again, and found the writing in plain black coloring.

This is one of the many experiments similarly conducted, the amalgams varying in age from six months to sixteen years, and immersed in both saliva and water, with a water bath attached to keep them at the normal temperature of the body. They were performed in the dark, as the rays of light decompose the ammonio-nitrate of silver. In each instance, the vapor of mercury responded to the test. To make sure that the amalgams caused the chemical test, an empty bottle was subjected to the same tests, with, of course, no results. The rapidity with which the evaporization of mercury takes place depende upon three factors, namely: the temperature, the area of exposed surface, and the amount of discoloration upon the filling, and not upon the quantity of mercury contained in the fillings.

The vapor is given off proportionately with the increase in temperature, the heat of the body being greater than the average atmospheric temperature; the vapor which exudes from a filling in the mouth, exceeds that from a like quantity of mercury exposed in the open air. Amalgams are generally inserted where large fillings and difficult operations are required; consequently the amount of exposed surface is great, and yields vapor abundantly.

The manufacturers are endeavoring to place upon the market amalgams which will not discolor in the mouth. Do they consider the disasters they are encouraging? The bright surfaces are favorable to vaporization, and Dr. Watt, who has considered this subject thoughtfully, says: "The worst cases of poisoning we have witnessed are those in which the amalgams retain their original bright color".

Dr. Bartholow in his work on THERAPEUTICS says: "As used in the mechanical arts by gilders and others, the fumes of mercury cause wasting, ptyalism, necrosis of bones, trembling, impaired intellect, and, in women, abortion".

Professor Haines while journeying on the Pacific coast this spring, visited the mercurial mines, and found, in consulting the resident physician, that few of the workmen escaped salivation, and those connected with the distilling process were obliged to protect the lungs by wearing a shield over the mouth and nose. The foreman of the works, while passing a leaking pipe, inhaled the vapor of mercury, and became so impregnated that he was for a time delirious. The doctor was puzzled that some of the miners, in digging the sulphide of mercury, were salivated, and others were not affected. Upon investigation he discovered that the smokers were the men who were affected by the poison; that in rubbing the tobacco in their hands they mixed the particles of the ore with the tobacco, and the heat in burning reduced the ore to pure mercury, which was drawn through the stem into the lungs. They ceased smoking in the mines, and were not affected after. Parish says that long trituration of calomel increases its power to salivate. This is applicable to all preparations of mercury used with an excipient medicinally. The homoeopaths rub up pure mercury with the sugar of milk into different grades, and these are the finest forms in which mercury is prescribed, and yet the severest cases of salivation and constitutional symptoms have been produced by these agents on account of their being so readily taken up by the blood. Is it not a reasonable supposition that, as the poisonous symptoms are produced in proportion with the subdivision of the particles of mercury, that the system will be more seriously affected by the vapor of mercury, which is finer than any mechanical subdivision can be. In order to ascertain the effects of the vapor of mercury, I have employed it in a series of experiments upon plants and animals.

I prepared three two-ounce bottles. The first contained ten grains of pure mercury; the second, an amalgam filling three months old; the third was an empty bottle. In each of the bottles I put two roaches, and then covered the mouths of the bottles with gauze. In two days the one in bottle with pure mercury died, the remaining one lived nine days. In bottle containing amalgam filling one roach lived four days, while the other lived eleven days. Those in the empty bottle lived fifteen and sixteen days. The numerous experiments of this sort proved that the roaches in the bottles containing amalgams invariably died before those in the empty bottles.

Among experiments upon animals was one upon a guinea pig placed on a gauze platform in a glass jar over pure mercury. He presented all the symptoms of mercurial poisoning. He became emaciated and trembling, the body and limbs were cold. He lingered along for two weeks, and died. It is the opinion of many eminent scientists that mercury inhaled into the lungs produces a more heightened effect than when taken into the stomach. Among this number Professor Stille in his THERAPEUTICS (Vol. II, page 789), says: "Of the several modes by which mercury is made to enter the body, inhalation most speedily produces the specific influence of the medicine, -which theory confirms the belief that the vaporization of mercury from amalgam fillings, occurring as it does constantly, and being carried into the lungs without cessation, is a most effective manner of producing mercurial poisoning. All persons are not equally affected by the vapor of mercury; while possible for some to inhale mercury without deleterious effects, others would express the most decided symptoms of mercurial poisoning with less quantity.

Colson states that in 1821-23 he, with several other interns and externs of the venereal wards of the Hospital de la Petite were salivated by the mercurial atmosphere, nor did they get rid of the affection while they continued to frequent these wards.

RESUME

FIRST. -Mercurial vapor is given off from amalgam fillings at all ages and from all varieties. Even from fillings sixteen years old the vaporization is sufficient in quantity to respond to chemical tests.

SECOND. -Minute doses of mercury, if taken internally three times a day, are capable of producing decided effect.

THIRD. -Mercury, when inhaled into the lungs, is far more active than when taken into the stomach.

FOURTH. -If small doses, taken into the stomach occasionally, are capable of producing marked effect, and the vapor is much more active than the solid preparation of the metal, is it not a necessary consequence that amalgam fillings, which, as I have proved, are constantly giving off mercury fumes to be inhaled into the lungs, not a few times daily, but always, without cessation day or night, is it not a necessary consequence that in many sensitive persons such fillings must produce deleterious effects?

FIFTH. -When tons of this material are consumed annually, is it not credible that many constitutions are affected?

SIXTH. -Physicians in treating dyspeptics, anaemics and persons suffering >from nervous debility, would do well to examine the mouths of patients, and know if artificial teeth on red rubber, or fillings of natural teeth, have in their composition mercury or any of its compounds.

Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

Mechanisms Documented by Which Mercury from Amalgam Dental Fillings and Vaccinations is a Cause or Major Factor in Over 30 Chronic Health Conditions

1. **Over 1500 peer-reviewed or Government studies have been compiled which document the mechanisms by which mercury from amalgam fillings is released in significant amounts and causes over 30 chronic health conditons.** (1,3)

2. **Over 60,000 clinical cases of recovery or significant improvement after amalgam replacement as followed and compiled by doctors have been documented. (1,3)**

The conditions for which mechanisms of causality were documented and for which recoveries were documented include:

(a) autoimmune problems such as arthritis, MS, Lou Gehrig's Disease(ALS), Parkinson's/ muscle tremor, Alzheimer's, muscular & joint pain /fibromyalgia, chron's disease, lupus, scleroderma, Chronic Fatigue Syndrome(CFS), endometriosis , diabetes (6,1)

(b) neurological and mood disorders including memory disorders, depression , schizophrenia , insomnia, anger, anxiety & mental confusion, neuropathy/paresthesia, tinnitus, dizziness/vertigo,

headaches/ migraines, epilepsy, ADD, dyslexia, learning disabilities, hearing loss, etc. (1,2,7)

© periodontal diseases such as gingivitis, oral lichen planus, amalgam tattoos, metal mouth, halitosis, oral keratosis(pre cancer); (1,4)

(d) immune system conditions such as allergies asthma, multiple chemical sensitivities, eczema, psoriasis, other skin conditions; cancer(breast,etc./ leukemia),susceptibility to infections, antibiotic resistant infection, sinus problems (1,6,7)

(e) cardiovascular conditions including tachycardia, angina, arteriosclerosis, other heart conditions, hypertension, and other blood conditions (1)

(f) hormonal problems such as hypothyroidism, adrenal problems, chronic chills, Hashimoto's Disease, alopecia/hair loss, urinary/ prostrate problems, (1,6)

(g) reproductive problems such as infertility, reduced sperm counts, PMS, spontaneous abortions, birth defects, children with learning disabilities and low IQ, etc. (1,2,3,7)

(h) chronic eye conditions: inflammation/iritis/ astigmatism/myopia /cataracts/macula degeneration , color blindedness, vision disturbances, etc. (1)

(i) stomach/digestive problems including leaky gut, malabsorption of essential minerals and essential fatty acids, blocked cellular enzymatic processes related to the ATPASE energy function and sulfur oxidation. (1,7)

There are extensive documented cases (many thousands) where removal of amalgam fillings led to cure or significant improvement of these serious health problems. Over 60,000 such clinical cases are compiled in the documentation as followed and compiled by doctors. The over 60,000 cases of cure or significant improvements were not isolated cases of cures; the clinical studies indicated a large majority of most such type cases treated showed significant improvement. (1,3)

Mercury's extreme cytotoxicity and neurotoxicity is a major factor in the neurological conditions, along with its inhibition of basic enzymatic cellular processes and effects on essential minerals and nutrients in cells. Mercury is also documented to cause imbalances in neurotransmitters related to mood disorders. A direct mechanism involving mercury's inhibition of cellular enzymatic processes by binding with the hydroxyl radical(SH) in amino acids appears to be a major part of the connection to allergic/immune reactive conditions such as autism, schizophrenia, lupus, eczema and psoriasis, scleroderma, and allergies. Immune reactivity to mercury has been documented by immune reactivity tests to be a major factor in many of the autoimmune conditions. (1,7,6)

The over 1500 peer reviewed studies mostly either Government studies or abstracted in the National Library of Medicine(www.nlm.nih.gov/) document that most people with several amalgam dental fillings get significant daily exposure to mercury that is the largest source of mercury exposure for most people and often above the Government health guideline for mercury. The reason for the high exposure levels from amalgam are mercury's high volatility that means it is constantly vaporizing, along with galvanic electric currents caused by mixed metals in the

mouth that drive mercury and other metals into the body. These are easily measured which has been widely documented. (1,4)

The studies also document that mercury from amalgam or other sources such as fish crosses a woman's placenta readily and accumulates to levels in the fetus at levels usually higher than in the mother. And that mercury in the mother is transferred at significant levels to a breast feeding infant. The fact that children have been exposed to levels of highly toxic mercury thimerosal in vaccinations well beyond Government health guidelines for mercury is also well documented. Studies document that such mercury exposures can cause developmental conditions and disorders such as autism, ADD, learning disabilities, etc. (2,7)

The studies also document that due to the high daily exposure from amalgam people excrete high amounts of mercury into home and office sewers which cause levels in sewer plants to be high enough to contaminate with mercury most of the water bodies they empty into, to the extent that fish and wildlife are contaminated with dangerous levels of mercury. Over 20% of the lakes, all Great lakes, 7% of U.S. river miles, and many bays are contaminated to the extent warnings have been issued to not eat the fish. Amalgam is documented to be a major source of mercury in many water bodies. (5)

References

(1) B. Windham(Ed.), Review of exposure level and health effects due to mercury from amalgam dental fillings, 2001; over 1500 peer-reviewed studies referenced;

www.home.earthlink.net/~berniew1/amalg6.html

(2) Developmental Effects of Mercury on Infants. www.home.earthlink.net/~berniew1/fetaln.html

(3) Common Exposure Levels and Adverse Health Effects from Amalgam Fillings, and

60,000 clinical cases of amalgam replacement followed by doctors

www.home.earthlink.net/~berniew1/indexa.html (over 1000 Peer Reviewed studies)

(4) Oral Galvanism: the Battery in Our Mouth, www.home.earthlink.net/~berniew1/galv.html

(5) DAMS, The Environmental Effects of Amalgam Affect Everyone;

www.home.earthlink.net/~berniew1/damspr2f.html

(6) Lou Gehrig's Disease(ALS), MS, Chronic Fatigue Syndrome(CFS), Fibromyalgia, Lupus, Parkinson's, and Alzheimers Disease: the Mercury Connection, www.home.earthlink.net/~berniew1/indexa.html

(7) Autism, ADD, and Pervasive Developmental Disorders: the Mercury Connection,

www.home.earthlink.net/~berniew1/indexk.html (over 100 PR studies)

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Health Effects to Dentists, Dental Assistants, and Dental Hygienists from Occupational Exposure to Mercury Vapor from Amalgam Fillings

DAMS has also compiled over 100 medical studies documenting the adverse health effects of dental office mercury exposure to dentists, dental assistants, and dental hygienists . **The studies reviewed found that:**

1. Dental office staff mercury exposure is comparable to exposure from more than 15 amalgam fillings and commonly more than the federal ATSDR/EPA health guideline (MRL) for mercury(1,2,3).

2. Dental staff exposure is proportionate to the number of amalgam fillings placed, removed, or polished- as well as the number of their own amalgam fillings(1,2,3).

3. Dental staff have significantly higher levels of mercury excretion than non-occupationally exposed controls(1,2).

4. Sensitization or development of allergic conditions such as dermatitis and systemic allergies is common among dental staff(1,2,8).

5. Dentists and dental staff commonly accumulate mercury body burden and develop

neurological conditions such as irritability, depression or mood disorders, memory deficits, headaches, neuropathies, motor function deficits, or tremors(1,2,9,10).

6. Dentists and dental workers have also been found to have higher levels of autoimmune or immune disorders, chronic fatigue, arthritis, myalgia or neuralgia (1,2,8,9)

7. Dentists and dental workers have been found to have higher levels of reproductive problems- including infertility, menstrual disorders, birth defects, spontaneous abortions, or children with lower than average IQ(1,2,5).

8. Some studies have found higher cancer rates, mood disorders, and higher suicide rates among dentists than in controls(1,2,8)

9. Patients and occupationally exposed workers who get their amalgam fillings replaced and avoid further exposure to mercury often recover from serious chronic systemic conditions(6,2).

10. Dental office waste and mercury in human wastes of those with amalgam fillings are a significant source of high mercury levels in sewers, waterways, fish, and wildlife. Over 7% of all U.S. river miles, 20% of all U.S. lakes, and many bays have warnings limiting fish consumption due to mercury accumulation(4,2).

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References

1. B. Windham(Ed.), **Health Effects to Dental Staff from Occupational Exposure to Mercury**

From Work with Amalgam Fillings, 2001 (over 75 medical study references)

www.home.earthlink.net/~berniew1/dental.html

2. Common Exposure Levels from Amalgam Fillings and the Mechanism by which mercury causes over 40 chronic health conditions including autoimmune conditions.

(Over 1000 medical study references, most from National Library of Medicine Medline)

www.home.earthlink.net/~berniew1/amalg6.html

3. DAMS Fact Sheet 1, Amalgam is the number one source of mercury in most people and

Exposures Commonly Exceed Government Health Guidelines for mercury, 2001.

www.home.earthlink.net/~berniew1/damspr1.html

4. DAMS Fact Sheet 2, The Environmental Effects of Amalgam Affect Everyone, 2001.

www/home.earthlink.net/~berniew1/damspr2s.html

5. Transfer of Mercury from Mother's Amalgams and Breast Milk to the Fetus and Developmental Effects of Mercury on Infants (over 140 medical study references, most from NIH Medline) www.home.earthlink.net/~berniew1/fetaln.html

6. Documentation of recovery from 60,000 clinical cases of serious adverse health effects after replacement of amalgam fillings as documented by doctors. . . www.home.earthlink.net/~berniew1

7. Effect of Mercury and Other Toxic Metal Exposure on Cognitive and Behavioral Problems of Children- including ADHD, dyslexia, juvenile delinquency, and crime (over 100 medical study references, most from Medline) www.home.earthlink.net/~berniew1/tmlbn.html

8. Autoimmune and Allergic Conditions: the connection to mercury immune reactivity and amalgam fillings (over 70 medical study references) .../~berniew1/indexa.html

9. DAMS Fact Sheet 3, Documentation of Mechanisms by which mercury/amalgam causes over 40 chronic health conditions, 2001. www.home.earthlink.net/~berniew1/damspr3.html

10. B. Windham, Mechanisms by which mercury/amalgam causes depression and mood disorders, 2001; www.home.earthlink.net/~berniew1/depress.html

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All backup technical papers with references available at www.home.earthlink.net/~berniew1

papers can be viewed or saved to your computer as html or txt file(file, save as, ...)

[abstracts or full copies of most references can be found at the National Library of Medicine

Medline at www.nlm.nih.gov/]

>
> Dear Chairman Dan Burton, Rep. Diane Watson and Members of the
> Committee on Government Reform,
>
>
>
> I am writing to go on record as one of the many people who have been
> poisoned by the mercury that was released from my dental amalgams.
>
> I had dental amalgams placed throughout the 35 years prior to becoming
> ill. At the age of 40, I started to develop vague neurological
> symptoms that soon progressed to symptoms of multiple sclerosis. I had
> been going to my family physician for almost a year and after a
> plethora of tests, he told me that all my problems were in my head. I
> did not believe that so I consulted with a nutritionist who sent me to
> see another doctor. He proceeded to ask me questions about my
> occupation and the possibility of mercury exposure. I am an
> electronics technician and had not been exposed to mercury at my job
> or any other source including diet. The test that he ordered was out
> of the ordinary. The protocol was for me to collect my urine for
> twenty-four hours then return to his office for an injection of DMPS.
> The DMPS was to draw out the mercury that had been stored in my
> tissues and dump it into my kidneys for excretion. The test results
> were as follows; pre DMPS was 3 mcg/L in a 24-hr period and post DMPS
> was 54 mcg/L. The reference range is 0-20 mcg/L. He also tested for
> nickel, lead, aluminum and arsenic. Nickel was 69.9 with a reference
> range of 1-5 and arsenic was at the top of the range with 24. Aluminum
> was within normal range. These levels were the highest that he had
> seen in a patient. My TSH level, that is thyroid stimulating hormone,
> had gone to 11.81 and the normal range is .35-5.50. Now I understood
> why my body was in a constant stated of being turned on. I had chronic
> insomnia.The mercury was interfering with my endocrine system. These
> tests proved that my mercury fillings where indeed poisoning my
> body. I found a dentist who knew the IAOMT protocol to remove my

> amalgams safely. The day after the last removal I went to the doctor's
> office for another DMPS push. It was to help clear some more mercury
> and also to see where my levels were. Test results were: pre DMPS was
> 5 mcg/L 24hrs and post being 8 mcg/L 24hrs. Arsenic had dropped to 11
> mcg/L 24hrs and nickel was not detected. Upon questioning my doctor
> as to where the arsenic came from, he said he suspected it was from
> the amalgam. Arsenic is used in metals to retard corrosion.
>
> Since removal, six years, I have been slowly progressing towards the
> health I once had.
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>
> Sincerely,
>
>
>
> David G Stahley
> digital@fast.net
> Member of DAMS
> www.amalgam.org
>
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>

Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Governement Reform.

I am deeply concerned about the hazards of mercury during fetal life, due to the transfer of mercury across the placenta. Let me illustrate this with a few cases.

Among about 415 female amalgam patients in my records, 49 women with altogether 123 children reported various disturbances in at least one child. Most of the mothers have heavy amalgam loads in their teeth. A few also, on the basis of their diaries, reported dental treatment with amalgam during or close before pregnancy. Some have given birth to healthy children during less exposed periods.

Intestinal disorders
Intestinal dysfunction in one or more children was reported by 18 mothers, manifested as diarrheas in 15 children, but sometimes as constipation (8 children) or colic (2 children). My first amalgam patient was a dental assistant, exposed for years to copper amalgam and with many amalgam restorations in her own teeth. Her eldest son had recurrent upper respiratory tract infections, and still at age 11 watery diarrhea every morning. He was given elemental sulfur about 50 mg t.i.d before meals and had normal stools within 3 days. His diarrhea relapsed when he skipped sulfur, but after a year he could stop. Sulfur binds mercury in the intestine, thereby breaking the all too efficient enterohepatic circulation of mercury.

Immunologic disturbances.
Eleven mothers reported that their children were prone to recurrent and long-lasting infections, just like the mothers themselves. A grown-up son of one dental assistant had scarlet fever thrice in one winter, something that was previously reported in children of mirror makers: "Die Kinder der Beleger wurden in grosser Zahl wiederholt von Masern und Scharlachepidemien heimgesucht" [Kussmaul 1861, p 211].

One woman had 5 healthy children and then 2 children with combination immune deficiences. Before her sixth pregnancy she had started chewing gum 6-7 hours a day, and during her seventh pregnancy she had had her amalgam removed.

One nurse with plenty amalgam and gold in one tooth had many symptoms typical of amalgam patients. Her son was diagnosed with multiple sclerosis at age 5. He had no amalgam. At age 14 his cerebrospinal fluid contained 3,8 μg Hg/liter.

One woman gave birth to three daughters who all died with nephrosis before the age of seven. Later she had a son.

Four women had children with strong reactions after vaccines containing merthiolate, an ethylmercuric sulfur salicylate. One boy had fever after triple vaccine and screamed

for three days. One boy given gammaglobulin with merthiolate had influensa-like symptoms for a week and markedly increased sleep dependence for another three weeks. Later, in military service, he was sick for several days after tetanus vaccine. One girl had severe reactions after triple vaccination at age one and after tetataus vaccine at age four (local abscess and facial eczema)

Eczema in children was reported by 10 women and asthma by three women.

One woman with 16 amalgam restorations and 4 gold crowns gave birth to three healthy kids. At age nine the youngest one got thrombocytopenia, half a year after placement of an amalgam restoration in a baby tooth. She was treated with cortison but recovered completely after dropping the amalgam-containing tooth.

Effects on the nervous system
In a letter to the Swedish Board of Health a woman expressed her suspicion concerning amalgam as a cause of anencephaly. Her diary revealed dental treatment on the the 14th, 19th and 21st days after conception, assuming that this occurred 14 days after day 1 of her latest menstruation . A large amalgam restoration in a molar had been replaced with a new one. One year earlier and two years later this woman gave birth to a healthy girl. Development of the brain occurs around the 20th day after conception.

One woman with heavy amalgam load and possibly dental work during pregnancy had a son with severe DAMP.
Four women had children with aggrressive tendencies
Several women had children with memory and concentration disturbances. Three women had children with hyperactivity.

Sensory organs.
One woman with exposure from her mother's and her own abundant amalgam had one healthy son, one daughter with asthma, and one daughter totally deaf. The woman had vertigo and tinnitus. During her third pregnancy she had spent much time in front of her computer.

Chromosomal aberrations
Two women had a child with Down's syndrome. One had dental work done 14 days before conception. The other was exposed to amalgam, root canal work and gold in her teeth. X-ray later showed three lead shots in her intestines, from eating elk meat.

One dental assistent with many amalgam fillings had a son with Fragile X syndrome.

Fredrik Berglund

References
Berglund f, Fredricsson B. Amalgam treatment during pregnancy is not without risk (in Swedish). Läkartidningen 1998;96:3918.

Kussmaul A. Untersuchungen über den constitutionellen Mercurialismus und sein Verhältnis zur constitutionelles Syphilis. Würzburg 1861.

I have tried to limit my statement to material that others may not cover and have omitted material I am sure will be well presented by others who testified or submitted statements for the record.

What medical textbooks say about mercury poisoning

While many discussions of science are obscured by long lists of journal citations without analysis, it is more useful to start by reading textbooks since these consist of the carefully analyzed and digested results from thousands and thousands of journal papers which have stood up to repeated testing and verification. Textbooks take a conservative position. Rational debate starts from "textbook science" and goes forward.

The most recent edition of *Harrison's textbook of internal medicine* states: "Low-level exposure from dental amalgams may also be associated with adverse immunologic reactions."

The 21st edition of *Cecil Textbook of Medicine* states: "Up to 10% of dental offices have excessive mercury vapor levels; and accidental spillage can lead to mercury poisoning."

"With mild exposure, the manifestations are likely to be subtle and diagnosis is difficult. Insomnia, nervousness, mild tremor, impaired judgment and coordination, decreased mental efficiency, emotional lability, headache, fatigue, loss of sexual drive, and depression are early manifestations and are often mistakenly ascribed to psychogenic causes."

"Because of the body's metabolism of mercury, blood and urine levels may be unreliable."

Blood and urine mercury levels are almost uniformly used as definitive criteria to exclude mercury poisoning in papers purporting to show that amalgam illness does not exist. When standard medical texts state this is an unreliable criterion, these papers can be dismissed out of hand as scientifically meaningless.

Also note a very important factor mentioned in Cecil. Under the present regulatory system, up to 10% of dentists and dental assistants are exposed to excessive amounts of mercury and may become intoxicated. They require protection from dental amalgam just as patients do.

Epidemiology is powerless to address the amalgam controversy

Epidemiological studies are often cited as "proof" that materials are safe, yet these studies are very poor methods of determining safety - which is why many drugs have recently been approved based on studies only to be recalled once adverse reactions started happening in the general population.

A simple example explains this. Let us say that we are going to conduct a study with 400 subjects, and exclude adverse reactions to the 95% confidence level. How much does this study tell us? If no adverse reactions are observed, we only know that they have less than 1 chance in 134 of happening. This is about 3/4 of a percent – a HUGE number in public health terms.

There has never been a safety study of amalgam of this sort to start with – and given the limitations of epidemiology the two studies currently under way (University of Washington/Lisbon and Massachusetts) do not have an adequate number of subjects to exclude adverse reactions to an acceptably low level even if they produce positive results. Because of the inadequate sample size in these studies it is inappropriate to await results before regulating – definitive results demonstrating safety could only be provided by studies not presently begun and such studies take about a decade to plan, organize, perform, analyze and report. The current studies combined can in theory only demonstrate that the adverse reaction rate is less than 0.37% (at the 95% confidence interval) which corresponds to saying that if less than three quarters of a million Americans become ill from their fillings – with many of the illnesses being permanently and totally disabling – that then amalgam fillings are safe enough to be used.

The Lisbon/U of Washington and Massachusetts studies of amalgam safety are deeply flawed in 2 ways. First, people in other than good health were excluded. A significant fraction of the population is not in good health, is generally at increased risk of adverse reaction from many medical products, and does routinely receive amalgam restorations. Any legitimate safety study must include such people. Secondly, these studies are in children who are not receiving the large numbers of restorations or other extensive dental work that adults accumulate over a lifetime. Their exposure levels are far below the average adult exposure level. Proper safety studies cannot be conducted at exposure levels substantially below those expected in clinical practice.

While the two present studies now under way might answer the question of "is amalgam dangerous" by finding adverse effects, they can not answer the question of "is amalgam safe enough for general use" due to their limited size. Thus these

studies are irrelevant both to the FDA's regulatory problem and to Congress' oversight role. Existing science must be used to answer the question of "is amalgam too dangerous to use?" Luckily the existing scientific literature does answer this question so further inquiry through future studies is not needed. See, for example, Hanson M, and Pleva J. (1991) The dental amalgam issue. A review. *Experientia* **47:** 9-22.

Mercury intake from amalgam fillings is high

The intake of mercury from amalgam fillings has been determined. It is the dominant source of mercury exposure for most people. Weiner JA, and Nylander M. (1995) An estimation of the uptake of mercury from amalgam fillings based on urinary excretion of mercury in Swedish subjects. *Sci. Total Env.* **168:** 255-265.

Routes of excretion have also been determined. These suggest that patients with impaired liver function are at great risk for building up excessive mercury levels, yet such patients are excluded from the relevant safety studies. Bjorkman L, Sandborg-Englund G, and Ekstand J. (1997) Mercury in saliva and feces after removal of amalgam fillings. *Toxicol. Appl. Pharmacol.* **144;** 156-62.

All sources of exposure for the "average person" have been enumerated, where the mercury goes in the body, and how it comes out have been laid out clearly by Skare I and Engqvist A. (1994) Human exposure to mercury and silver released from dental amalgam restorations. *Arch. Environ. Hlth.* **49;** 384-394.

A monte carlo simulation of the health effects of mercury showed that the number of amalgam fillings the "average person" could tolerate was lower than the number in many people's mouths (Richardson GM, and Allan M. (1996) A Monte Carlo Assessment of Mercury Exposure and Risks from Dental Amalgam. *Human and Ecological Risk Assessment*, **2:** (4) 709-761). This study assumed everyone was exposed to the same amount of mercury per filling with no account for individual variations in emission rate or metabolism, and no account taken of people with medical conditions that impair their excretion of mercury (e. g. gallstones).

These "average person" studies are not adequate to base public policy on. There is a log normal distribution of population exposure to mercury from amalgam, and some individuals have a very high exposure. Bårregard and Sallsten report on 3 individuals who have a demonstrated level of mercury exposure from their amalgams greater than the industrial exposure limit of 50 mcg/l (in urine). By comparison, the "average person" with an "average number" of fillings will excrete about 5 mcg/l. Two of these individuals have serious chronic health problems. Barregård L, Sällsten G, and Järvholm B. (1995) People with high mercury uptake from their own dental amalgam fillings. *Occ. Environ. Med.* **52:** 124-8.

Amalgam fillings are the major source of population exposure to mercury. Standard methods show that even at an "average" emission rate, the number of fillings per person should be limited to fewer than many people currently have. By definition, half of all people absorb MORE than the average amount of mercury from their fillings – some dramatically more – and these people are at substantial risk of morbidity from this mercury exposure.

Controlled trials demonstrate that amalgam mercury causes disease, and removing it cures disease

Stenman and Grans (Stenman S. and Grans L. (1997) Symptoms and differential diagnosis of patients fearing mercury toxicity from amalgam fillings. *Scand. J. Work. Environ. Hlth.* **23:** 59-63) clearly demonstrate that some people do in fact have mercury poisoning from their amalgam fillings. The authors gathering several hundred patients who believed they had it and evaluating them extensively in a hospital. Some patients did indeed have something else wrong. Of the patients who had no obvious diagnosis (other than amalgam illness), those who replaced their fillings were cured a year later, while none of those who kept their amalgam fillings were cured.

Two different dentists who removed amalgams from patients surveyed patients a year later and found great improvement. Control groups were also surveyed. See Engel P. (1998) Observations on health before and after amalgam removal (translated from original German) *Schweiz Monatsschefte für Zahnmedizin* **108** nr 8 as well as Lichtenberg H (1993) Elimination of symptoms by removal of dental amalgam from mercury poisoned patients, as compared with a control group of average patients. *J. Orthmol. Med.* **8** 145-148.

These 3 papers are compelling proof that amalgam causes health problems. While the health problems here were many and varied from the standpoint of physicians who were not willing to accept the diagnosis of mercury poisoning, it is commonly seen in practice that not only do such patients improve clinically, but their previously abnormal laboratory results normalize as well – mooting any discussion of psychogenic causes.

While some physicians complain that "amalgam illness" is not a simple clinical entity, some specific, well recognized, easily diagnosable diseases do appear to be caused by mercury poisoning from dental amalgam. For example, much evidence supported the involvement of mercury amalgam fillings in multiple sclerosis.

Fillings appear to cause multiple sclerosis (Siblerud, R. L. & Kienholz, E. (1994). Evidence that mercury from silver dental fillings may be an etiological factor in multiple sclerosis. *Sci. Tot. Env.*, 142, 191-205). Mercury from amalgam fillings appears to cause the hearing loss and nerve problems MS victims have (Siblerud, R. L. & Kienholz, E. (1993). Evidence that mercury from silver dental fillings

may be an etiological factor in reduced nerve conduction velocity in multiple sclerosis patients. *J. Orthmol. Med.*, 12, 169-72 and Siblerud, R. L. & Kienholz, E. (1997). Evidence that mercury from dental amalgam may cause hearing loss in multiple sclerosis patients. *J.. Orthmol. Med.*, 12, 240-244). Filling removal improves the health of multiple sclerosis patients (Siblerud, R. L. (1992). A comparison of health of multiple sclerosis patients with silver/mercury dental fillings and those with fillings removed. *Psychological Reports*, 70, 1139-1151). MS patients tested for biochemical markers of the disease before and after treatment showed a striking improvement following amalgam replacement (Huggins and Levy (1998), Cerebrospinal Fluid Protein Changes in Multiple Sclerosis After Dental Amalgam Removal, *Alt. Med. Rev.* **3**(4) 295-300).

Overwhelming scientific evidence demonstrates that mercury from dental amalgam fillings causes multiple sclerosis, and that removing the amalgam fillings improves it.

Research shows that amalgam mercury causes certain specific fatal illnesses

Mercury has been shown to be associated with various cardiovascular problems (Siblerud, R.L. (1990). The relationship between mercury from dental amalgam and the cardiovascular system. *Sci. Tot. Env.*. 99, 23-35, also Nakagawa, loc. cit. showed it associated with hypertension)

For one specific disease it was shown that mercury (and antimony) concentrations in heart muscle of patients with this condition were dramatically elevated compared to patients with other heart diseases (Frustaci *et al.* (1999) Marked elevation of myocardial trace elements in idiopathic dilated cardiomyopathy compared with secondary cardiac dysfunction, *J Am Coll Cardiol* **33**(6) 1578-83). Since this kind of research requires surgical biopsy of the heart it is not surprising it hasn't been done for many conditions.

Another condition where mercury was found to be dramatically elevated was in thyroid cancer (Zuichik V, Tsyb A and Vtyurin B (1994) Trace elements and thyroid cancer. *Analyst* **120:** 817-21). This research found vastly elevated levels of mercury in cancerous thyroid nodules removed at surgery but not in benign ones.

Research shows that mercury exposure levels much of the general population experience cause neurological and psychiatric impairment

Recent work by Echeverria and others shows that the neurobehavioral impact of mercury exposure on a cohort of dentists who were selected for having very low exposure is substantial and dose dependent. The most highly exposed dentists were substantially impaired cognitively and physically compared to the least

exposed. Not mentioned in that study is the fact that over 10% of the adult population has a mercury exposure from their dental amalgams greater than the highest exposure cohort in that study. It is not reasonable to assume that these members of the general population suffer no detrimental effects from their mercury exposure when substantial negative effects are observed in dentists with lower exposure levels. See Echeverria D, Aposhian HV, Woods JS, Heyer NJ, Aposhian MM, Bittner AC Jr., Mahurin RK and Cianciola M. (1998) Neurobehavioral effects from exposure to dental amalgam Hg^{o}: new distinctions between recent exposure and Hg body burden. *FASEB J.* **12:** 971-980. The article may be downloaded for free at

The mercury exposure of these neurologically impaired dentists is compared to that of college students and of the general population in figures 1 and 2 of Amalgam Illness: Diagnosis and Treatment (ISBN 0967616808, Andrew Hall Cutler, published 1999). A few percent of the population has a level of mercury exposure from their fillings over twice that of the highest exposed – and most impaired – dentist studied. Thus it is not surprising to find a strong correlation between mercury levels and dementia as well as strokes (Nakagawa R (1995) Concentration of mercury in hair of diseased people in Japan. *Chemosphere* **30:** 135-40).

Research also implicates amalgam mercury in other serious diseases

Nakagawa *loc. cit.* showed that elevated mercury levels were associated with allergy and diabetes as well as hypertension, dementia and stroke.

Smoking is a major health risk factor. The cost to society is enormous. Studies suggest that mercury from amalgam fillings increases the likelihood people will be smokers (Siblerud, R. L., Kienholz, E. & Motl, J. (1993). Evidence that mercury from silver dental fillings may be an etiological factor in smoking. *Toxicol Lett*, 68, 307-310).

Studies suggest that mercury from amalgam fillings may be a factor in many psychiatric problems, from depression, anxiety, and excessive anger to bipolar disorder and schizophrenia. (Siblerud, R. L., Motl, J. & Kienholz, E. (1994). Psychometric evidence that mercury from silver dental fillings may be an etiological factor in depression, excessive anger, and anxiety. *Psychological Reports*, 74, 67-80; Siblerud RL, Motl J and Kienholz E (1998) Psychometric evidence that dental amalgam mercury may be an etiologic factor in manic depression. *J. Orthmol. Med,* **13:** 31-40; Siblerud, R. L. & Kienholz, E. (1999). Psychometric evidence that dental amalgam mercury from silver dental fillings may be an etiological factor in schizophrenia. *J. Orthmol. Med.*, 14, 201-209).

It has been shown that white blood cell counts – an indicator of the body's level of immunity to disease – increase on amalgam removal, decrease again if amalgam is placed back in the subject's mouth, and subsequently increase if the amalgam is

again removed (Huggins, H. and Levy, T, *Uninformed Consent*, ISBN 1571741178, 1999).

Conclusions

Amalgam is the main source of mercury exposure for most people. Mercury has been conclusively shown in the scientific literature to cause severe health problems such as multiple sclerosis, thyroid cancer and idiopathic dilated cardiomyopathy. Compelling evidence also links it to many other serious health conditions. Careful studies have shown dose dependent decrements in physical, mental and psychological condition at relatively low levels of exposure experienced by most people who have dental amalgam in their mouths.

Dear Sir.

Good friends have informed me of the Hearings on 14. Nov. and that written contributions are wellcome during the next 2 weeks to be sent to your address. I should like to contribute to your fight against amalgam.

I hold a M.Sc. in Chemistry and due to severe diseases from amalgam in the near family I have intensively studied its attack on our body, i.e. what is going on within the single cells when they are being damaged.

The reason for the scientific disagreement between on one side ADA and FDA and on the other side all those who are suffering is easy to demonstarte: **FDA and ADA neglect the Laws of Nature. They rely on inaccurate medical statistics which further are built on wrong and misunderstood methods.** A mighty scientific blunder. The political disagreement is wellknown and outside this letter.

The Laws of Nature are described in Chemistry and Physics, e.g. those of gravity and electricity, in the astronomy a.s.o. and all of them are eternal and of the same validity to the phenomina, we observe inside and outside our body. Thus findings according to these laws as described below are indisputable.

In the medical world they showed their superiority when 10.000 malformed babies were born by mothers having been subscribed thalidomide forty years ago, in the

catastrophe of Minimata and now in the catastrophe of amalgam and Hg-containing vaccines.

Recently I was invited to present a paper at the International Medical Conference of Health-Trends 2002 in Copenhagen. I.a. Professors Boyd Haley, Samuel Epstein and Lester Packer also presented their contribution to the theme: "Healthy Ageing in a Polluted Future". My paper is printed below. As I, due to lack of time for presentation, had to give priority, the list of symptoms and diseases could not be included and they are printed at the end. I can also refer to the peer-reviewed US-medical journal, Clinical Practice of Alternative Medicine, Vol 2 No. 3, 2001 pg. 181-87, The Journal of the Am College for Advancement in Medicine.

I hope you will find the information of interest. Questions, comments and criticism are wellcome.
You may distribute it wherever you think it suits the purpose to get rid of amalgams.

Kind regards,

Poul Møller, 21 B Augustenborggade, 11th floor, DK-8000 Aarhus C, Denmark

HEALTH-TRENDS 2002. Sunday, Sept 1, 8,30 a.m.

Mercury, Ageing and the next Generation.

Introduction. The Number of chronically sick and mentally retarded children accelerate much. The authotirities do not and will not consider, that the Laws of Nature are ruling Hg in the body. 1958-62 they demonstrated their superiority similarly, as 10.000 malformed children without arms or legs were born worldwide by mothers prescribed thalidomide, or in the Minamata case.
However, our government admits: Inorganic Hg is neurotoxic, organic Hg strongly neurotoxic creating extensive damages to the CNS and peripheral nerves. But these severe chronic toxicities cannot be compared to the minimal amounts released from fillings and stored in the organism.
Norway advises against amalgam, because more Hg is released than one thinks. It correlates with the amounts in the brains of dead people, in the fetus and in breast milk. The Danes know, that Hg in the fetus and infant correlates with the Number of fillings, but it has never been proven dangerous! They use wrong methods.
Combining these confessions we are close to the end of the fight: Amalgams ARE poisoning the patients.

The Chemical Impact of Mercury on the Body. Some people do not suffer much from their amalgams; and others are severely hit, about 20%. Yesterday we heard Prof Boyd Haley speaking of the genetic differences.
Healthy people are in balance, chemically. Hundreds of biochemical papers reveal that people with chronic diseases respond positively to antioxidants, i.e. they are in a chronic oxidative imbalance, caused by free radicals, very aggressive particles demolishing what they happen to hit.
Nothing is by far so active as Hg in highly toxic quantities inside all cells, 24 hrs. a day, life long. The release from a filling starts as soon as it has been placed and

reaches maximum in two days. It is enhanced by hot and acidic food, bruxism, chewing gum, polishing and gold, creating an electric current. After the systematization of amalgam in the last mid-century people got 12-14 fillings on average. They have 10 grams Hg placed 2 inches below the brain with open access for its vapours along the smelling nerve. Toxicity is counted in micrograms, g. Controlled fillings lost 50% Hg in 5 yrs. i.e. >1,300 g/day. More than 3 grams are still in the body equal to 120 m. Hg-atoms in each of our 75 trillions of cells.
Three chemical reactions are of importance:
1) Hg recycles quickly between its 2 valencies. One radical is created in each cycle, so the effect is multiplied. For comparison we have 3.000 m. DNA´s per cell. The recycling is similar of that of hemoglobin as the colour of the blood changes from pink to dark red, back to pink a.s.o.
2) Further Hg combines avidly with sulphur. Our proteins are built up from 20 amino acids. Two are fundamentally different; cysteine and methionine, containing SH-groups. Cysteine is often placed in active sites in enzymes, in some hormones, in DNA and in our most important antioxidant, glutathione. The attack on exactly these sites is simply a tragedy.
3) Like most other organisms we convert Hg bacterially into organic Hg. We do it in the mouth and the GI tract. Being soluble in lipids it penetrates all otherwise protecting membranes. We have no barriers at all: Cell membranes are penetrated as well as the blood/brain and the blood/

2

retina barriers, the placenta and mammary glands. Organic Hg is one of the worst environmental
threats. It accumulates in the food chain.
Already 1975 Dr. B Weiss, Univ. of Rochester, N.Y. wrote: "Metals such as mercury and lead have been recognized for many years as CNS poisons. Their presence may pose hazards difficult to specify because the changes in function, even by relatively low, but chronic levels may unfold only gradually and subtly in ways that current methods are unprepared to evaluate. Organic Hg displays an extraordinary affinity for the CNS, it kills nervous tissue. It must be assumed that once distinct neurological signs appear, widespread damage to the brain has occurred".
HgS-compounds and organic Hg are those finally stored. They are extremely insoluble in water. We have no enzymes to change that. The half-time in the CNS is therefore long, above 25 years. When cells die, they stay and enter a neighbour cell to continue destruction.
The other amalgam metals, copper, silver and tin behave similarly, organic tin is related to TBT used in boat paintings to kill adsorbing algae, bivalves etc.

Mercury and Health. We can now conclude that chronic toxicity is the major cause of chronic diseases in people having too little genetic resistance to heavy metals. <u>These diseases having a common chemical origin, also have a common chemical cure.</u>

To-day´s medical science has achieved marvellous results in fighting infectious diseases and in surgery. Chronic diseases lag behind. The Establishment does not understand the Laws of Nature, as universities do not teach them. Clinical methods do not fit: Amalgam is claimed safe because no systemic toxic effects are found in blood and urine. They are for transport, not for storage of toxic Hg, that has long been stuck to the organs. The toxicity is claimed "neutralised", when Hg fixes in the final filling. Both statements are scientific blunders. Finally amalgam has a character of a taboo and authorities are unwilling to consider the risk.

Normally medical science requires fully controlled experiments. In modern times amalgam is the largest uncontrolled experiment. To observe what happens to a cohort of humans, the now middle-aged, left to go through life with potentially intolerable mercury-leaking implants in their mouths with open access to the brain. Authorities do not worry about people getting sick, how they are helped, some of their diseases are not even accepted.
The result is a vast waste of ressources: Wrong diagnoses, treatment and medication of "non-diagnosable" diseases. Depression and anxiety are most frequent symptoms. Unnecessary operat-ions are reported, biochemists are ignored, and very costly medical research show modest results. It looks as if drug companies are searching for drugs, that can compensate for Hg-toxicity without knowing of it. Stem cell research is highest fashion. How much are they polluted?
Dr. Hal Huggins, US-dentist is the most experienced one in replacement of amalgams according to his "protocol" including adjustment of food and food supplements before and after to rebuild the defence of the body. Having helped more than 2,000 patients he tells in his book: Uninformed Consent, 1999, that i.a. leukemia, epilepsy and fibromyalgia have disappeared, and hypertension and hypercholesterolemia have been normalised.

The Influence on Psychical Ageing. Dr. Weiss quantified the long-term toxicity of organic Hg
by comparing biological age with functional capacity of the brain. "Taking 25 years of age as the

3

100% baseline, the next 45 years show about 20% decline of functional capacity". The normal rate of cell loss was 0.5 % p.a. If that is enhanced with 20, 100 or 200 %, a 40 year old person gets a functional brain age of 46, 56 and 95 years respectively. Due to the long span of time even moderate increases have great effect. "Estimates are conservative; exposures begin *in utero,* not at the age of 25".
It seems evident that all three chemical processes accelerate the ageing process. Large excesses of free radicals demolish any compound hit, essential cysteine containing compounds are blocked and the cell killing s by organic Hg put brakes on the steady renewal of cells. All of them promote age-degenerative diseases.
Also some of the "non-diagnosable" symptoms add to feeling older, e.g. depression, migraine, tremor, chronic fatigue, loss of memory, lack of concentration and visual disorders.

The Damage to the Next Generation. The blood of the umbilical cord and breast milk contain up to 8 times as much organic Hg as the mother´s blood. Dr. Vimy, Univ. of Calgary, used radio-active Hg for these analyses. The blood has a constant Hg-concentration over time. The supply of the poison is therefore proportional to the amount of blood entering the embryo, the fetus, and the amount of milk during the nursing period, i.e. the first 15 months of the small creature. The load will have to be considered per unit of weight. At start it is very high due to the small weight.
The proliferation period of the neurons is complete at mid-gestation. Then the intense interact-ions start and continue to the age of 2 years. Cell dividings on the way to 100 bn neurons and as many glial cells may be interrupted by the organic Hg. The poison is supplied just during brain formation and never more, if the child do not get any fillings. Disturbances at any stage may cause persisting intellectual and/or behavioural impairments to the incomplete brain.
The brain is metabolically very active accounting for some 25% of the body´s

metabolic rate at rest. Its unsaturated lipids, EPA and DHA take about 60% by weight.It is therefore specially susceptible to attack from free radicals.
These days we experience mental retardation as reduced IQ, demand for social assistance and special education at schools, DAMP-children, autism, ciabetes-2 at school age, hyperactivity, violence and criminality. These phenomena escalate because a so called "high copper amalgam" was introduced to children in the 70´s. It is easier to handle, but deteriorates 50 x faster. The girls have now reached fertile age and transfer their Hg to the next generation.
The same effects were observed from leaded petrol in large cities in the US, UK, on the conti-nent and in developing countries. The chemistries of lead and mercury are identical.

Conclusion. It is even worse. Contemporarily with these escalating problems in the young end, the old, the filling generation, who got victims of the systematization in the mid-1900´s, show escalating age-degenerative chronic diseases. In a few years both these disasters.which had been preventable, will reach a level, which societies have neither capacity nor knowledge to handle. At present they take up some 50% of the total public cost of care in this country Alone the special education is a little less than 1 bn . Add to that the sufferings of the patients and their families.
We must act now to remove the hatched area in this fig. showing the potential of well-being. THE END.

From an unpublished paper:

4. Symptoms and diseases
All the above-mentioned facts make amalgam-Hg by far the most dangerous cause of heavy oxidative stress. Mental symptoms occur such as:
depression anxiety shyness headache
visual disorders suicidal thoughts irritability nervousness
loss of memory lack of concentration fatigue muscle and joint pains
tremor vertigo numbness tingling of lips and fingers
cold extremities.
Physicians assuming amalgam safe, might easily fail to associate the symptoms with the presence of dental amalgam. Patients then risk being considered hypochondriacs. They are not, they are suffering from Hg toxicity.
Diseases pointed out by biochemists to be connected with oxidative stress are i.a.
senile dementia Parkinson´s and Alzheimer´s dz. MS and ALS,
schizophrenia fibromyalgia epilepsy migraine
tinnitus chronic fatigue atherosclerosis cancer (22)
osteoporosis some rheumatic dz some allergies - asthma and psoriasis
age-related eye diseases, cataract, AMD reduced quality of sperm. (1) - (7).
The CNS is severely influenced and the associated diseases, that normally take many years to develop, are explained by biochemistry. They arise, when our defence systems no longer resist the attack.
A genetic relationship has been discovered as regards apo-lipoproteins E (30). ApoE2, 3 and 4 have two, one and zero cysteine-SH-groups in substitution for arginine groups without S. The protection from the ApoE´s against AD increases with the number of SH-groups as shown by the age of AD onset. In the US some 12% in the best group show an age of onset above 90 years, 65% in the interval 80 - 90 and 24% between 70 and 80 years. This finding has been proposed as a method for large scale genotype screening of those potentially at a higher risk of mercury poisoning

(31), where a physician and a dentist sum up their more detailed experience. The physician (MEG of New Zealand) has started the screening of those getting 16 fillings on the average in the 1950s to 1970s in the socialized school dental care program. He wrote: "These 500,000 of a population of 3.5 m. now the middle-aged who have effectively been an uncontrolled experiment that has never previously been done, namely to observe what happens to a cohort of humans left to go through life with a potentially intolerable amount of mercury-leaking implants in their mouths". 180 patients have been tested so far. "We are facing a 100.000 new AD cases, a horrendous scenario that could be totally pre-empted once MDs are instructed to look at teeth, doing ApoE genotyping, then getting the amalgam out with the help of competently trained dentists. All this will take a decade to establish, so we have to act NOW". (Godfrey ME, personal communication).

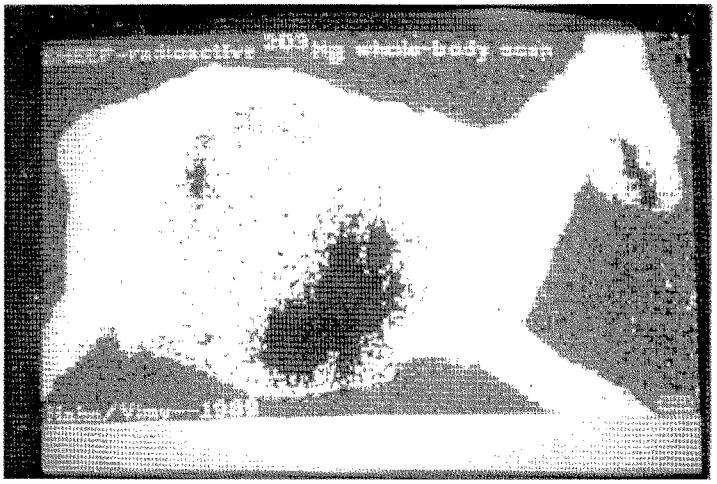


Fig.1. Whole body scanning of sheep. 4x3 fillings containing 425 mg Hg each with radioactive 203, implanted in the molars. After 29 days of normal eating habits, the teeth were removed, animal killed and scanned. Ex. Hahn LJ et al. Dental "silver" tooth fillings: a source of mercur exposure revealed by whole-body image scan and tissue analysis. FASEB J 1989; 3: 2641-6.

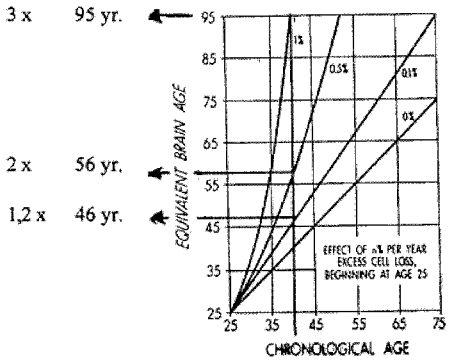
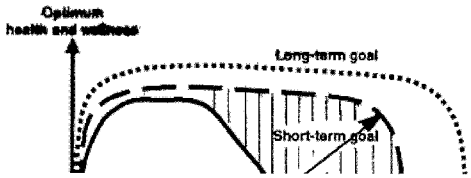


Fig.2. Chronological age plotted against equivalent brain age for different increased r
brain ageing. Left column: Calculated increase of normal rate of cell death. Ex 15 W
Quantitative perspectives on the long-term toxicity of methylmercury and similar p
B, Laties VG, Eds. Behavioral Toxicology. Plenum Publ Corp; 227 West 17th St, I
York:1975. p. 429-37.



For submission to the Congressional Record, November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science.

To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

Mercury is constantly leaking from amalgam fillings, but the doses we receive from this source are not "toxic" in a technical sense since they are too small to poison amalgam bearers who don't have a particular sensitivity. Most of us tolerate amalgam fillings quite well. Adverse effects are only found in a minority.

In these respects dental amalgam is very similar to drugs. As we know, the latter have more or less uncommon adverse effects. It is unusual for a drug to be given in toxic doses. A typical adverse effect, therefore, occurs at *subtoxic* doses and affects individuals who are highly sensitive to the particular chemical substance.

A drug may have a large number of different adverse effects listed in the Physicians' Desk Reference and similar sources. Indomethacin (a common antiinflammatory drug) is a case in point, see <http://www.rxlist.com/cgi/generic/indometh_ad.htm>. The symptoms and states mentioned in such a list are *unspecific*, meaning that they are known to occur also as adverse effects of other drugs as well as in diseases that are not connected with drugs. If the physician does not know that the patient is taking indomethacin, the diagnosis will often be quite difficult.

Common adverse effects will usually have been observed during the pre-marketing testing of the drug. However, many important adverse effects that are uncommon or rare will only be discovered after the drug has been on the market for some time, so that a large number of patients have been exposed to it. In this phase the accumulation of knowledge is wholly dependent on spontaneous, unsystematic reports of actual cases. Controlled studies simply cannot replace this source of knowledge, because these adverse effects are below the detection threshold of any reasonably sized systematic study. In other words, accumulating spontaneous reports is the most sensitive method, and there are no cost-effective alternatives.

When suspected adverse effects are being studied, the concept of *challenge/dechallenge* is important. What happened when the patient stopped taking the drug (dechallenge)? What happened if the patient started taking it again (rechallenge)? This is quasi-experimental evidence of causation, much more convincing and direct than any kind of epidemiological study in situations like this.

25/11 2002

Mercury is a many-sided poison, and any textbook list of the symptoms of overt mercury poisoning is very long. Effects of mercury can be found in all bodily systems, but the nervous system is the one most often involved. When mercury is absorbed in *subtoxic* doses, individual sensitivity will be the decisive factor. The great majority of amalgam bearers are apparently in good health. If there are symptoms, however, the versatility of mercury will help to make *the range of possible symptoms* wider than with many other poisons.

Patients who present with a story that may have its origin in mercury sensitivity will not have a uniform and easily recognizable set of symptoms. Physicians expect to be able to identify a well-known *picture* which consists of at least some *specific, or cardinal symptoms*. When this is lacking, and the symptoms seem to be highly unspecific, the physician usually starts a routine investigation by ordering various blood tests and perhaps x-rays and other things. If the cause of the patient's complaint is mercury sensitivity, this investigation will reveal nothing of importance, and the doctor is then faced with a choice between admitting failure due to lack of knowledge, or suggesting that the symptoms may somehow be of a psychological origin. There is usually no compelling reason to choose the second alternative, but this is nevertheless what contemporary medical culture tends to favour.

Amalgam removal is obviously a form of *dechallenge* in the sense described above. In well-studied cases where mercury sensitivity was suspected, some 75 % experience relief from one or more long-standing symptoms. It takes time to excrete enough mercury, and improvement may continue over a year or longer. Reports of such cases are only rarely accepted for publications by medical journals. Adverse effects of drugs can be reported to national and international centers, and as we know, this results in collections of practically very important information that are being continually updated on a world-wide basis. There is no similar system for collecting reports of adverse effects from dental materials. The lack of adequate information in this area is sometimes taken as evidence that no significant problem exists!

The continuing controversy over the "existence" of adverse effects of mercury released from dental amalgam seems to be based on a limited number of misunderstandings. The amalgam problem is not recognized as analogous to the familiar problem of drug side effects. What the latter problem has conclusively shown us is that no foreign substance can be introduced into the body without giving rise to adverse reactions in at least some cases. If we keep looking for such cases, we are bound to find them. So far the dental establishment has not recognized any other adverse effects from amalgam than strictly local, intraoral ones. On the medical side we have tended to believe in the unfounded assurances by dentists that the situation is under control, and that nothing can happen outside the oral cavity in spite of a constant systemic absorption of mercury.

The first misunderstanding is that we can exclude that adverse effects other than local ones exist when we have in fact done nothing to collect reports of such cases. Actively collecting spontaneous reports is an absolutely necessary thing to do. No other kind of scientific effort can replace this simple, basic effort to learn what is going on.

The second misunderstanding is that this problem can be studied as if *the dose of mercury* was the important factor. It is obvious that the dose is almost always below toxic levels in amalgam bearers, and its variations between individuals are too small to justify a standard toxicological approach to the problem. The fact that most but not all amalgam bearers are free from symptoms cannot be explained as a matter of dosage differences. Individual sensitivity is of paramount importance.

25/11 2002

The third misunderstanding is that epidemiological studies, either of the case-control variety or something more sophisticated, can be offered as proof that no adverse effects exist. Epidemiological studies are weak and insensitive in situations of mass exposure, where it is hard to find sufficient numbers of truly unexposed controls. Furthermore, the symptoms to be registered are both unspecific and diverse, which makes it almost impossible to define what should be considered as a "case". The fame of epidemiology is founded on the proof (in the 1950s) that smoking causes lung cancer. This was a simple problem compared to what we have before us here. Again, the only sensible thing to do is to start collecting case reports in the way we are doing in the drug area. Epidemiology can in no way overrule such basic methods in the area of uncommon adverse effects.

Sincerely,

Per Dalen, M.D., Ph.D.
tel +46 42 224073
Per Dalen <pdalen@algonet.se>

To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform

Re: For submission to the Congressional Record, November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science.

When I began my career as an acupuncturist over 20 years ago, my training prepared me to treat chronic pain and functional disorders. Since many patients come to me as a last resort after failing conventional diagnosis and therapy, I find many patients suffering from the effects of mercury poisoning from dental amalgams, causing such diverse syndromes as chronic sinusitis, Meniere's disease, optic neuritis, acute transverse myelitis, trigeminal neuralgia, Bell's palsy, drug resistant seizures, autism, multiple sclerosis, amyotrophic lateral sclerosis, ulcerative colitis, recurrent urinary tract infections, Parkinson's disease, and Alzheimer's. I cannot begin to describe the suffering of these patients, who have been passed from doctor to doctor until the amalgam problem is diagnosed and properly treated. I am infuriated by the statements of the American Dental Association and California Dental Association insisting there is no scientific research to back claims of dental mercury poisoning. There are over 12,000 citations in the medical literature on mercury toxicity. Below are titles of a few recent papers on the amalgam issue:

Oxidative damage to nucleic acids in motor neurons containing mercury. J Neurol Sci 1998 Aug 14;159 (2):121-6 Pamphlett R, Slater M, Thomas S Department of Pathology, The University of Sydney, New South Wales, Australia.

Activation of the immune system and systemic immune-complex deposits in Brown Norway rats with dental amalgam restorations. J Dent Res 1998 Jun;77(6):1415-25 Hultman P, Lindh U, Horsted-Bindslev P Department of Health and Environment, Linkoping University, Sweden.

Mercury in human colostrum and early breast milk. Its dependence on dental amalgam and other factors. J Trace Elem Med Biol 1998 Mar;12(1):23-7 Drasch G, Aigner S, Roider G, Staiger F, Lipowsky G Institute of Forensic Medicine, Munich, Germany

Systemic transfer of mercury from amalgam fillings before and after cessation of emission. Environ Res 1998 May;77(2):115-23 Halbach S, Kremers L, Willruth H, Mehl A, Welzl G, Wack FX, Hickel R, Greim H Institute of Toxicology, Institute of Biomathematics and Biometry, GSF-National Research Center for Environment and Health, Neuherberg, Oberschleissheim, D-85758, Germany.

Shrinkage of motor axons following systemic exposure to inorganic mercury. J Neuropathol Exp Neurol 1998 Apr;57(4):360-6 Pamphlett R, Png FY Department of Pathology, The University of Sydney, New South Wales, Australia.

This brief list indicates that mercury is a neurotoxic, mutagenic compound that can cross the placental barrier. The EPA finds water to be unsuitable for human consumption if it contains more than 1 part per million of mercury. How can we rationalize placing this toxin in the mouths of dental patients where it may remain in close proximity to the brain for twenty or thirty years? The majority of international research on amalgam in addition to the clinical experience of many health care practitioners demands the elimination of mercury from dental practice.

sincerely,

M.M. Van Benschoten, O.M.D., M.A., C.A.
Doctor of Oriental Medicine
Board Certified Acupuncturist

Subject: For submission to the Congressional Record, Nov. 14, 2002
Hearing on Mercury in Dental Amalgam: An Examination of the Science

Dear Chairman Dan Burton, Representative Watson, and members of the Committee on Government Reform:

I know from personal experience how destructive to one's life mercury dental fillings can be. Since the age of 19 I have struggled with chronic fatigue, which I believe came about as a result of placement of mercury fillings. It is only within the last year that I began reading about them and then initiated testing to see if my teeth were involved in my chronic ill health. I discovered that a molar on the right side (#4) filled with mercury and capped with gold had an electrical charge of negative 157. This electrical charge occurring when dissimilar metals are mixed and bathed in saliva is reffered to as "oral galvanism" and is written about in scientific literature worldwide.

By the time I arrived for treatment at a mercury-free dentist's office on Oct. 21, 2002 my symptoms included: brain fog, weak knees, decreasing vision, and on the right side of my body - a bulging eye, earache, pain of the mastoid bone, neck, and upper back with numbness and tingling from my head to and including the upper back.

Immediately after the removal of the tooth #4 with the high negative charge, I felt a tremendous release of tension on the right side. Since this appointment which included the removal of 3 mercury-filled teeth and a filling change in a fourth tooth, I no longer experience any pain. Normal feelings are returning where there was only numbness and tingling. Sometimes my right eye is the same size as the one on the left. My vision is improving. I continue to detoxify with natural methods and look forward to my next dental appointment to remove the mercury on the left side of my mouth.

A friend from Dental Amalgam Mercury Syndrome typed this letter for the computer. Please vote for the Bill #4163 to ban mercury from dental fillings.

Sincerely,
Lorraine Weldemere

Chairman Dan Burton, Congresswoman Diane Watson, and Members of the Committee on Government Reform:

I am appalled thjat the FDA has not already banned the use of mercury containing dental amalgam fillings. Mercury is the most toxic, non - radioactive element on earth. If we have said that lead is a poison, and has no use in any application that results in human exposure, how can we even assume that mercury, which is more toxic than lead, is safe to use in dental amalgam, where exposure is documented. The fact that exposure to mercury in micro quantities, does not result in obvious health consequences or symptoms, is irrevelent. That just means that all the scientific facts about mercury, especially as used in dentistry, are yet to be discovered. Lack of information does not equate with lack of consequence. As a non - mercury dentist, I frequently am beseiged by people who are suffering from chronic health problems with a common denominator of neurologic, autoimmune and loss of energy symptoms. The American Dental Association's assertion that the only affect of mercury in amalgams is "allergic", and only a small subpopulation is susceptible, defies both logic, and all that currently is known about mercury. Many of these people feel better, sometimes much better, after their amalgams are removed. This may be anecdotal, but it cannot be ignored, when it occurs time and time again.

If the FDA continues to allow mercury fillings to be used in dentistry, by either classifying them as a Class II device, or not classifying at all (the current status), this will give the American Dental Association exactly what it wants, which is the preservation of the status quo, and the governmental support that amalgam fillings are safe for virtually everyone. The ADA has created the ridiculous senario that would have everyone believing that mercury, as used in dentistry, is a hazard everywhere but in the mouth. The ADA has even gone on record, stating that mercury and amalgm are not the same thing. This defies both logic, and all that is currently known about the human physiology of mercury.

12/16/2002

There is sufficient current scientific research concerning the health risks associated with mercury to pregnant women and children to raise a very red flag for the scientists at the FDA. Why is this not happening? Why did the FDA recently close down a small business that tried to manufacture and sell a veterinary medicine containing mercury, yet the dental use of the same toxic element continues without FDA intervention? The public is not stupid. They will know when the FDA appears to be protecting dentists and the ADA, rather than the public that congress mandated the FDA protect. If the FDA chooses to classify amalgam as a Class II device, Congress should investigate the FDA.

Classifying dental amalgam as a Class III device by the FDA, is the only apprppriate way to handle amalgam, considering all that is known about mercury, especially if all the current research in the non - dental literature is considered. Conventional dental implants are classified as a Class III device. Amalgam is as much an implant, as the other implants, except that the body tissue is different. Amalgam has been implanted in bone for decades, when it is used as a root end seal for surgical root canal fillings. Mercury containing amalgam even meets the current FDA defination for an implant. When Amalgam is made a Class III device, the burden of proof for safety, will shift to the dental profession, which is the way it should be, since dentists, and the ADA (which receives much of its financial support from amalgam using dentists), stand to gain financially by its continued use. If amalgam were to be classified as a Class II device, the burden remains with happless patients, who often don't even know that mercury is being implanted in their bodies, and the growing number of dentists who refuse to use amalgam.

I urge the Committee to pursuade the FDA to classify dental amalgam fillings as a Class III device or, to outright ban the use of this toxic filling material.
I also urge the Committee to support the passage of H.R. 4163, sponsored by Congressman Dan Burton, and Congresswoman Diane Watson.

Respectfully,

Dr. Paul Gilbert
Mercury-free Dentistry

Respectfully,

Dr. Paul Gilbert

Subject: For submission to the Congressional Record, November 14, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science

Dear Chairman Dan Burton, Representative Watson, and members of the Committee on Government Reform:

In 1985 at age 45 my health deteriorated rapidly within a few months. I was battling weakness, depression, memory loss, visual problems, urinary and kidney infections, dizziness, and yeast overgrowth. Previously I had enjoyed hiking and jogging- I was reasonably fit. I consulted five medical doctors but none of them could make a definitive diagnosis. One doctor thought I might have a clinical depression but the test disproved that diagnosis. Another, an Endocrinologist, stated that I had a sympathetic nervous system dystonia and prescribed exercise. But I knew his prescription for me was not possible as I barely had the strength to sit through his examination.

By this time I was unable to work. I consulted a biochemist/nutritionist who had an expertise in mercury toxicity. He determined that I had a hypersensivity to my 13 'silver' amalgam fillings. He said that my immune system had been virtually destroyed and that it would have to be brought back,step by step. His findings were later corroborated by an immune cell assay test my doctor ordered. The biochemist placed me on a regime of high supplementation. Within one month I began having my amalgam fillings replaced with composites by a mercury-free dentist.

The first thing the dentist did was to test the emission levels of my fillings. Based on this, he replaced the highest negative quadrant. Later he replaced the next highest, down to the least. The dentist discovered that I had amalgam deposits under my three metal crowns.

Results: Following the removal of my first quadrant, I noticed that my eyes were no longer crossed for the first half hour of each day. When the last quadrant was removed, my visual field symptoms disappeared virtually immediately. I noticed also that my body temperature went up slightly so that my legs no longer felt quite as cold and weak. After this I had many years of treatments and many types of detox.

It is my considered opinion that my health at present would not be 80% normal, nor would I have been able to continue working as a reference librarian had not the mercury amalgam not been removed from my mouth.

I hope very much that the members of the Government Reform Committee will support H.R.4163 to ban mercury from dental fillings so that others may be spared what I and many others have endured.

Sincerely,

Carol J. Ward

This testimony is given as a private person, not as a testimony for any organization or employer.

For submission to the Congressional Record, November 14, 2002, Hearing on Mercury in Dental Amalgam: An Examination of the Science.

To: Chairman Dan Burton, Rep. Diane Watson, and members of the Committee on Governmental Reform.

Mr. Burton,
Mrs. Watson,
Ladies and Gentlemen,

I would like to bring two different aspects of amalgam instability to your attention. They are unknown to most decision-makers, dentists and the public. Both are of great educational value easily understood by the layperson. The two are:

1/ The formation of droplets and increased emission of mercury vapor on market leading non-gamma-two amalgams.

2/ Mercury in feces in subjects with dental amalgam.

Droplets
Non-gamma-two amalgams were introduced some 30 years ago. They were marketed as more resistant to corrosion than the old, conventional ones. They however also display a new, most striking phenomenon of instability. When subjected do polishing and wear small droplets/deposits starts forming on the surface. This goes on for 24 hours or more. My own investigations are described on the Internet (1).

As striking as the phenomenon itself is the fact that no scientific article has been published devoted solely to this subject. Two articles mention it, one briefly in only one sentence; one non-dental investigator gives a deeper analysis in a non-dental journal (2, 3). The International Association for Dental Research, IADR has published six short abstracts presented at IADR meetings. Dentists outside a small group of materials experts have never heard about it. One gets the impression that the dental community wishes to prevent this phenomenon from becoming common knowledge.

Prof. Nikhil K. Sarkar of Louisiana State University is the researcher having studied this phenomenon the most. In a letter he states: "In the past, the dental research community has ignored this as a polishing artifact. But we felt all along that there is more to it and have studied this phenomenon in considerable depth." (4)

In 1994 Prof. D.B. Mahler et al published an important paper were they found that the emission of mercury vapor was influenced by the amount of tin in one part of the metal (5). The more tin the less mercury vapor. Prof. Mahler agrees with my

conclusion that non-gamma-two amalgams emit more mercury vapor than the conventional ones (6). Unfortunately this new fact is not clearly stated in the paper itself but the facts are there if the reader possesses enough knowledge to identify the different types of amalgams(1).

In order to get a more stable metal - less corrosion – the industry ended up with a more unstable one - forming droplets and emitting more mercury vapor. Mercury leakage rates have not been a part of materials testing programs. In fact procedures for such testing has not even been agreed upon.

Mercury in feces

Approximately 90% of the mercury emitted from dental amalgam fillings leaves the body via feces (7). One part of this mercury comes from the excretion of systemically absorbed mercury; one part passes right through the gastrointestinal tract. The part systemically absorbed is of cause of great importance to the amalgam issue. The other part is however also important because of its potential of creating local adverse effects on the bacterial flora and the GI-tract itself.

The main route of amalgam mercury excretion has been almost totally ignored in the scientific discussions of the amalgam issue! After 1960 I have found only 2 (TWO!) scientific articles presenting investigations of mercury excretion in subjects with dental amalgams, both Swedish (7, 8)! The true picture of amalgam instability is given by the sum of mercury excreted via urine and feces.

Skare and Engqvist have measured emission of mercury vapor, mercury dissolved in water held in the moth for 2 minutes, mercury and silver excreted via feces and urine (7). "The worst-case individual showed a fecal mercury excretion amounting to 100 times the mean intake of total Hg from a normal Swedish diet."
"As evident from figure 5, even individuals with a moderate load of amalgam are predicted to show fecal mercury excretions exceeding the WHO dietary standard. By intense chewing or bruxism, the intake rate levels of total mercury will be further elevated."

Björkman et al removed all amalgam fillings in ten subjects using water spray cooling and a high volume evacuator (8). Two days after the treatment the subjects had a mercury concentration in feces more than 100 times greater than the amalgam free controls. Still at day 60 after the treatment the Hg concentration in feces was slightly greater than that of the controls.

When trying to determine the mercury load on the body many researchers have started out by measuring the emission of mercury vapor in the oral cavity. These results have then been processed via a mathematical model based on a number of assumptions. Depending on these you can calculate an uptake within a wide range. Investigations often used by dental organizations have made assumptions giving extremely low uptake rates.

One such emission rate - 1,7 micrograms/24h – has often been used by the dental community. It originates from an investigation by Berglund (9). In this paper he has measured one of the highest emission rates of mercury vapor in the oral cavity published in the scientific literature. By applying a mathematical model to these

figures he has reached one of the lowest uptake rates published. He concludes that approximately 1/10 of emitted mercury vapor enters the body. By looking at the excretion of mercury via urine alone one can easily refute the uptake-rate concluded by means of Berglunds own figures given in the investigation.

Most of our knowledge about inorganic mercury toxicity comes from occupational hygiene measurements performed in industrial environments in a healthy, predominantly male workforce. There are no fetuses, no children, few women, no elderly people and no unhealthy individuals in these investiagtions.

Dental amalgam gives a multi-exposition situation. Mercury vapor is inhaled, corrosion products, Hg dissolved in saliva, amalgam particles and vapor dissolved in saliva are swallowed. Investigations targeting this specific situation has to be performed.

Due to heavy financial and organizational involvement by the industry in dental scientific organizations these investigations have to be performed by medical science (10).

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6/ Personal communication from Prof. David B. Mahler. January 6, 1996.

7/ Skare I, Engqvist A. Human Exposure to Mercury and Silver Released from Dental Amalgam Restorations. Arch Environ Health 1994;49:384-394.

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10/ http://www.gbg.bonet.se/bwf/art/symbiosis.html

To : Rep. Dan Burton, Rep. Diane Watson, and members of the Committee on Government Reform
From: Judith Trustone,

Since getting my amalgams removed in 2000, I no longer suffer from:
fibromyalgia
chronic fatigue syndrome
hypertension
severe chronic sinus infections
allergies
terrible brain fog and memory problems
a low-grade fever of ten years' duration which puzzled doctors

I also had such bad knee pain I had to go down stairs sideways. One hour after the first removal, which obviously lowered my body burden of toxicity, I was able to walk up and down stairs with total comfort. In one month, my feet had goen down one full shoe size.

My experience and that of so many others has convinced me that there is no place in dentistry or medicine for this neurotoxin. I urge you to safeguard American citizens, especially vulnerable children, from mercury poisoning.

>>To Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on
>>Government Reform:
>>
>>I am writing to you regarding my own personal experience with mercury
>>toxicity. My health began to decline in 1991 after I had an old mercury
>>amalgam removed. I went to several physicians and was diagnosed with
>>fibromyalgia, overuse syndrome, systemic candidiasis, chronic fatigue,
>>endometriosis. I was not diagnosed with mercury toxicity until
>>1998. During
>>this time my health spiraled downward. I could no longer eat without severe
>>gastro problems. I was bedridden and desperate. Two physicians said
>>that my
>>condition was life-threatening and it was confirmed that I had high
>>levels of
>>mercury in my body. I had a choice to make; have the fillings removed and
>>hope that my health would improve, or, at the age of 39, make my decisions
>>regarding a burial and enjoy what time I had left.
>>In 1999, I chose to have all of the mercury fillings removed, along with
>>having the nickel crowns replaced, and teeth pulled where there were root
>>canals. It had taken me a year to make the decision because my insurance
>>company had sent me to "specialists" who said that "there was no such thing
>>as mercury toxicity" and another doctor said that if I had the mercury
>>fillings removed, he would work with the group who he was involved with to
>>have me placed in jail along with my doctors and dentists. He said my
>>medical claim was fraudulent. I paid for the procedures with the last of
>>the
>>money that I had in savings.
>>Having the amalgams removed completely changed my life. My health was
>>restored and I was able to go back to college and obtain a Masters degree in
>>Liberal Studies. There are still health problems but they are not like the
>>devastating problems that I had before. I know that having the dental
>>revisions saved my life. I had felt my life slipping away; and after the
>>dental revisions I began seeing many of my symptoms going away. The
>>unfortunate part of this is that I did not have to go through all of the
>>health problems. Mercury was placed in my mouth without informed consent.
>>Please listen to the scientific reports and the personal stories of people
>>such as myself and ban the placement of mercury amalgams in the United
>>States. My life was saved through reading scientific reports, and
>>talking to
>>other people who had the mercury removed. I made an informed decision which
>>changed my life. Most people are unaware of the scientific research. There
>>are people who have no choice because they are uninformed.
>>You are in the position to make the choice for them.

>>Please make an informed decision and ban mercury from dentistry once and for
>>all.
>>Sincerely,
>>Sharon Lallman

To Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform

Chronic Mercury toxicity had me in my death bed in 1984. Health problems had slowly worsened over a period of 30 years until I had received the diagnosis of Chron's Disease, possibly Multiple Sclerosis and Spasmotic Torticullis- all of unknown origin or cure. In 1985 I had amalgams removed and have not had any symptoms of my previously unrelenting health problems.

My husband, my mother-in-law, my son, my daughter, and dozens of friends have taken my advice and had amalgams removed and also experienced improved health. Amalgam is not safe. Ban amalgam. It is the right thing to do.

For submission to the Congressional Record, November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science.

November 24, 2002

Honorable Chairman Dan Burton, Rep. Diane Watson, and Members of the House Committee on Government Reform,

Thank you for the opportunity to participate in this discussion. I will attempt to keep my remarks as brief as possible however, the number of factually inaccurate statements by the ADA makes that task difficult. For the sake of clarity I will number the remarks. pp.1/5 ADA refers to page 1 paragraph 5 of the ADA statement. This report will rebut with references to the scientific literature the inaccurate and misleading statements made by American Dental Association (ADA) representative Rodney Mackert before the House Committee on Government Reform during the November 14th Hearings on Mercury released from dental amalgam.

pp.1/5 ADA

The ADA statement makes an inappropriate misleading comparison between salt that is a covalently bonded compound and amalgam which is a mixture and has no covalent bonding. The statement by the ADA is in direct conflict with the statement by Lawrence Tabak, Director of the NIDCR, who correctly stated that amalgam is " a mixture_." When you squeeze salt you do not get free chlorine gas, but when you squeeze amalgam you get highly toxic elemental mercury vapor gas. The analogy between salt and amalgam is incorrect, inappropriate and misleading.

pp. 1/6 ADA

This paragraph alleges that epidemiological data dose not support the theory that people are made ill by dental amalgam and then goes on to claim that less than 100 cases of allergy have been reported. These are two different issues. Allergy to mercury and allergy to amalgam has been investigated extensively in the scientific literature by experts in allergy. The numerous documented effects of allergy to mercury in the scientific literature are; chronic atrophic dermatitis [i] <#_edn1> , contact dermatitis [ii] <#_edn2> [iii] <#_edn3> [iv] <#_edn4> [v] <#_edn5> , eczematous dermatitis [vi] <#_edn6> , multiple polyposis [vii] <#_edn7> , generalized allergic reactions [viii] <#_edn8> [ix] <#_edn9> [x] <#_edn10> [xi] <#_edn11> , oral lichens planus (62% of those with lichens planus tested allergic) [xii] <#_edn12> [xiii] <#_edn13> [xiv] <#_edn14> [xv] <#_edn15> , chronic oral ulcerations [xvi] <#_edn16> , and burning mouth [xvii] <#_edn17> . White and Brandt [xviii] <#_edn18> found that greater than 10% of junior and senior dental students tested allergic and Miller et al [xix] <#_edn19> found a few years later that 31% of the freshman dental class had developed allergy to mercury chloride and that the amount of allergy was proportional to the number of amalgam fillings in their mouth.

Djerassi tested for allergy and found that of those with amalgams, 16.1% tested allergic, whereas none of the 60 control subjects without amalgams tested allergic. [xx] <#_edn20> That would make the total number of people in the United States who test allergic to mercury approximately 500,000 and not 100 as the ADA claimed.

Critics of this research will claim that the positive patch test is actually a chemical burn and is not related to mercury hypersensitivity. [xxi] <#_edn21> This is unlikely because the controls for both the Miller study and the Djerassi study found that 0% of those who had no amalgam fillings were hypersensitivity to the mercury patch test.

pp. 1/7 ADA

The ADA alleges that dentists and their staffs suffer "no demonstrated ill effects on their health." This is patently false for a number of reasons. In California the CalEPA lists mercury as causing infertility. This is due in part to a case controlled study of California dental assistants that found a 40% decrease in fecundability (ability to conceive a child) of females involved in placing amalgams. [xxii] <#_edn22> This evidence further confirms numerous studied dating from the late 70's that found infertility and birth defects from maternal exposure to elemental mercury vapor. [xxiii] <#_edn23> [xxiv] <#_edn24> [xxv] <#_edn25> [xxvi] <#_edn26> [xxvii] <#_edn27> [xxviii] <#_edn28> [xxix] <#_edn29> A large study of German women found that their

fecundability was dramatically improved with amalgam removal and treatment for mercury poisoning. These women were exposed to mercury from their fillings and not from their occupations.

Studies of dentists and dental personnel have shown that they suffer disproportionately from neurological impairment, kidney damage, cardiac arrhythmias and numerous other mercury related illnesses. [xxx] <#_edn30> [xxxi] <#_edn31> [xxxii] <#_edn32>

pp. 5/5 The ADA statement alleges that the WHO supports their position on mercury which is not entirely true. While the dentists at the WHO do agree with the ADA the official WHO position based upon their scientific expert committee's review of mercury exposure from amalgam in 1991 estimated that a person with multiple amalgams would be exposed to 17 µg/day (micrograms per day). [xxxiii] <#_edn33> This exceeds the minimum risk levels established to protect the public. They reviewed Rodney Mackert's research and chose to ignore it because it did not agree with numerous other relevant published studies.

In fact, even the NIDCR apparently does not agree with the ADA because on page 1 paragraph 4 they estimated the urinary levels range from 1.2 to 20 µg/day. The higher range would extrapolate to a total exposure of about 100 µg/day or 100 times higher than the level of exposure that Dr. Mackert estimated.

Both the ADA and the NIDCR touted the prospective study of young children looking for neurological impairment from receiving mercury-leaking fillings. This study is unethical, in my opinion, and very cleverly designed to not show a relationship. What parent would knowingly allow their child to participate in such a study of lead exposure much less mercury? The medical review board at the University of Calgary Medical School determined in 1985 that based upon the then available scientific literature that such experiments would violate the first tenants of medical ethics. In order to find a definitive result you must first harm a child.

Furthermore, no one is saying that first grade children suffer immediate harm from amalgams. Alzheimer's Disease is from a lifetime of chronic exposure to intra-oral mercury vapor. Autism is from fetal and neonatal exposure to mercury potentially from the mother's teeth or vaccines. There are separate genetic factors and numerous confounding variables that make the NIDCR study meaningless.

Lead research in the 70's confirmed that early childhood lead exposure produced profound risks of violent behavior and diminished IQ in adulthood. Adolescent and adult exposure did not carry the same risks.

These studies are designed to show no effect and that is exactly what they will do. The NIDCR does admit however that, "Over the course of the trials several children have shown higher than acceptable urinary mercury levels." (pp. 4/1 NIDCR) Thus, the NIDCR has already confirmed our principal concern, that children and adults are exposed to measurable amounts of mercury leaking from their fillings.

Sincerely,

David Kennedy, DDS
Past President International Academy of Oral Medicine and Toxicology

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> Hon. Dan Burton
> Rep. Diane Watson
> Members of the Committee on Government Reform
>
> Subject: For submission to the Congressional Record
> November 14, 2002
> Hearing on Mercury & Dental Amalgam: Examination of the Science
>
> In '97 I became extremely ill with a mystery ailment. After 18 mos.
> of many tests and no results I was finally tested for mercury
> toxicity. I was off the chart, the highest level my doctor had ever
> seen. I had multiple symptoms, including symptoms mimicking MS. I
> traced it back to nine amalgam fillings being replaced (with more
> amalgam) within a short amount of time in early '97. I then had all
> amalgam fillings removed and replaced with composite fillings the
> correct way. I have spent the past 4 years detoxing the mercury from
> my system. I am now better, but still have residual effects. It has
> effected many areas of my health. My children and grandchildren will
> never have amalgam fillings.
>
> Debbie Pianki

> >
> >To: Chairman Dan Burton, Rep. Diane Watson, and Members
> >of the Committee on Government Reform.
> >
> >Re: For submission to the Congressional Record,
> >November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the
> >Science.
> >
> >Dear Members Of Congress,
> >
> >In an independent investigation, I locate an ADA funded study done by Dr
> >Diana Echeverria, Battelle Centers for Health Research. Her segment on 60
> >Minutes, "Mercury In Your Mouth" was banned by the ADA because certain
> >testimonies were damaging to the ADA endorsement of mercury amalgam
> >fillings. Because of a conflict of interest, she cannot testify for us. In a
> >telephone conversation, Dr Echeverria related to me that Dr Michael Martin
> >would be willing to help us. Dr Martin testified to the King County Council
> >in Seattle Washington that it has been common knowledge for the last ten
> >years that mercury in dental fillings does indeed release vapor. Dr Barry's
> >testimony that mercury as a dental filling remains inert is contrary to Dr.
> >Martin's testimony, and is out of step with leading edge research.
> >
> >ADA funded study reference:
> >THE CRITICAL TARGET organ of elemental mercury vapor is the central nervous
> >system. There is little debate regarding the toxicity of exposure to Hg
> >associated with urinary concentrations above 50ug/l, no consensus exists
> >with respect to a safe lower Hg exposure level among either dental
> >populations that handle Hg amalgam or the general population with amalgam
> >restorations, Battelle Centers for Public Health Research and Evaluation,
> >Seattle Washington; The FASEB Journal 1998; 12: 971-980]
> >
> >When Poison Control testified that amalgam fillings are safe because the
> >dose makes the poison, they continue to compromise the quality of human life
> >in doing so. Though it may not instantly cause death, it is clear that the
> >bio-accumulative effects make it unacceptable for human use, especially when
> >safer alternatives exist.
> >
> >In 1999, Centers for Disease Control and Prevention survey estimated 10
> >percent of adult women had blood-mercury levels higher than the
> >Environmental Protection Agency considers safe. And a National Academy of
> >Sciences study in 2000 estimated that 60,000 U.S. infants a year face
> >increased risk of brain damage because their pregnant mothers had elevated
> >mercury levels. (Printed in the Seattle Times, Oct. 27, 2002)
> >
> >The EPA treats mercury as a dangerous toxic substance before it is placed in
> >your mouth, and a toxic substance when disposed of as scrap amalgam. Are we
> >to believe the only safe place for the second most toxic substance known to
> >man is in the human mouth? How can you make a toxic substance any less toxic
> >in the human mouth?

> >
> >The ADA chooses to recognize a 1992 report from the US Department of Health,
> >Agency for Toxic Substances, when a newer 1999 report exists. In addition
> >there are a vast number of Government studies on the hazards of mercury in
> >dental amalgam. Keep in mind that there has never been a study proving the
> >safety of mercury in dental fillings before approval for use. The burden of
> >proof has not been satisfied in the eyes of the public.
> >
> >Dentsply Caulk is a manufacturer of mercury amalgam dental fillings, which
> >contain 52% elemental mercury. The packing slip from Dentsply Caulk states
> >that its' product is, "Contraindicated" (which means, DO NOT USE!) for
> >certain vulnerable populations including EXPECTANT MOTHERS, and CHILDREN
> >under six!
> >
> >Young vs. Group Health as case law in Washington gave us medical and
> >pharmaceutical informed consent, which discloses to the consumer the risks
> >or side effects with respect to a medical treatment or prescription drug.
> >Clearly informed consent is not being enforced in the State of Washington
> >with regard to dentistry as a treatment.
> >
> >Part of our Mercury resolution in Washington stated: [Believing that the
> >American Dental Association and manufacturers of dental amalgam should have
> >no viable objection to accurate labeling of materials already deemed
> >"hazardous materials."] Is it any wonder that the Democratic Party voted in
> >favor of dental informed consent at the Washington State Democratic Caucuses
> >in 2002?
> >
> >The Mercury Awareness Team of Washington submits that consumers have the
> >"Right To Full Disclosure" that a silver dental filling is really 52%
> >Mercury, and is the main component in a 'silver Mercury Amalgam" dental
> >filling. Rightfully it should be labeled as a Mercury filling!
> >
> >We will continue to raise the awareness of consumers on the hazards of
> >Mercury in dental fillings Nationwide. We have faith that our Government
> >will carefully weigh the issue of money verses human health, and we will
> >rely on your political integrity where our safety is involved. The future of
> >our health and well-being depend on it!
> >
> >
> >Respectfully submitted,
> >
> >
> >
> >Doreen Randal
> >
> >Mercury Awareness Team of Washington
> >38th Secretary LDCC
> >
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> Part 1.2 Type: application/msword
> Encoding: base64

Dear Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

I work for the FDA as a review chemist and regularly evaluate manufacturing and control protocols used in the approval process for drug product formulations often involving controlled release capsules and tablets. Since amalgam is akin to a controlled release formulation releasing mercury, if I were apply scientific requirements applied to drug submissions to an amalgam I would consider the following analytical perspective.

The real benefit of a well-designed scientific study should be to demonstrate a certain degree of consistency between all aspects of our scientific understandings about the use of amalgams and should involve the classification of amalgam formulation types in terms of the extent each type may display specific mercury emitting properties.. In this connection, study protocols need to be designed to utilize both good (i.e., poor mercury emitters - PMEs) and bad (i.e., good mercury emitters - GMEs) amalgam formulations. Study outcome would be expected to provide both positive and negative results. It is very important to rationalize all negative results in terms of known understandings concerning why they would be expected to be negative. Attention can be given to the following negatively based factors that should become incorporated into the overall study-design process.

(1)The inclusion of background supporting information demonstrating how easy it may be to prepare bad (GMEs) formulations (e.g., by not following proper amalgam preparation instructions such as metal mixing proportions and mixing times). As an example of incomplete mixing, pocketing effects of toxic chemicals in rubber stoppers and their leaching effect into drug solutions are taken into account by FDA.

(2) The inclusion of known "bad" (GMEs) amalgams into the study design akin to "spiking" a sampled study population. The intent is to be able to observe expected margin differences between the "good' and the "bad" amalgams utilized in the study. In this regard, it is also important to include amalgams that are known to represent different intermediate degrees of toxic risk (i.e., a graded group of intermediate emitters going from real good to real bad) to establish an expected profile of unwanted outcome results that can be explained in terms of rationalized understandings derived from the initially established study protocol.

(3) The study design should include the search for not only elemental mercury but also other forms that are known to be toxic (i.e., methyl mercury). In this connection, it is important to provide for a study arm that seeks to provide for understanding factors in the mouth such as bacteria interactions, elevated immune system response, pH cycling, etc. and the potential they may have to degrade amalgams and produce other possible mercury compounds which may have unique routes of entry into organs. This means that attention needs to be given to the development and validation of appropriate analytical methods to be utilized to detect and quantify all such relevant mercury substances at very low levels of possible exposure.

(4)-The study protocol needs to take into consideration expected amalgam transformation effects such as aging effects (i.e., cracking and loosening in the tooth cavity). Such effects may be expected to provide for greater mercury releasing events. Even teeth-grinding (i.e., while sleeping) needs to be factored into the overall study protocol design. There may be a synergistic rate effect between physical amalgam distortion and bacterial/immune system attack. Also, galvanic effects arising from the use of different metals in touch with each other (i.e., adjacent teeth filled having different metal compositions – copper amalgams) would be a worst-case mercury releasing circumstance necessitating study.

(5)-It is difficult to link unwanted mercury exposure effects to disease conditions since there are not strong endpoints like death (body counts) to use in the finalized assessments (statistical study plans involved). It is suggested that appropriately designed "case control methodology" be utilized in the overall study protocol design that provide for comparative matching of persons with and without mercury amalgams in certain disease states and the determination of the proportion of members in each group that could be linked in a casual manner to such a state.

(6)-Finally, it is very important to allow for an optimum degree of open-minded scientific input into the design of this global scientific query. Efforts should be made to ask for helpful suggestions from all relevant scientific groups that may be expected to offer expertise about how to best design studies that will provide for understandings concerning all the critical risk based relationships involved (e.g., as discussed above as well as any others that may surface). One such scientific group is the Controlled Release Society that has a web site at www.controlledrelease.org. This society may be helpful for fully utilizing new analytical methods for low-level detection and analysis of various mercury compounds and in the objective study of principles in the time-release mechanism(s) of mercury from amalgams.

FOR SUBMISSION TO THE CONGRESSIONAL RECORD, NOV.4, 2002-HEARING ON MERCURY IN DENTAL
AMALGAM: AN EXAMINATION OF THE SCIENCE

Dear Chairman Dan Burton, Representative Diane Watson and Members of the Committee on Government Reform

It is scientifically proven that mercury rapidly depletes the immune system, induces a number of autoimmune disease, and increases the number and severity of allergies. Mercury is highly toxic to the nervous system and is stored preferentially in the endocrine glands (pituitary and hypothalamus) It may also be a skin and pulmonary sensitizer.
Mercury dental fillings were initially placed in my mouth at an early age (preteen years) on several occasions. I began to show signs during my teen years of my first autoimmune disorder, eventually diagnosed by the medical profession as Hashimotos Thyroiditis. Beginning in my 20's and during a span of 10 years, 13 mercury fillings (restorations) were placed in my body. It is estimated I have been exposed to mercury over 20 times in order to have mercury either placed or removed (crowning) for dental care, not counting the daily exposure I receive from the

vaporization of the 13 mercury fillings that remain in my mouth at present. During my adult years I developed severe environmental allergies, requiring desensitization therapy. My immune dysfunction resulted in the development of cancer in 1986. Through my adult years, I have also developed chronic fatigue problems, chronic muscle pain and received a diagnosis of severe fibromyalgia., which has
both immune and neurological implications. I have been affected by sinus and frequent respiratory infections, GI problems and unexplained cardiac problems (palpitations and sinus tachycardia). In addition I have unexplained tooth/facial/jaw pain..

There is medical documentation that in just the past few years, I have further developed additional autoimmune problems, having had a positive lupus test that has required monitoring. In addition I have unexplained visual problems-- dim vision, flashes of light, and a blood test positive for antiretinal antibodies, indicates another autoimmune condition involving my eyes. My most recently diagnosed autoimmune problem is oral lichen planus, it is noted in the amalgam manufacturers warnings that this condition may develop from the electrochemical processes. The warnings state that mercury is an irritant to the skin and respiratory tract. Further more, I have unexplained eyelid twitches, night sweats, internal racing and pulsating sensations, burning sensations and insomnia. In the past four years, I have been ill from a strange form of tinnitus, tormenting noises in my ear/head that are exacerbated by normal environmental sounds.Both my neurological
and immune problems have continued to worsen.I am concerned that I am experiencing memory problems Presently my thyroid condition is unstable and efforts by the medical profession thus far to stabilize it have not been successful. I am in my retirement years and have carried the mercury body burden for many years. Mercury dental filling is regarded by government agencies as hazardous material before it is placed in the mouth and treated as toxic waste after removal. Thus, it has been hazardous to my health during these years it has been in my body, and caused or contributed to a gradual decline in my health. Three blood tests have shown that I am immune reactive to mercury. Other testing have shown metabolic problems, insulin resistance, poor liver detoxification and retention of mercury in my body, also high oral levels of vapor from my mercury fillings. Mercury dental fillings need to be banned and highly regulated in the meantime. In light of
all the preceding information, I submit this as testimony to the congressional record.

Mary Jo Griffin
113 N Edgemont Ave. apt C
Gastonia, NC 28054
704-865-7510 (phone)
November 24, 2002.

Mrs. Marie G. Flowers
Former school teacher, currently a prison volunteer
108 Farmer Lane, Vinton, VA 24179
540-890-4233

Dear Honorable Chairman Dan Burton, Representative Diane Watson and Members of the Committee on Government Reform:

In July of 2001, while on vacation, the side of a tooth with a very large amalgam broke off. When a local dentist patched the tooth, I started tasting metal in my mouth. I did not know that the placement of incompatible metals with mercury could cause a galvanic current that would cause me to taste metal and

poison me.

On August 8th, I saw my regular hometown dentist who pleaded ignorance to the cause of the metallic taste. When he drilled into the filling to resize the tooth for its new crown, he exposed me to mercury vapor that entered my brain. The Materials Safety Data Sheet (MSDS) that comes with the Amalgam Capsule states that a person can be mercury poisoned through inhalation of mercury vapors and through the use of incompatible dental materials. It states that one of the symptoms of mercurialism is a metallic taste.

My dentist did not use an oxygen mask to protect me from the mercury vapors. I informed my dentist I had been taking prednisone for the treatment of Belle's Palsy one month previous to the dental appointment. I believe my immune system was already in jeopardy by taking the prednisone and that made me more susceptible to mercury poisoning. Dentists should take an impaired immune system into consideration before exposing a patient to mercury. All dentists should incorporate the use of oxygen masks, dental dams, and other precautions biological dentists use, into the Standards of Care whenever an amalgam needs to be removed. By banning the use of dental mercury altogether, these toxicity issues could be avoided.

Both the temporary and the permanent crown was placed directly over the mercury filling. Now I became nauseated along with an increased metallic taste. Later my biological dentist told me that the "high metals" in the porcelain crown was interacting with the mercury. Because there was a cavity under the mercury filling, this chemical action caused my tooth to decay rapidly. He said the interaction (called oral galvanism) also caused mercury to leak from the filling at an accelerated rate.

On August 13th, I felt something move inside my brain. Three days later I felt a little circle at the top of my head begin to burn, my scalp was sore, and it tingled all over. I had a slight headache. On August 17th, 8 days after exposure to the mercury vapor, I woke up with my whole brain feeling like it was on fire! My brain was vibrating inside my skull and my head was throbbing. I started feeling electrical charges surge up and down my body from the top of my head to the tips of my toes. In people with Multiple Sclerosis this electrical surging is called L'hermette's Sign. I don't have MS and I don't want to contact MS from exposure to dental mercury. I went to my internal medicine doctor that day with symptoms of my "brain burning," headache, swollen lymph nodes, disorientation, inability to focus and "feeling spacey." She had no idea what was wrong with me.

My symptoms increased: allergies to almost all food and food additives (especially milk and vinegar), muscle aches, chemical sensitivities, chronic fatigue, vertigo, sinusitis, floaters in my eyes and twitching eyelids, ringing in the ears, tingling in extremities, numbness and tingling in my face, loss of concentration, anger and emotional outbursts in public, paranoia, loss of memory, loss of concentration and intellectual abilities, sleeplessness because of the metallic taste and nausea.

I saw two internal medicine doctors, as osteopath, two eye doctors, a chiropractor who suspected mercury toxicity but was medically unqualified to help me, a neurologist who confessed he knew nothing about mercury toxicity. Two doctors suggested I see a psychiatrist. The emergency room doctors dismissed the idea of mercury poisoning from dental fillings. Not one traditional doctor was able to recognize the symptoms of mercury toxicity from dental fillings.

After two months of desperately searching for help, I attempted to phone an alternative physician. However, my thinking was so distorted I couldn't comprehend I needed to use an area code to call him. After repeatedly failing to call him, one day my fog lifted in my brain sufficiently for me to realize I needed to use an area code. The alternative doctor, who is also a psychiatrist, diagnosed me with mercury toxicity. He told me I must have my amalgams safely removed, and prescribed the following:

1) Natural hormones, because mercury interferes with hormone balance which causes "foggy" thinking,
2) Vitamins to combat free radical damage caused by the toxicity, and minerals to replace minerals that are pulled from the body while the mercury is being removed by a chelation drug,
3) Probiotics to replace good digestive bacteria that are destroyed by mercury,
4) Immune enhancing supplements to rebuild the immune system which is damaged by mercury,
5) Enzymes to help digest food since the mercury destroys enzymes in the gut,
6) Anti fungal medication because mercury causes overgrowth of yeast,
7) DMSA, a sulfur drug, to chelate (remove) the mercury from the body.

Even though my heavy metals test failed to show toxic levels of mercury, the alternative physician

recognized the symptoms of mercury toxicity and treated me because of the symptoms.

The biological dentist used special precautions when he removed all the mercury fillings and didn't poison me further. As soon as all the mercury and the crown with "high metals" were removed, I started recovering. I lost the metallic taste and nausea after one dental appointment.

My head has not felt normal for the past 15 months. Symptoms I still experience in my brain include pressure, "crawling sensations," itching, stinging, burning and headaches. These symptoms are decreasing in frequency and intensity as long as I manage my supplements and DMSA prescription correctly. If not, the pain intensifies. The most bothersome symptom has been loss of memory.

I have spent thousands of dollars on all of the dental work, supplements and prescriptions. Insurance has paid some but alternative care is not recognized as it should be by insurance companies. I have no idea how long it will take before I am completely well.

I am a former public school teacher and I volunteer my time as a Bible teacher in prisons. Others are teaching in prison for me now because of my memory problems.

I want to thank the Committee for all the hard work they are doing to reform dental care in America.

Sincerely,
Marie G. Flowers

Gail Dennison
Teacher, author
326 Paine Avenue,
Ventura, California, 93003

Nov. 25, 2002

Subject: For submission to the Congressional Record,November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science.

Dear Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform,

Nearly 30 years ago, at the age of 26, I had several mercury fillings removed in a 2-week period, without benefit of a rubber dam. Five years later, as the porcelin deteriorated, the amalgam was replaced.

Soon after, I began to experience allergies, dizziness, joint pain, ringing in the ears, and a recurring "metal" rash near the corner of my mouth. . . none of which I had never previously had.

In the years that followed, I was diagnosed with such varied labels as systemic candidiasis, Chronic Fatigue Syndrome, facial neuralga, cancer, Fibromyalgia, chronic digestive disturbance, and Reynard's Syndrome (a painful form of arthritis that causes the fingers to turn cold and blue). Thousands of dollars and many doctors down the road, I finally received the diagnosis of "silver amalgam poisoning," and began a program of amalgam removal and herbal therapy to remove the amalgam from my tissues.

Happily, today I have nearly regained my health, and can foresee a full recovery. I can trace many "near miracles" of improvement to specific days on which I had almalgams removed.

Dentists now have wonderful materials available for use instead of silver amalgam. I urge you to recognize that silver amalgams are toxic, harming the lives and health of thousands.

Please outlaw this deadly material from the field of dentistry.

Sincerely,

Gail Dennison

> For Submission to the Congressional Record Hearing on Mercury in
> Dental Amalgam, an examination of the science.
>
> A graduate of Swarthmore College, I have been a qualified
> therapist for over 23 years. I have sat on 2 professional Boards,
> advocating for the recently passed consumer protection Licensure Bill
> which recently passed in Pa., licensing Professional Counselors and
> Marriage and Family Therapists.
> All my life I have been unusually active, including engaging in
> skiing, swimming, biking, hiking, and dancing. In June 1996, my
> dentist informed me that I need 3-4 amalgam (silver/mercury) fillings.
> Within a month of the amalgam fillings being placed into my teeth, I
> began to notice that I was having frequent signs of Fatigue and Viral
> and Flu-like symptoms which, over time, increased and became chronic.
> During the 3 subsequent years, neither my family Dr. nor a Harvard MD
> who specialized in infectious diseases, had any idea what was wrong.
> My blood tests were fine. I became increasingly sick and weak, with
> additional symptoms of repeated urinary tract infections and at times
> mild symptoms of multiple sclerosis - I began, from time to time, to
> limp.
> During the 4th and 5th year of my illness, I was only able to
> work in my therapy private practice part-time. I discovered that my
> immune system had been 'compromised'/damaged from the mercury, so that
> I caught colds and the flu very easily. There were several periods of
> time wherein I would have to cancel therapy clients and social events
> at the last minute, and just go to bed, feeling sick and exhausted.
> There were days when I couldn't walk around the block, from fatigue.
> I also began to notice that my memory, concentration, recall, and
> multi-tasking abilities were compromised. Doing laundry felt like
> hiking up a mountain.
> During the 5th years of my illness, upon the recommendation of
> a friend, I went to a local wholistic dentist who, using a special
> meter device, concluded that I had over 7 times the amount of mercury
> in my mouth than was considered 'safe' to the human body. Shortly
> thereafter, a reputable wholistic MD determined from a 'urine
> challenge test' that I had very elevated and unsafe mercury levels in
> my body. Over the next year I had all of my amalgam fillings replaced
> with white composite fillings. Special advanced techniques were used
> to safeguard my body during removal. The mercury from the fillings had
> leached into the jawbone above 2 of my teeth, so that I underwent
> successful jaw bone surgery. Within an hour of 1 of the surgeries, I
> noticed some improvement in my ability to concentrate!
> Currently, it has been 1 1/2 years since I have had the

> mercury out of my teeth. I have continued to use oral supplements to
> support organs which have been compromised (liver, bladder/UTI, immune
> system, and otheres) as well as supplements that slowly take mercury
> out of my cells/blood/organs. As affordable, chelation therapy has
> also helped in ridding my body of mercury. I am grateful to say that I
> am now in advanced stages of healing from amalgam illness/mercury
> poisoning. I have returned to work full-time, my activity level is
> greatly improved (tho not back to normal), and the cognitive symptoms
> are greatly improved. My quality of life is almost back to normal.
>
I have been
> fighting for my health for 6 1/2 years. The dangers of mercury
> poisoning, for me, are very real.
> My illness should never have occurred. of
> I encourage all of you to take the necessary steps so that
> others in our communities - adults and children- can avoid the illness
> I have been experiencing. May our nation follow in the footsteps of
> our informed and wise European allies that have banned the use of
> mercury in dental fillings.
> Please feel free to contact me for more information on my
> experience and/or for competent research sources on this topic.
>
>
Sincerely,
>
>
>Sara Moore-Hines, LPC
>
>
>
>
>

November 25, 2002

Dear Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform:

I am writing regarding House Bill HR 4163 -legislation to eliminate
the use of mercury containing dental amalgam for the use of tooth restorations.

When deciding on how to vote, please consider the following well documented facts:

1. Dental Amalgam releases mercury -a highly toxic substance [1,2,3].
The amount of mercury released routinely exceeds health guidelines [4].

2. The mercury from dental amalgams accumulates in body tissues [5,6,7] and has been observed to cross the placental barrier into developing fetuses [8,9,10,11].

3. There are many good mercury-free alternative materials for dentists to use for tooth restorations [12].

4. Many people have been made sick by their dental amalgams and have benefited by replacing their amalgams with mercury-free materials [13,14,15,16].

My background is not in dentistry, medicine or medical research. I am however, a published electrophysicist and have degrees in physics and electrical engineering. For many years, I have suffered from chronic illness that I believe was caused primarily by the mercury leaking out of my dental amalgams. After extensive research, I decided to replace my dental amalgams with mercury-free materials and to receive treatment for chronic mercury poisoning. My health has greatly benefited from this decision; in short, I now have my life back. I hope that my story and your vote will spare others some unnecessary suffering.

Over ten years ago, I began experiencing a series of chronic recurring health problems. At first they were just an annoyance, including headaches, pain in my neck and back, and, a few years later, seasonal allergies. About six years ago, I began experiencing symptoms of depression, difficulty concentrating and fatigue. Periodically, I would seek medical attention. I was prescribed pain and allergy medicine, scanned with MRI and X-rays, and consulted neurologists. I also received chiropractic manipulation, physical

therapy, and psychiatric counseling. Sometimes I would receive temporary relief from the various treatments; usually I would just become frustrated and assume I was suffering from overwork and stress.

About four years ago, I developed chronic fatigue, irritability and regular depression. I also began experiencing overall aches and pains, what some doctors describe as fibromyalgia. Exercise would help somewhat, but often it would make me feel worse. Eventually, the chronic fatigue made it impossible to work full time and, about two years ago, my health reached a low. Whole days would go by when all I could do is sleep and eat. Typically, I would feel okay two days a week, fair to poor most of the week, and really miserable two days a week. I received blood tests to check my thyroid and the possibility of anemia -they came back negative. Last year, I developed sciatica in my left leg and numbness in my right foot.

Finally, the fatigue and one other symptom, a persistent metallic taste in my mouth, prompted me to look into amalgam illness. I was shocked by what I found --numerous scientific papers regarding the amount of mercury released by dental amalgams and linking mercury to illness [17]. Some, like the work of Alfred Stock [18], was done in the 1920s! I was even more surprised by the lack of research demonstrating the safety of dental amalgam. The web site for the American Dental Association lists a handful of unconvincing papers, most lacking peer review. I collected several articles on the subject and read a few books [14,15,16]. I interviewed dentists and doctors to understand the treatment options and costs involved.

I learned that all of the symptoms I had experienced were typical of chronic mercury poisoning. I started a health journal, keeping track of my symptoms and sleep patterns. I began taking several supplements to combat the effects of mercury on the body. I began to feel better. After about eight weeks, I started the process of replacing my amalgams with mercury-free materials. I did one quadrant at a time, completing the process over a ten-week period. During the period of amalgam removal, my health continued to improve but fluctuated quite a bit. This is expected since the replacement process involves drilling out the old fillings, which releases a significant amount of mercury.

In October, I began taking medications to remove the mercury from my brain and body -a process called chelation. This treatment has actually caused some of my symptoms to worsen a bit. As mercury is removed from the body through chelation, there is a tendency to redistribute some of the mercury causing a temporary exacerbation of symptoms. However, after several weeks of chelation, the progress has been positive. Today, the allergies, sciatica, depression, and metallic taste are gone. I sleep an average of eight hours a night instead of eleven, and most of the other symptoms are greatly diminished. In short, I have my life back.

I believe that thousands of people are suffering needlessly from mercury poisoning and that dental amalgam is a primary source of exposure. In Norway, where amalgam illness is well known; surveys indicate that 2-3% of the people with amalgams believe they are made sick by them [19]. Even if 0.1% of the amalgam using population were affected, this would imply that hundreds of thousands of US citizens are made sick needlessly.

There is no reason why anyone should suffer. A large variety of alternative restoration materials are available including: gold, glass isomers, and composites. It can take months or years before one is made aware of the problems caused by chronic mercury exposure and can takes months of treatment before one is rid of the effects. With your help, this significant source of mercury body burden can be eliminated.

Please consider enacting legislations curbing the use of mercury containing dental restoration materials.

Thank you sincerely for your attention to this matter,

Robert F. Cartland
University of Southern California
Electrical Engineering -Electrophysics

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52, Feb. 1997.

12. Non-toxic alternative dental restoration materials include gold, cast glass, porcelain, and composite resins. Many dentists currently conduct successful mercury-free practices.

13. Richardson, GM, Assessment of Mercury Exposure and Risks From Dental Amalgam; Final Report, Medical Devices Bureau, Environmental Health Directorate, Health Canada, 18 Aug 1995.

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amalgam. An exploratory questionnaire," Ned Tijdschr Tandheelkd, Vol.
101(7), pp. 268-72, Jul. 1994. [Article in Dutch] English abstract is available which includes the following: "it is concluded that probably 17% of the Dutch population regard amalgam to be potentially harmful. At least 4-5% worry about their health because of amalgam fillings and 2-3% attribute existing health problems to amalgam."

Dear Chairman Burton, Rep Diane Watson and Members of the Committee on Government Reform,

I am submitting for congressional record my personal story that I sent to the American Dental Association on June 15, 2000.

I am extremely grateful to this committee for looking into this important topic of mercury in dental fillings. I trust that given all the scientific information to show that mercury fillings are not safe and cause many health issues that the members of this committee will work to protect the health of all Americans by working to ban the use of mercury amalgam fillings.

Sincerely,
Mary Ann Newell

June 15, 2000

Dear ADA,

I want to be added to ADA's list of people with mercury poisoning due to amalgam/ mercury fillings. Here is my personal story that I share with everyone to include my state and federal officials. I am working hard to expose the dangers of mercury fillings because I know it is real. If you need copies of my test results, please don't hesitate to call me.

I am a 47 years old woman and consider myself a very lucky mercury poisoned survivor. I started getting sick in June 1995 and got sicker and sicker with time. I started going to my local traditional medical doctors looking for why I had the following symptoms:
1. Excessive saliva.
2. Constant sore throat.
3. A painful mouth including different teeth that hurt at different times but all the time.
4. The inability to distinguish tastes.
5. A constant metallic taste in my mouth.
6. I could not sleep on my right side of my face for over eight mouths because of unexplained pain.
7. Really dry skin.
My symptoms got worse with time and the doctors could not tell me why but they prescribed many drugs trying to mask my symptoms. None of the drugs ever worked. In January 1996, my husband and I wanted answers, we wanted a "WHY I was sick", so we went up to Oregon Health Science University (OHSU) in Portland, Oregon to get an ANSWER. Surprise, six months there and no answer either but lots more tests and more drugs. After going to five different medical departments, my symptoms had only gotten worse. I was sick and no one was helping me. Because of the metallic taste in my mouth, I started to wonder if my mercury fillings were the cause of my health

amalgam.

pp.1/5 ADA

The ADA statement makes an inappropriate misleading comparison between salt that is a covalently bonded compound and amalgam which is a mixture and has no covalent bonding. The statement by the ADA is in direct conflict with the statement by Lawrence Tabak, Director of the NIDCR, who correctly stated that amalgam is " a mixture_." When you squeeze salt you do not get free chlorine gas, but when you squeeze amalgam you get highly toxic elemental mercury vapor gas. The analogy between salt and amalgam is incorrect, inappropriate and misleading.

pp. 1/6 ADA

This paragraph alleges that epidemiological data dose not support the theory that people are made ill by dental amalgam and then goes on to claim that less than 100 cases of allergy have been reported. These are two different issues. Allergy to mercury and allergy to amalgam has been investigated extensively in the scientific literature by experts in allergy. The numerous documented effects of allergy to mercury in the scientific literature are; chronic atrophic dermatitis (1) , contact dermatitis (2)(3) (4) (5) , eczematous dermatitis (6) , multiple polyposis (7), generalized allergic reactions (8) (9) (10) (11), oral lichens planus (62% of those with lichens planus tested allergic) (12) (13) (14) (15), chronic oral ulcerations (16), and burning mouth (17). White and Brandt (18) found that greater than 10% of junior and senior dental students tested allergic and Miller et al (19) found a few years later that 31% of the freshman dental class had developed allergy to mercury chloride and that the amount of allergy was proportional to the number of amalgam fillings in their mouth.

Djerassi tested for allergy and found that of those with amalgams, 16.1% tested allergic, whereas none of the 60 control subjects without amalgams tested allergic. (20) That would make the total number of people in the United States who test allergic to mercury approximately 50,000,000 and not 100 as the ADA claimed.

Critics of this research will claim that the positive patch test is actually a chemical burn and is not related to mercury hypersensitivity. (21) This is unlikely because the controls for both the Miller study and the Djerassi study found that 0% of those who had no amalgam fillings were hypersensitivity to the mercury patch test.

pp. 1/7 ADA

Please accept this correction of my submission. There was a math error in the 4th paragraph. The number of people in the US who would likely test allergic to amalgam at 16% of the population would be more like 50 Million and not 1/2 million as typed. I've also included the reference for Gerhard's study of infertile German women.

November 24, 2002

Honorable Chairman Dan Burton, Rep. Diane Watson, and Members of the House Committee on Government Reform,

Thank you for the opportunity to participate in this discussion. I will attempt to keep my remarks as brief as possible however, the number of factually inaccurate statements by the ADA makes that task difficult. For the sake of clarity I will number the remarks. pp.1/5 ADA refers to page 1 paragraph 5 of the ADA statement. This report will rebut with references to the scientific literature the inaccurate and misleading statements made by American Dental Association (ADA) representative Rodney Mackert before the House Committee on Government Reform during the November 14th Hearings on Mercury released from dental

amalgam.

pp.1/5 ADA

The ADA statement makes an inappropriate misleading comparison between salt that is a covalently bonded compound and amalgam which is a mixture and has no covalent bonding. The statement by the ADA is in direct conflict with the statement by Lawrence Tabak, Director of the NIDCR, who correctly stated that amalgam is " a mixture_." When you squeeze salt you do not get free chlorine gas, but when you squeeze amalgam you get highly toxic elemental mercury vapor gas. The analogy between salt and amalgam is incorrect, inappropriate and misleading.

pp. 1/6 ADA

This paragraph alleges that epidemiological data dose not support the theory that people are made ill by dental amalgam and then goes on to claim that less than 100 cases of allergy have been reported. These are two different issues. Allergy to mercury and allergy to amalgam has been investigated extensively in the scientific literature by experts in allergy. The numerous documented effects of allergy to mercury in the scientific literature are; chronic atrophic dermatitis (1) , contact dermatitis (2)(3) (4) (5) , eczematous dermatitis (6) , multiple polyposis (7), generalized allergic reactions (8) (9) (10) (11), oral lichens planus (62% of those with lichens planus tested allergic) (12) (13) (14) (15), chronic oral ulcerations (16), and burning mouth (17). White and Brandt (18) found that greater than 10% of junior and senior dental students tested allergic and Miller et al (19) found a few years later that 31% of the freshman dental class had developed allergy to mercury chloride and that the amount of allergy was proportional to the number of amalgam fillings in their mouth.

Djerassi tested for allergy and found that of those with amalgams, 16.1% tested allergic, whereas none of the 60 control subjects without amalgams tested allergic. (20) That would make the total number of people in the United States who test allergic to mercury approximately 50,000,000 and not 100 as the ADA claimed.

Critics of this research will claim that the positive patch test is actually a chemical burn and is not related to mercury hypersensitivity. (21) This is unlikely because the controls for both the Miller study and the Djerassi study found that 0% of those who had no amalgam fillings were hypersensitivity to the mercury patch test.

pp. 1/7 ADA

The ADA alleges that dentists and their staffs suffer "no demonstrated ill effects on their health." This is patently false for a number of reasons. In California the CalEPA lists mercury as causing infertility. This is due in part to a case controlled study of California dental assistants that found a 40% decrease in fecundability (ability to conceive a child) of females involved in placing amalgams. (22) This evidence further confirms numerous studied dating from the late 70's that found infertility and birth defects from maternal exposure to elemental mercury vapor. (23) (24) (25) (26) (27) (28) (29) A large study of German women found that their fecundability was dramatically improved with amalgam removal and treatment for mercury poisoning. These women were exposed to mercury from their fillings and not from their occupations. (34)

Studies of dentists and dental personnel have shown that they suffer disproportionately from neurological impairment, kidney damage, cardiac arrhythmias and numerous other mercury related illnesses. (30) (31) (32)

pp. 5/5 The ADA statement alleges that the WHO supports their position on mercury which is not entirely true. While the dentists at the WHO do agree with the ADA the official WHO position based upon their scientific expert committee's review of mercury exposure from amalgam in 1991 estimated that a person with multiple amalgams would be exposed to 17 µg/day (micrograms per day). (33) This exceeds the minimum risk levels established to protect the public. They reviewed Rodney Mackert's research and chose to ignore it because it did not agree with numerous other relevant published studies.

In fact, even the NIDCR apparently does not agree with the ADA because on page 1 paragraph 4 they estimated the urinary levels range from 1.2 to 20 µg/day. The higher range would extrapolate to a total exposure of about 100 µg/day or 100 times higher than the level of exposure that Dr. Mackert estimated.

Both the ADA and the NIDCR touted the prospective study of young children looking for neurological impairment from receiving mercury-leaking fillings. This study is unethical, in my opinion, and very cleverly designed to not show a relationship. What parent would knowingly allow their child to participate in such a study of lead exposure much less mercury? The medical review board at the University of Calgary Medical School determined in 1985 that based upon the then available scientific literature that such experiments would violate the first tenants of medical ethics. In order to find a definitive result you must first harm a child.

Furthermore, no one is saying that first grade children suffer immediate harm from amalgams. Alzheimer's Disease is from a lifetime of chronic exposure to intra-oral mercury vapor. Autism is from fetal and neonatal exposure to mercury potentially from the mother's teeth or vaccines. There are separate genetic factors and numerous confounding variables that make the NIDCR study meaningless.

Lead research in the 70's confirmed that early childhood lead exposure produced profound risks of violent behavior and diminished IQ in adulthood. Adolescent and adult exposure did not carry the same risks. These studies are designed to show no effect and that is exactly what they will do. The NIDCR does admit however that, "Over the course of the trials several children have shown higher than acceptable urinary mercury levels." (pp. 4/1 NIDCR) Thus, the NIDCR has already confirmed our principal concern, that children and adults are exposed to measurable amounts of mercury leaking from their fillings.

Sincerely,

David Kennedy, DDS

Past President International Academy of Oral Medicine and Toxicology

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To: Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform.

I am recovering from mercury toxicity caused by the dental amalgams that were placed in my mouth begining when I was 6 or 7 years old. I'm 70 now and making a good recovery. At one time I had merury fillings in every molar in my mouth. Several years ago, when I had my fillings removed, I also had grey areas in my mouth where mercury had leaked into the tissues. That mercury had to be surgically removed. The cure has been expensive because the detoxification therapies are not covered by my HMO. We had to pay for the treatment out of pocket at a clinic that specializes in treating heavy metal toxicity. Of course, all the dental revision cost more than my dental insurance would cover. I thank God that we had the money to pay for my recovery. Many people with mercury toxicity are too sick to work; are disabled and haven't the money to pay for treatment that might enable them to work again.

Mercury affects many parts of the body. In my case, I had severe asthma, multiple chemical sensitivity, chronic nasal infections, some symptoms of MS, depression and anxiety attacks, muscular and joint pain, chronic peridontal disease (in spite of excellent teeth cleaning) Irritable Bowel Disease, peripheral neuropathy.

Since dental revision and chelation therapy I am no long hypersensitive to ordinary chemicals like fragrances, auto exhaust, and most cleaning supplies, though I now know better than to breath them on purpose. My chronic nasal infections are gone. I have not had an asthma attack in two and a half years. I'm now holding my chiropractic adjustments for long periods and have very little pain except occasionally in my right knee. My digestive tract is very good as long as I stay away from tomatoes and mushrooms. I still do have the tingling of peripheral neuropathy in both feet, but it is not now painful. I no longer have peridontal disease. My gums are healthy. I'm doing very well.

While not everyone becomes as sick as I was from their mercury fillings, I believe that it is time to end their use altogether, since there are plenty of other ways to fill teeth.

12/16/2002

November 25th, 2002

Dear Honorable Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform

Subject: For submission to the Congressional Record, November 14, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science.

My employer does not use mercury amalgam fillings any longer, due to the potential risk and the availability of alternatives. However, he does not tell patients they need to have their amalgams replaced. And he made it clear to me-not to tell patients to have their amalgams replaced, even though I am aware of its toxicity. What is the risk here for health care professionals? How come we are not allowed to mention the concern of mercury amalgam fillings? We know they are toxic. FEAR. Why are we fearful and of whom? The answer: the ADA still endorses amalgams and states they are safe, regardless of the science. Health care professionals fear litigation. It is a fact: amalgams do release a vapor. Incredible amount of vapor and I am scared to death to polish them. This is a health risk to myself, the patient and everyone exposed in the office.

On a more personal note-my older sister became ill shortly after the placement of her amalgam fillings during the early teens. She was randomly diagnosed with mono, epstein-barr, chronic fatigue, etc. I watched her struggle all through school. She experienced a general decline in her health. By 9th grade she began to have changes in her blood sugar, to problems with her menstrual cycles then severe fatigue. She also began to have food allergies and severe digestion disturbances She went to college to study chemical engineering. She was too ill to finish. Her allergies to more food became greater and the severe digestive disorders resulted in malnutrition, malabsorption and dysbiosis. In 1989, she was so ill she was admitted to the hospital. She was 5'10" and almost weighed a 100 pounds. My mother cared for her and had to make very special food preparations due to her numerous allergies. We almost lost her. She later developed seasonal allergies and then full blown chemical allergies.

Several alternative practitioners wondered about mercury. Unfortunately, it was not until 1996, that a naturopathic doctor diagnosed her illness as mercury poisoning. It was highly recommended for her to have her amalgams replaced. In 1998, a medical doctor came up with the same diagnoses after a challenge was done with urinalysis. She was recommended not to have children due to her serious condition. There are concerns whether she is able to handle the pregnancy, care for the baby and the potential risk to the fetus. Her condition is chronic and there has been a substantial amount of damage to her body. She has attempted to detox with DMPS, but became deathly ill and her body was not able to deal with it.

My sister has been chronically ill for 21 years of her life. She is 38 years old, an intelligent, wonderful, amazing and caring person. However, due to MERCURY POISONING her life has been put on hold and most of her days are in bed. Sometimes she can not even get up because she is so sick. Most of us take this for granted. She constantly deals with fatigue, migraine headaches and vomiting. (In addition to everything else that has been mentioned.) She suffers from toxicity and liver dysfunction. She has not been able to complete a college degree, hold a

job, have children or do normal everyday things. This spring she was diagnosed with peripheral neuralgia (dying back of her long nerves).

Mercury is a serious issue. Do not ignore the science.

Sincerely,

Karlene Waltman, Registered Dental Hygienist

To the Attention of Chairman Dan Burton, Rep. Diane Watson, and members of the Committee on Government Reform:

I am a concerned citizen who has been affected by mercury, and I am writing to support the discontinuation of the use of amalgam fillings due to the unnecessary damage they can do to a person's health. I was about 12 years old when I received my first mercury filling and had continued to have amalgam fillings placed in my teeth. Over the past 40 years I have seen many dentists and not one of them ever informed me that there was mercury in the material they used to fill my teeth. Consequently, over the years I had 15 amalgam fillings. All my molars had been filled and refilled and some had more filling than tooth. It seemed that no matter what I did, my ill health was increasing. I was referred to an environmental allergist who had me take a whole series of tests. One of the tests was the Red Blood Cell Elements which measured nutrient elements and potentially toxic elements. One of the toxic elements was mercury and my results from August 14, 2000 was in the 99% with a result of 0.25. Learning that I had extremely high levels of mercury and knowing what a hazardous substance it is as it is a hazardous waste and needs to be carefully and specially disposed of, I was horrified knowing I had so much in my mouth. I did a lot of reading and I decided I was going to have any and all amalgams removed and replaced with biocompatable materials. This also included the removal of 4 mercury tattoos that were in my gums. Upon removal, it was noted that several of the teeth were cracked and leaking mercury into my system. I was not surprised to learn this, as laboratory tests revealed high levels of mercury in my body.

Before removal of the amalgam fillings the most pronounced reaction I had which was immediately remedied by removal of the mercury was, that in the evening after eating dinner, the room would start to spin and I would feel dizzy, weak, nauseous and the room would appear to get darker. Since removing all my amalgam fillings I do not have these reactions anymore after eating. Other health issues I had before the mercury fillings were removed were: extreme insomnia, endless energy and restlessness, poor memory, difficulty concentrating and completing tasks, mental fog, nervousness, headaches, visual disturbances, muscle weakness, hypothyroidism, food sensitivities, chemical sensitivities, indigestion, leaky gut, parasites, candida, lowered immune function and antibiotic resistance.

Mercury has affected my life for many years in a negative way. It is a hazardous substance that wrecks havoc on the body. Although very costly, I have never regretted my decision to have all amalgam fillings and tattoos removed from my mouth! In support of the removal of the mercury was my latest Red Blood Elements test on September 19, 2002 with a result of mercury of 0.001 and just a dot on the percentile side.

Good strides have been made in the proper disposal for old mercury

thermometers and special protocols for mercury spills. With this in mind, how can it possibly be considered safe to be placed in a person's mouth? I am writing this letter in support for the discontinuance of mercury in dental fillings. It is not a safe product, and I do not want to see others needlessly go through what I have endured over the years. There are much safer alternative materials available and I do not understand why are these safer products not used exclusively.

As American citizens we have a right to be informed that Mercury can cause harm! I would like to see the use of Mercury discontinued entirely! I hope we all have the same goals in mind; that is the use of materials that are safe and do not cause harm to life and the needless further deterioration of our environment.

Thank you for reading my comments and your consideration of this extremely important issue!

Sincerely,
Marilynn Carter

Greetings Honorable Chairman Burton, Rep. Diane Watson and
Members of the Committee on Government Reform:

I would like to submit my testimony for the Congressional Record concerning my personal experience and detrimental health effects experienced because of the numerous dental amalgams put into my teeth over the last 33 years.

In 1969, 2 years after being diagnosed with insulin-dependent diabetes mellitus, eighteen cavities were filled with amalgam. I was never told by any dentist I saw, or by the dentist who filled these cavities, that dental amalgam could be dangerous to my health, especially in light of the diabetes. In 1973 after the birth of my son (after a stillbirth and several miscarraiges), my teeth literally began to disintegrate down to the gums. Numerous root canals, with amalgam posts, were put into those teeth. From1973 through 1988, numerous other new fillings and root canals were placed in various teeth. In 19981 began to experience severe complications from the diabetes, including retinoopathy of the eyes, digestive tract and kidneys. I began wearing an insulin pump in 1993 and for the next 7 years, until new complications forced me to get off the insulin pump and begin intense monitoring of blood sugar levels. In 1988 insensitivity to hypoglycemia resulted in convulsions as often as 2 times a month that required glucagon or 911 emergency treatment. In 1997 breast cancer woke me to the dangers of the synthetic filled diet I had been ingesting, and I immediately began eating only natural foods, preferably organic. In 2000 all upper teeth were removed after a bio-dermal test revealed what a toxic wasteland my mouth was, and it was a slow recovery from there. I am finally recovering my health. During the period from 1998 through 2001 my mouth, gums and teeth suffered a great deal, including outbreaks around the mouth, on the lps, of canker sores and breakouts that were painful and debilitating. I could hardly open my mouth without extreme pain.

I have done much to cleanse from my body the residues of the toxic products used all my life (all the 'commercial' synthetic products such as toothpaste and other personal care products, cleaning products and more. I know that the amalgam fillings I have had most of my life are responsible for the debilitating health effects I have suffered and continue to suffer.

Please restrain the use of mercury in fillings.

With sincerity,
Shirley Carroll

Dear Chairman Dan Burton, Rep. Diane Watson, and
Members of the Committee on Government Reform,

I almost died from the mercury vapors created from my mercury fillings when heat was against my head from my cellular phone for around 500 minutes per month. I came down with all kinds of health problems and almost died - had I not figured out myself what the problems were and had doctors who could help me. I know have diffuse sensory motor polyneuropathy, Grave's disease, thyroid eye disease, and heart problems. I had bone infection in my jaws under those mercury fillings and osteoporosis. I have biopsies, MRI's, and xrays showing the proof - as well as all my doctors. They all believed me when I told them what was going on. They didn't know what to do. I ALMOST DIED. God intervened and saved my life. I now have a website called www.tohellandback.com that tells what happened. I promised God I would tell the story later if he would get me to the doctors who could help. I had so much pain and burning in my head and neck - I would not be here today without the doctors and dentist who helped me.

Please ban mercury fillings for good. They do not belong in any human tooth. This action is for the good of our health.

Thank you,
Debbie Bevel

Dear Chairman Burton, Rep. Diane Watson, and Members of the House Committee for Government Reform:

I am a 58 year old dental consumer who had had 13 silver amalgam fillings placed in my mouth over a period of years. When I was 56 I began to have these amalgam fillings removed for health reasons.

It was in 2000 that I saw a dentist on an emergency basis for a broken tooth. During the course of his work, he explained to me that a different dental filling material might be better for me than silver amalgams as some people are adversely affected by these fillings due to the leaking of mercury from them.

When my next dental emergency occurred, this same dentist recommended all my silver/amalgam fillings be removed and replaced. My symptoms then included Lupus, allergies, Multiple Sclerosis (in remission since 1988) and Chronic Fatigue Syndrome (1992-1993) With each removal, I found myself becoming incrementally stronger.

Ten months after 2/3rds of my silver dental fillings were feplaced, I finally became strong enough to resume most of my normal activites. My experiences have shown me that mercury fillings were not safe or stable.

Thank you for this opportunity to contribute to your Committee's Congressional Record on this important matter which affects the health and safety of so many Americans.

Yours Truly,

Leslie Joy Smith

My name is Joyce Van Haaften. I am fifty-six years old, a farm homemaker,the wife of a sheriff and an anti-amalgam activist. I became an activist because of my experiences with amalgams.

I had a large number of amalgams even as a child and continued to have new ones added over the years. I was never told that amalgams emit mercury so I never worried about them. In 1991 I began to experience severe, burning pain in my head that never let up. During the next three years I also developed many other symptoms, including muscle spasms, partial numbness and tingling in the extremities, fatigue, concentration problems, unexplained restlessness and finally fine tremors.It was then that I heard about the possibility of mercury poisoning from dental amalgams.

At my request a mercury-free dentist removed my amalgams and took care to avoid exposing me to additional mercury during the removal process. My symptoms all disappeared within two months and never returned. I received no other treatment during that time and took no medication other than ibuprofen. I have no explanation for my getting well other than the removal of my amalgams.

I strongly support legislation to end the use of mercury in dentistry, not only because of my experiences, but because of scientific evidence that mercury amalgams are unsafe. I applaud your courage in holding a hearing on dental amalgam and I thank you for the opportunity to testify.

Joyce Van Haaften

November 26, 2002

Subject: For submission to the Congressional Record, November 14, 2002 hearing on "Mercury in Dental Amalgam: An Examination of the Science"

Attention: Chairman Dan Burton, Rep. Diane Watson, and Members of the U.S. House of Representatives Committee on Government Reform

CC: Representative, Jeff Flake, (R) - Arizona, Fax: (202) 226-4386

Dear Chairman Dan Burton, Representative Diane Watson, and Members of the Committee on Government Reform,

Bravo! You are my heroes! I appreciate you having hearings on this most important issue of mercury in dental amalgam fillings. I whole-heartedly support banning dental amalgam fillings and informed consent by dentists with patients. I have a personal experience that tells me unequivocally and scientifically that amalgam fillings are not safe.

Background: I was diagnosed with mercury poisoning from my dental amalgam fillings in 1999. I know from my own personal experience mercury from dental amalgam fillings is an acute immunotoxin and neurotoxin. I have had extensive testing done and know that I have no "autoimmune" disorder or allergy. I have reviewed the FDA's site regarding mercury levels in seafood. I eat seafood only occasionally on the order of less than 20 times per year. I do not regularly consume any of the seafood that is identified with high mercury levels as listed on the FDA's web site.

My initial symptoms of the mercury poisoning included extreme dizziness, fatigue, and impaired thinking. The source of the mercury poisoning was my dental amalgam fillings. The mercury poisoning was initially diagnosed using a DMPS challenge. I am still detoxing (chelating) elevated levels of mercury currently and have laboratory results from the last 3 1/2 years using a provocative challenge protocol. "Mercury binds very tightly to our cells...This is part of the reason mercury is so toxic."[1]

I have never been advised by the dentists, in any of the following states, that when they were putting silver colored fillings called amalgams that they were putting mercury in my mouth. I have lived in the following states as an adult and have had amalgams put in: IN, CT, TX, AL, and AZ.

None of the dentists in any of the states listed above have ever advised me about the potential dangers of the mercury in dental amalgam fillings. Nor have any of these dentists ever asked if I had kidney problems prior to placing dental amalgam fillings. Mercury is very toxic to the kidneys. It is my understanding that amalgam manufacturers label their product with warnings that amalgams are contradicted for anyone with kidney problems.

In 2000, I also had two nickel crowns and one gold crown removed. There were more mercury fillings underneath. During this removal, I had blood in my urine for a number of weeks following the additional removal of the fillings because of the stress that the mercury puts on the kidneys.

I have been told that leaving the amalgams in place when putting on a crown is a very common dental practice. I was never advised in neither CT nor AZ that the mercury fillings were being left under the crowns or any potential dangers.

I am concerned about the long-term impact on my health. The mercury poisoning from my dental amalgam fillings has taken a tremendous toll on my health, my quality of life, my family, my career, and my finances. I am still actively dealing with the health issues resulting from the mercury poisoning 3 1/2 years after my initial diagnosis.

I appreciate that there is a portion of the population that is more genetically susceptible. However, since the Food and Drug Administration (FDA), National Institute of Health/National Institute of Dental and Craniofacial Research (NIH/NIDCR), and the American Dental Association (ADA) cannot accurately predict which individuals are more at risk for mercury poisoning, then dental amalgam fillings should be banned.

I fully support the bipartisan efforts of Representatives Dan Burton(R) and Diane Watson (D) on HB 4163 to abolish mercury dental fillings in the U.S.

[1] Dr. Charles Schwengel, D.O., MD (H) Mesa, AZ.

Questions and Comments: I have a couple of questions and comments regarding the testimony on November 14, 2002.

1. ***Question: To whom and how do I report mercury poisoning from my dental amalgam fillings?***

   I have written the Center for Disease Control (CDC), NIDCR, and ADA with this exact question.

   I did file an online report using the FDA's Medwatch. However, I am not clear that the FDA tracks mercury poisoning from dental amalgam fillings. I have recently sent an email to the FDA's Center for Devices and Radiological Health (email DSMICA@cdrh.fda.gov) to see if they track mercury poisoning from dental amalgam fillings.

   The CDC sent my email to the NIH/NIDCR. The NIH/NIDCR sent an email back stating that *"Research to date has not proven that mercury-containing amalgams are harmful to anyone except those rare individuals who are hypersensitive to mercury. Our researchers state that if you have health problems, it is important for you to see a doctor who can correctly diagnose what the problem is and make sure that whatever may be causing it is addressed."*[2] NIH/NIDCR still has not told me to whom and how I report mercury poisoning. I have re-emailed NIH/NIDCR again re-asking the same question, "To whom and how do I report mercury poisoning from my dental amalgam fillings?"

   The ADA has not responded at all after 5 business days.

   Comment: If no one is tracking and reporting mercury poisoning from dental amalgam fillings, how can the FDA, NIH/NIDCR, and ADA be so sure that they are safe? Medical doctors are not required to report mercury poisoning. I personally have 2 friends that have also been also been diagnosed with mercury poisoning from their dental amalgam fillings by different doctors. Statistically, this is more than a rare individual who is hypersensitive from mercury.

2. ***Question: In the studies that Dr. Tabak, NIH/NIDCR referenced in his November 14, 2002 testimony before the U.S. House of Representatives Government Reform Committee, do the studies use a provocative protocol (e.g. DMPS, DMSA, or D-penicillamine) in the blood and urine analysis or are these unchallenged blood and unchallenged urine tests?***

   Comment: I have emailed the NIH/NIDCR and have asked this question. I have not received a reply from the NIH/NIDCR yet. Because mercury binds so tightly with our cells, mercury would not show up in blood or urine tests unless a provocating agent is used. Blood and urine tests without a provocating agent are called unchallenged tests. Provocating agents for mercury include DMPS, DMSA, or D-penicillamine. "Elemental analysis of hair can be a corroborating test for methylmercury burden, but mercury derived from dental amalgams is not nearly as readily incorporated into hair. Blood and especially blood cell analyses are only useful for diagnosing very recent or ongoing organic (methyl) mercury exposure."[3]

   In other words, mercury will only show in unchallenged blood or urine tests soon after a dental amalgam filling placement or removal. Unchallenged blood or urine tests will not show chronic low-level mercury poisoning. The testing protocols for total body burden of mercury are very similar to lead poisoning testing. If the NIH and/or FDA understand testing for total body burden from lead poisoning, then they also understand testing for total body burden from mercury poisoning.

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[2] Email November 26, 2002 from Sally Wilberding, Public Information and Liaison Branch, National Institute of Dental and Craniofacial Research, sally.wilberding@nih.gov, 301-496-4263 (T), 301-496-9988 (F).
[3] Doctors Data Urine Toxic Metals Analysis and Discussion, October 14, 2002.

3. ***Question: Could Dr. Feigal provide a list of "symptoms" of an allergic reaction to mercury?***

In his statement, Dr Feigal, Director of the Center for Devices and Radiological Health (CDRH) at the FDA stated, " By requiring disclosure of amalgam ingredients, the rule would help dental providers to quickly diagnose and treat rare allergic reactions arising from exposure to amalgam components." I could not find anything on the FDA's web site listing the symptoms of an allergic reaction to mercury.

Comment: I am really offended that Dr. Feigal would call mercury poisoning an allergic reaction. "Early signs of mercury contamination include: decreased sense of touch, hearing, vision and taste, metallic taste in mouth, fatigue or lack of physical endurance, and increased salivation. Symptoms may progress with moderate or chronic exposure to include: anorexia, numbness and paresthesias, headaches, hypertension, irritability and excitability, and immune suppression, possibly immune dysregulation. Advanced disease process from mercury toxicity include: tremors and incoordination, anemia, psychoses, manic behaviors, possibly autoimmune disorders, renal dysfunction or failure."[4] I asked 3 different dentists for over 10 years prior to being diagnosed with mercury poisoning about the metallic taste in my mouth. Not one of the dentists ever suggested mercury contamination. The signs of early mercury contamination do not resemble a traditional "allergic" reaction.

Let me close by relaying a story: A mercury thermometer was broken at a school in Flagstaff, AZ in 2000. The school was evacuated and a hazardous clean up crew was sent in complete with the hazardous substance suits.

I am appalled that a substance that is considered an environmental toxin is still being used in dentistry in this country. How could a substance that is hazardous to the environment not also be hazardous to humans? What really is behind the NIH/NIDCR and ADA's position that dental amalgam fillings are safe? What really is behind the FDA's "bipolar" policy on mercury?

Sincerely,

Carolyn Dohrenwend

To: Hon.Dan Burton, Hon.Diane Watson, and Members of the Committee on Government Reform

This is 2002. About 8 years ago, my father began experiencing rather dramatic memory loss which increased at an alarming rate. During this same time period I began to also experience memory loss so severe that I gave up teaching and turned my energy toward finding answers for the two of us.

I was introduced to two Japanese doctors visiting this country;they had a screening device which could measure the amount of toxins in the body. We targeted heavy metals, including mercury and did a complete examination of my father's brain. They were surprised to find such high levels, stating that they had not tested anyone with so much mercury in the brain.

I became a coordinator in the DAMS organization and I obtained much useful information.

Briefly, we had my father's amalgam fillings removed and began a detox protocol. The following year I had my amalgams removed and began a similar detox. He and I have gradually gained memory capacity. We were both generally in good physical health but our problems were specific to brain toxicity and memory loss. In my father's case, his situation had been really severe. He could not converse without crying because he could not remember what he was trying to say.He also suffered from intense temper flare-ups.

After many treatments, my father progressed far enough to move at age 84 to a new town, a new house and neighborhood, takes daily walks alone, and meets and greets new neighbors on a daily basis. This is a man who would not go out of the house as recently as 5 years ago for fear of meeting anyone who might know him.

As for me, I am teaching again and studying for my doctorate.

Submitted by June Wulff, CHNP

"For Congressional submission - November 14th Hearing"

MARY A. PUFF MINNEAPOLIS, MN 55391

We—millions of us—have been part of a vast medical experiment. It failed.

And the ADA knew—as did Big Tobacco and Big Pharmaceutical with the neurotoxins they also produce—but chose to keep quiet and punish those who spoke about the dangers of mercury amalgams. Having come back from the dead, paralyzed and bedridden with Multiple Sclerosis, I do not intend to remain silent.

Diagnosed by 3 neurologists at The Minneapolis Clinic of Neurology with Multiple Sclerosis in 1995, I—rather than following my doctor's advice to "get a wheelchair" —read "Is Mercury Toxicity an Autoimmune Disorder?" by Keith W. Sehnert, M.D., Gary Jacobson, D.D.S., Kip Sullivan, J.D. and fired my neurologist.

The following day I contacted Dr Gary Jacobson and began a month of removing so-called "Silver" (Mercury) Amalgams. During the first week of amalgam removal, as filmed by Twin Cities Public Television, I regained my speech, ability to walk, coordination in my paralyzed right hand, and cognitive acuity. Less than a month later, on December 19, 1995, I authored testimony and appeared as Expert Witness for"Informed Consent" legislation in Minnesota (S. 1229) in dental materials, vehemently opposed by President of MN Dental Board George Kinney and doctors from Mayo Clinic, arguing that it would "frighten" the public to know the composition of amalgams. Informed Consent legislation was defeated in Minnesota, with the opposition arguing the public does NOT have a right to know the composition of implanted dental materials—which leak, a fact the ADA has been forced to admit since 1984.

My Background Prior to Being Mercury-Poisoned by the ADA

I hold a BA from Carleton College, MA from The University of Chicago, and was accepted at Harvard and Columbia University Graduate School of Management, where I studied for an MBA while founding a management consulting practice in New York. Recipient of 3 fellowships to France, England, and Italy. For 20 years I served as Principal and Managing Director of ITAD, an international management consulting firm specializing in economic development in food and technology before becoming mercury toxic which ended my career. Strategies I developed and directed on our Teams include the largest wheat and dairy projects in Saudi Arabia and the Gulf states (www.almarai.com) and in 75 other countries.

I have suffered twin toxicities by being treated with the neurotoxin Prozac to treat the neurotoxic mercury-induced poisoning. Currently I am writing and producing a Film with from her manuscript "Twin Towers: Twin Toxicities." My first office in New York was on the 55th floor of World Trade One.

What We Know about the Trickster Mercury

The Greeks knew Mercury as Hermes: Commerce and Messenger God of thievery, invention, cunning, trickery, slight-of-hand, scribes.

Six months later in 1996, Attorney General Skip Humphrey and the MN Dental Board carried out a witch hunt and stripped my dentist, Gary Jacobson, who saved my life by using Hal Huggins' dental protocol, of his dental license. Jacobson was guilty of nothing more than refusing to obey the "high" standard of care (sic) which the ADA uses to mandate mercury: it is illuminating to discover who owns the patents to this high standard of care. The ADA and the manufacturers who profit by this poisoning. Orwellian language and fraudulent marketing ("silver") have disguised the true nature of dental fillings. I learned firsthand of the "gag" orders used by the ADA "ethics" to silence dentists who refuse to place mercury amalgams. I have read the ADA's entire 150 year history premised on using poison.

The ADA should be dismantled immediately and sued and stripped of its assets and despotic unregulated powers.

What Dentists imagine or pretend: MN Mercury Ban and Fighting the Gag Order

This fall however I will lobby to introduce the first Mercury Ban in Minnesota. As former member of the Board of Directors of the MN Civil Liberties Union, I have brought this issue to the Executive Director to abolish the MN gag order on dentists, as did Sandra Duffy and Attorney Charlie Brown in Portland, Oregon this year.

What I Know Now thanks to Dr Alfred Stock of the Kaiser Wilhelm Institute of Chemistry, Berlin

Metallic mercury is Hg as in amalgam and thermometers, as opposed to mercury salts as sublimate (HgCl2) or calomel (Hg2Cl2). ***Dentists imagine or pretend*** that Hg in amalgam is firmly bound as in a chemical compound or salt which is a "direct lie as any chemist knows" according to Mats Hanson, Phd of Sweden. Dr. Alfred Stock in the 1920s and even Talbot in 1874 directly demonstrated that Hg vapor is continously given off. My scientific advisors have stated: "I can hardly think of something **more unstable** than an alloy (solid solution) where the main component continously evaporates at ordinary temperatures." The dentists claim that once the alloy and Hg is mixed and "free mercury" has been squeeezed out (the non-binding Hg) the rest is firmly bound and can not come out except in "extremely small amounts" which only modern, sophisticated instruments can detect (Talbot could in 1874!) and Stock demonstrated that the amounts were not "small" at all—Dr Boyd Haley calls theses amounts "enormous." I have learned much from reading the published papers of Dr Alfred Stock of the Kaiser Wilhelm Institute of Chemistry, Berlin. When I found his papers I found a gold mine of information!

But the ADA ridiculed and suppressed the science: read their own accounts for yourself.

On November 14, 2002, Diane Watson of LA (D-CA) opened the Congressional Hearings with words of warning about the decades of testimony she has heard on the Mercury Amalgam: all of which have been spoken for two centuries since the American Society of Dental Surgeons published its early warnings in the 1840s. The opposing "quecksilber" (quicksilver "quacks" or Mercury users) of the ADA however *allowed and promoted* the toxic mercury because it "cost less" and prevailed: a 200-year financial blunder that created the largest mass poisoning history by man——should we let the ADA continue its deadly deception? Over my dead body, nearly literally.

Changes in the Brain

From my daily international metals lists, I have learned how ubiquitously mercury kills everything in our fragile pathways: in my case, I forgot my name, got lost everyday in my own home, lived in excruciating daily pain, becoming a 20th century Mad Hatter, suicidal, obsessive compulsive, an imbecile, born with 3 kidneys, a mercury-induced birth defect. Once I had been the Valedictorian.

It was in our celebrated Decade of the Brain of the 1990s that I collapsed from mercury in my brain. According to the numerous scientific studies and The Institute of Toxicology in Boca Raton, 89% of our body burden comes directly from our amalgams—it is all in your head. Huggins is right: (cf. *It's All in Your Head* and *Uniformed Consent*). From my files:

"Methyl mercury inhibits essential neurotransmitters in the Brain, resulting in loss of short- and long-term memory, poor concentration, cognitive dysfunction, incoordination and gait abnormalities, visual and auditory disturbances, i.e., blindness and deafness, decreased or aberrations of the sense of taste and smell, slurred speech, tingling and numbness of the extremities, especially of the hands and feet, tremors of the head and limbs, weakness and fatigue; all symptoms which are pathognomonic of multiple sclerosis.

Acetylcholine is the most prevalent neurotransmitter in the body and the primary neurotransmitter between neurons and muscles. The stomach, spleen, bladder, liver, sweat glands, blood vessels, and heart are just some of the organs that this neurotransmitter controls. The body's synthesis of acetylcholine is vital because of the neurotransmitters role in motor behavior and memory.

Low levels of acetylcholine can contribute to lack of concentration and forgetfulness and may cause light sleep. The body synthesizes acetylcholine from the nutrients choline, lecithin, and DMAE, and ancillary nutrient cofactors, such as vitamins C, B1, B5, and B6, along with the minerals zinc and calcium. Acetylcholine helps control muscle tone, learning, and primitive drives and emotions. It also controls the release of pituitary hormone vasopressin, which is involved in learning and in the regulation of urine output."

Loss of any life diminishes us, yet the trajedy of my World Trade Center must be seen against this Silent Holocaust: what is truly terrifying is the white smile of the ADA and its use of ***the most toxic*** heavy metal on earth—mercury—and its 150-year deceptive poisoning. Al-Queda is a mosquito in comparison to those terrorist cells in DC and Chicago who have maimed, brain-damaged, and chronically poisoned us until death—brought to you by by the unregulated American Dental Association.

Fire the ADA after Two Centuries of Deceit

Disband and Fire the ADA. Governor Grey Davis (CA) fired the CA Dental Board after failing for 10 years to draft an honest "Fact Sheet." We need courage. As I fired my Neurologists, who pooh-poohed any amalgam connection to neurology, while at the same time admitting they "hadn't read it and didn't need to read it."

The ADA suppressed this deadly information in Amalgam War I in the early 1800s; Amalgam War II in the 1920s; and now in Amalgam War III since the 1970s launched by the whistle-blower and courageous dentist who spoke out and was stripped of his license, Dr Hal Huggins.

I close my Testimony with this part of our history: Incidentally, on December 27, 2001 the ADA offered Huggins his license back, but with one small proviso: *that he never speak again about the mercury amalgam.* Huggins declined the offer to practice with a gag, prefering to retain his First Amendment Right until his death. While this may be the story of David and Goliath, it is important to remember who won.

For my brother Michael, who never had a life having been born with cerebral palsy to our mother with a mouthful of mercury who suffers 2 auto-immune diseases, and my other sibings who are plagued.

Chairman Dan Burton, Rep. Diane Watson, and Members
of the Committee on Government Reform.

Dear Mr. Chairman and members of the Committee on Government Reform:

My name is Dr. Murray Vimy, Clinical Associate Professor of Medicine at the University of Calgary, Canada. The ongoing issue of mercury exposure from dental amalgam is a direct bi-product of my published peer-reviewed research, published in the most respected medical research journals over the last 20 years. Much of our data has already been presented to you, as our research involved a co-operative effort of both Canadian and American institutions (e.g. Dr. Anne Summers, University of Georgia and Dr. Boyd Haley, University of Kentucky)

I trust you will not be swayed by the anecdotal opinions of dental associations, the dental manufacturing industry and dental 'academics" the likes of Dr. Mackert [a paid apologist for a number of dental groups, including the ADA and Syberon (one of the largest amalgam manufacturers)]

I am sending you several submissions. Our original published experimental works can be obtained by your staffs through Medline.

Should the Committee wish to have me present or debate this issue before it, I would be pleased to attend upon invitation. Regardless, this is one of the most important health issues facing the modern world. Since you represent the most powerful and democratic nation on the planet, your tasks and responsibilities extend far beyond your borders. Your decision on this issue will impact the health of future generation.

I remain, respectfully yours,

Murray J. Vimy, BA, DMD
Clinical Associate Professor
University of Calgary

MERCURY DENTAL FILLINGS:
ARE THEY LEGAL AND APPROVED?

Associate Professor Murray J. Vimy**

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June 19, 1996

Dental amalgams, commonly known as "silver" fillings, contain approximately 50% mercury by weight, mixed with an equal weight of the amalgam alloy containing silver (70%), tin (26%), Copper (4%) and a trace of Zinc. Dentists, as well as the general public, believe these mercury/silver tooth fillings to be certified safe for human use by the American Dental Association (ADA) and the United States Food and Drug Administration (USFDA). Actually, nothing could be further from the truth!

The ADA (a private corporation and professional trade union) and the American National Standards Institute (ANSI, a private corporation) have collaborated to set standards for dental materials in the USA. The ANSI/ADA document, "Recommended Standard Practices for the Biological Testing of Dental Materials", clearly states that the mixed dental amalgam requires biological evaluation and certification. Interestingly, the ANSI/ADA does not certify the mixed amalgam placed in your teeth. Rather, it separately certifies amalgam alloy (ANSI/ADA specification #1) and the mercury (ANSI/ADA specification #6), based upon physical characteristics and manufacturing qualities.1 It is apparent that neither of these specifications includes biologic testing for the components of the mixed dental filling material.

Dr. John W. Stanford, former Secretary for the ADA's Council on Dental Materials, Equipment and Devices, writing on behalf of the ADA has explained, "The amalgam does not form until the dentist mixes the alloy with the mercury. Therefore, dental amalgam per se cannot be certified. We cannot certify a reaction product made by the dentist."2 Unbeknownst to its membership, while the ADA steadfastly continues to advocate mercury/silver fillings based on 150 years of anecdotal use,3 it apparently places the burden of risk for the safety of mercury fillings in the hands of the individual practising dentist. In fact, the ADA has no legal authority to certify dental materials as safe for public consumption. Only the USFDA has that duty, as bestowed by the Congress and the President of the United States.

In 1976 under the direction of the President and the U.S. Congress, the USFDA was directed, under the Food, Drug and Cosmetics Act, to "evaluate all medical devices for human use" and to classify them according to "safety and effectiveness".4 A panel of "experts" was formed to review and advise on the safety of dental materials, instruments and devices. The chairman of this USFDA Dental Products Panel was Dr. John W. Stanford, who was at the same time also Secretary of the ADA Council on Dental Materials, Equipment and Devices. Rounding out the panel were 4 dentists, 1 dental laboratory technician, 1 dental school materials instructor, 1 consumer representative, and 1 representative person from the private dental manufacturing industry.5 Notably missing were experts from medicine, toxicology and medical physiology. Considering that the function of this panel was to ensure the medical safety of dental materials, a proper evaluation of dental amalgam was hardly possible. Apparently, the USFDA relied heavily on input from the ADA and as a result may have incidentally abdicated regulatory control. Recent USFDA Dental Product Panels have had similar voting membership.6

The USFDA operates under a specific rule stating that "voluntary or privately recognized performance standards will not be a substitute for the formal promulgation of standards under section 514 of this act for any device that is classified in the performance standard category."4

This USFDA Dental Products Panel declined to classify the mixed dental amalgam.21 Rather, it accepted private standards for dental materials, which the ADA developed and put forward as American National Standards. Two of the standards addressed the mercury fillings, covering the amalgam alloy and the mercury, separately. In an identical fashion to the ANSI/ADA specification, the USFDA initially recommended that the amalgam alloy component and the mercury component be considered as Class II devices. A Class II device, according to USFDA rules, acknowledges a potential risk for harm and requires documentation demonstrating safety.4 While recognizing the possibility of adverse reaction, especially to the mercury, the USFDA Dental Products Panel (1980) recommended acceptance of "dental mercury and amalgam alloy as safe and effective dental devices based only on the members' personal knowledge of, and clinical experience with, the device in the practise of dentistry"7 and one office environmental study published in the Journal of the American Dental Association.

The USFDA Dental Products Panel's Final Classification of Dental Devices (1987) accepted the mercury and the amalgam alloy as safe and effective devices, placing the mercury in a Class I category.8 According to USFDA rules, a Class I category is reserved for those devices that have been documented to present no health risk!21 The final classification for the amalgam alloy was still Class II. By placing mercury, a well known human toxin, into a category not needing research evidence of safety and by ignoring the requirement for experimental evidence of dental alloy safety, all USFDA Dental Products Panels since 1975 have contravened Congressional direction.9 This process has ensured that the ANSI/ADA standards became law. Nonetheless, United States law is clear on this issue. The USFDA must classify all medical/dental devices accepted for human use. If a dental device is not classified, then, it is not approved.10 The USFDA has still not approved the mixed dental amalgam material that the dentist places into your teeth.11

The USFDA employs two criteria when approving a product or device for human use. The product must be both safe and effective. Obviously alone, mercury is neither safe nor effective. Similarly, the amalgam alloy is not effective as a filling material unless mixed with mercury. To rationalize the FDA opinion, Dr. Lillian Yin of the FDA contended that the "FDA does not certify any product". Rather she claimed that the "FDA regulates manufacturers of medical devices. No manufacturer produces mixed dental amalgams. The mixed dental amalgam is prepared by dental clinicians."12 This sounds suspiciously similar to the ADA's position espoused by Stanford. But, one can reasonably argue that dentists are manufacturers - manufacturers of prosthetic tooth parts and therefore should be under USFDA rules. So, the USFDA was obligated, by law, to classify mixed amalgam. But, in a fashion similar to the ADA, the USFDA has placed the burden of risk for the safety of mercury fillings in the hands of the individual practising dentist.

In 1993, the Environmental Law Foundation charged 36 amalgam manufacturers and distributors for violations of Proposition 65 passed by California voters in 1986. This Proposition directed the Governor of California to publish a list of offending chemicals and mandates measures to prohibit individuals from "knowingly and intentionally" exposing others to these chemicals. Furthermore, information must be provided to consumers regarding chemicals that can cause birth defects and reproductive problems. Mercury has been on the list of offending chemicals since 1990.13 The Environmental Law Foundation then singled out and sued Jeneric Pentron (one of North America's largest amalgam producers and distributors) in San Francisco Superior Court. As part of their settlement, an agreement was reached where Jeneric Pentron would put warning labels on its amalgam packaging and furnish signs for California dentists to display in their clinics.14

The signs reads:

Warning

This office uses amalgam filling materials which contain mercury, a chemical known to the State of California to cause birth defects and other reproductive harm. Please consult your dentist for more information.

It was hoped that other dental material manufacturers would comply. On August 23, 1994, in a counter legal action brought by the American Dental Trade Association, U.S. District Court Judge Rudi Brewster ruled that the Proposition 65 cannot extent to dental amalgam. According to the judge, mercury and amalgam alloy are regulated only by the USFDA! The ADA News proclaimed, "the decision is a victory for the 10 companies from the American Dental Trade Association."13 Interestingly, John W. Stanford has recently retired as an employee of the ADA and now acts as a lobby consultant for the American Dental Trade Association. As part of his duties, he champions mercury fillings before the present FDA Dental Product Panel.15

In the last several decades, experimental medical research evidence, has questioned the safety of these mercury fillings.16 The experimental data disturbed many American dentists to such an extent that in 1987, the Code of Ethics of the ADA was amended, making the "removal of amalgams restorations from the non-allergic patient for the alleged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation or suggestion of the dentist, improper and unethical." 17 In the ADA's view, a dentist is "ethical" to place the mercury material and recommend its safety. But, if the dentist suggests that the mixed dental amalgam (not approved by the USFDA) is potentially harmful or that exposure to unnecessary mercury can result, then the dentist is acting "unethically". Clinically serviceable mercury fillings can be "ethically" removed if done for aesthetic reasons,; if done at the request of a physician; or if done at the patient's request (without prompting).

The ADA does not have the authority to regulate any aspect of the practice of dentistry. It is merely a professional trade organization - a union. Mary K. Logan, the ADA's General Counsel and Assistant Executive Director of the ADA Division of Legal Affairs, has stated this very clearly in response to the American Association of Endodontists and the American Endodontic Society, who are battling over the use of another questionable chemical - formaldehyde in root canal treatments. She asserts that "the ADA does not establish standards of care, nor does it recognize other dental organizations as responsible for doing so either... Standards of care are established only through a combination of case law, dental textbooks, opinion of dental experts, custom, scientific articles and the guidelines of professional societies."18

This statement is in marked contrast to what the ADA is actually doing. Some very fine traditional dentists, who's only transgression is that they oppose the use of mercury in dental practice, are undergoing the indignity of quasi trials by State Dental Boards, where constitutional rights are not always fully protected. Often these hearings lead to revocation of licensure and loss of livelihood. To stifle open debate of this issue, the ADA has publicly volunteered to supply "expert" witnesses, gratis, to encourage State Boards to prosecute "offending" dentists.19 And prosecute they have!

The ADA's Code of Ethics also clearly states, "dentists have the obligation of making the results and benefits of their investigative efforts available to all when they are useful in safeguarding and promoting the health of the public." 20 What is the dentist to do when faced with reputable experimental evidence demonstrating that mercury fillings are a potential health hazard? Does he inform his patients and risk censure? The ADA may be acting beyond its authority and by such intimidation tactics curtailing the dentist's freedom of speech and ability to practise, while at the same time jeopardizing the patient's freedom of choice by limiting appropriate informed consent.

Dental mercury fillings: Are they legal and approved? The evidence speaks for itself. Both the ADA and the USFDA are attempting to extricate

themselves from accountability. In so doing, they have placed the burden of responsibility on the practising dentists - the dentists who the mistakenly look to these very institutions for leadership and protection. And the patient - to whom does he turn for accurate advice? It is a pity, Very few dentists read medical research journals!

POST SCRIPT 2002
Little has changed since I wrote these words in 1996. The American Dental Association and its corporate friends still control the FDA and Congress with money. Hopefully, the Burton Committee will have the courage to bring about real change. As the Canadian dentist who undertook the academic challenge to prove "the safety or lack thereof of amalgam fillings, I now look to the south - to the U.S. Congress to step up and take charge. While the resent concern is towards external terrorists, perhaps it is time to look inward to those who subvert the health of all Americans and who pollute the environment in the name of profit.

Respectfully submitted,

Murray J. Vimy, DMD
Associate Professor of Medicine

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Chairman Dan Burton, Rep. Diane Watson, and Members
of the Committee on Government Reform.

Dear Mr. Chairman and members of the Committee on Government Reform:

My name is Dr. Murray Vimy, Clinical Associate Professor of Medicine at the University of Calgary, Canada. The ongoing issue of mercury exposure from dental amalgam is a direct bi-product of my published peer-reviewed research, published in the most respected medical research journals over the last 20 years. Much of our data has already been presented to you, as our research involved a co-operative effort of both Canadian and American institutions (e.g. Dr. Anne Summers, University of Georgia and Dr. Boyd Haley, University of Kentucky)

THE FOLLOWING REVIEW WAS PUBLISHED IN CHEMISTRY AND INDUSTRY, BY REQUEST OF THE EDITOR.

I hope this helps inform you as to the many facets of the "AMALGAM DEBATE".

TOXIC TEETH: THE CHRONIC MERCURY POISONING OF MODERN MAN.

Vimy, M.J. "Toxic teeth: the chronic mercury poisoning of modern man." Chemistry and Industry, 2 January 1994, p. 14-18.

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Running Title ? Chronic Hg exposure from dental fillings.

The issue of mercury exposure from dental "silver" fillings has gained considerable notoriety in the general media during the last decade. Specific attention has focused on the potential for human health consequences and the general well-being of the global environment. The modern silver amalgam (amalgam meaning mixed with mercury), traditionally known as a "silver" filling, has been employed as the principal tooth restorative material for over 180 years and presently accounts for 75-80% of all tooth restorations.1 These "silver" fillings contain approximately 50% mercury by weight, 35% silver, 13% tin, 2% copper and a trace of zinc.2 Each tooth restoration has a mercury mass of about 750-1000 mg and should more properly be called a mercury filling. They have a functional life of approximately 7-9 years, after which they are usually replaced with another mercury filling.3,4

Hundreds of metric tonnes of mercury are placed into teeth world wide each year and some of this material, as particulate waste from the dental office, finds its way into the sewerage and refuse systems.

Within the dental profession, the issue of mercury filling safety has cyclically recurred. After the introduction of the modern dental amalgam in 1812 by a British chemist, a "silver paste", which was a combination of silver filings from coins and mercury, became fashionable for tooth restoration. Since the coins were not pure, expansion of the material often resulted in tooth fracture and/or a "high bite". In America during the 1800s, concern regarding the possibility for mercury toxicity caused the American Society of Dental Surgeons to make mercury usage an issue of malpractice, mandating that its members sign an oath not to use mercury-containing materials. However, mercury fillings usage increased because it afforded an economic advantage to those dentists employing it; it is user friendly; and because of its durability in the mouth. By 1856, the American Society of Dental Surgeons was forced to disband due to dwindling membership over the mercury filling issue. In its place arose the American Dental Association, founded by those who advocated silver amalgam - mercury use in dentistry.5-7 Again in the 1920s, a controversy erupted after the publication of articles and letters by a German chemistry professor, who attacked mercury filling usage for possible toxic effects.8-13 That debate abated and the dental profession's opinion still remains unchanged.

Today, 182 years later, the American Dental Association has amended its Code of Ethics to make the removal of serviceable mercury fillings an issue of unethical conduct, if the reason for removal is to eliminate a toxic material from the human body and if this recommendation is made solely by the dentist.14 In the American Dental Association's view, a dentist is "ethical" to place the mercury material and recommend its safety. But, if the dentist suggests that the mercury fillings are potentially harmful or that exposure to unnecessary mercury can result, then the dentist is acting "unethically". Clinically serviceable mercury fillings can be "ethically" removed if: done for aesthetic reasons; at the request of a physician; or at the patient's request (without prompting).
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Release of mercury from dental fillings.
Mercury vaporizes continuously from dental fillings, being intensified by chewing,15,16 tooth brushing17 and hot liquids.18 After mastication or tooth brushing ceases, it takes almost 90 minutes for the rate of vaporization to decline to the lower prechewing level (Fig. 1).16 Also, the greater the number of fillings and the larger the chewing surface area, the larger the mercury exposure.15,16 Thus, the average individual is on a roller coaster of mercury vapor exposure during the day. Breakfast will cause the release rate to increase and just as the rate is slowing again it is time for the midmorning coffee break. Lunch, mid-afternoon coffee or tea, the evening meal, and a snack before bedtime all contribute to the daily exposure to mercury from dental fillings.

It is estimated that the average individual, with eight biting-surface mercury fillings, is exposed to a daily dose uptake of approximately 10 micrograms mercury per day from dental fillings.19 Select individuals may have daily doses 10 times higher (100 micrograms per day) because of factors which exacerbate the mercury vaporization. Some of these factors are: frequency of eating, chronic gum chewing, chronic tooth grinding behaviour (usually during sleep), the chewing pattern of the individual, consumption of hot foods and drinks, mouth and food acidity.16 Corroborating human autopsy evidence20-22 showed that brain and kidney tissues contained significantly higher mercury in individuals who had mercury fillings. Furthermore, the concentration of brain mercury in the subjects with mercury fillings correlated with the number of these fillings present.

The historically espoused opinion of dentistry insists that, once mixed, the mercury is locked into the fillings.23 The aforementioned body of experimental evidence suggests that their opinion is totally without merit. Despite these replicated research findings, many national dental trade associations still claim that mercury fillings are safe.24 They base their

conviction on the anecdotal facts that mercury fillings have been used for over 150 years, billions of fillings have been placed, and they do not see sickness or death from the mercury exposure.25 But, the diagnosis of mercury toxicity lies outside the purview of dentistry, falling more appropriately within the jurisdiction of medicine. Dental institutions do not have the scientific expertise or the resources to undertake the necessary studies to scientifically resolve this issue. Thus, the issue of mercury filling safety has not been suitably addressed until recently, when academic medicine became aware of this insidious exposure to mercury. From the medical perspective, dental amalgam fillings are a significant mercury source, having potential medical consequences.

Tissue uptake of mercury from dental fillings.
Recent investigations in sheep and monkey animal models demonstrate that dental mercury accumulates in all tissues of the adult, being highest in the kidney and liver. This accumulation is so extensive that it can be visualized on a whole-body image scan (Fig. 2).26,27 Research also shows that a high level of dental amalgam mercury in monkey kidney is still present at one year after mercury filling placement.28 Also, mercury from dental amalgam will cross the placenta and begin accumulating in the developing fetus within two days after the filling placement in pregnant sheep and is highest in the fetal liver then the kidney. The mother's milk also showed evidence of mercury, suggesting that the newborn would have an additional exposure to mercury.29 Recent human chelation studies show a association between urinary mercury excretion and the presence of mercury fillings.30-33 For example, one study showed that, after a chelation challenge with DMPS, urinary mercury excretion is significantly higher from subjects with mercury fillings than from those with no such fillings. It was concluded that at least two-thirds of the excreted mercury originates from the dental restorations.30

On the basis of the research cited here, there is now international scientific consensus that the mercury from dental tooth restorations constitutes the largest non-occupational source of mercury in the general population, being greater than all other environmental sources combined!34-36 Yet, the dental profession still insists, without evidence, that the exposure is insignificant and has no potential to produce harm.

Pathophysiological consequences of mercury from dental fillings.
During the last several years, medical research has demonstrated a relationship between mercury exposure and pathophysiology in various animal models.

In sheep exposed to mercury from in situ tooth fillings, kidney function has been shown to be impaired. After 30 days of chewing the sheep lost 50% of their kidney filtration ability; they began to have difficulty regulating sodium and they demonstrated a reduced albumin excretion. Control sheep treated with non-mercury dental fillings did not show such effects.37 In a study of 10 humans with mercury fillings, it was demonstrated that the plasma mercury level dropped by 50% and the urinary mercury level declined by 25% over a twelve month interval after filling removal compared to the pre-removal level. Most notable was the finding that 12 months after filling removal, the urinary albumin level was significantly higher than the level 4 months prior to removal.38 In the sheep, the placement of mercury fillings caused a fall in the urinary albumin, signifying renal pathophysiology. In humans, the removal of mercury fillings results in an elevation in urinary albumin, indicating a renal homeostatic readjustment. The agreement between this sheep and human data is remarkable.

In a recent collaborative paper between three North American universities, it was demonstrated in a primate model that oral and intestinal bacteria (eg. streptococci, enterococci, enterobacteriaceae) exhibit a significant increase in mercury and antibiotic resistance within two weeks following mercury filling placement.39 The mercury resistant bacterial species exhibited resistance to various antibiotics such as, ampicillin, tetracyclines, streptomycin, kanamycin, erythromycin, and chloramphenicol, which they had not demonstrated prior to placement.. This is the first

direct experimental confirmation of a non-antibiotic factor, mercury, producing antibiotic resistance. This occurs because in some bacteria mercury-resistance and antibiotic-resistance are encoded on adjacent small genetic sites within plasmids.40 When exposed to environmental mercury, this genetic material is activated to protect the bacteria from the lethal mercury. The plasmid is also replicated and passed on to other bacteria, insuring species survival. In so doing, the antibiotic resistance also spreads to the other bacteria. Antibiotic resistance is a important issue in medicine today.41 It has been estimated that 80% of mercury-resistant bacterial strains also show an increased resistance to one or more conventional antibiotics. Thirty percent of all hospitalized patients in North America receive antibiotic therapy42 and antibiotics compromise 10% of the total $5.1 billion drug sales in Canada during 1992.43 Moreover, ten of the top 20 generic drugs prescribed during 1990 in the U.S.A. were antibiotics.44 Yet, antibiotics appear to be losing their clinical potency and stronger antibiotic medications at increasing dosages are necessary to combat many common infections.41

Recently, investigations have suggested that mercury may be involved in common brain pathologies and that the source of the mercury is likely the dental fillings45-47 In a human autopsy study, brain tissue from persons having Alzheimer's Disease at death were compared to an age-matched group of control brains from subjects without Alzheimer's Disease. The only significant difference in metal content between the two groups was mercury, being considerably higher in the Alzheimer group. The mercury concentration was prominent in the hippocampus, the amygdala and particularly in the nucleus basalis, all brain structures involved in memory function. Other metals examined were not significantly different in the two groups of subjects. The effect of mercury on cental nervous system neuron membrane integrity has been examined and shown that mercury specifically affects tubulin, a brain neuronal dimer protein responsible for proper microtubule formation of brain neurons.48 Both in vivo and in vitro experiments demonstrated that mercury chelated to amino acids maintains an abnormal polymerization state of tubulin. This effect may produce neurofibrillar tangles. Such tangles are a recognized lesion of Alzheimer's Disease. Inorganic mercury affects ADP-ribosylation of the rat brain neuronal proteins tubulin, actin and B-50, in both in vivo and in vitro experiments.49 ADP-ribosylation is the rate limiting process involved in polymerization of tubulin and actin monomers into the structure of the neuron membrane. Most recently, our laboratory has demonstrated that ionic mercury and elemental mercury vapour markedly diminishes the binding of tubulin to GTP and thus inhibits the polymerization of tubulin which is essential for the formation of microtubule in the central nervous system50 These studies are direct quantitative evidence for a connection between mercury exposure and neurodegeneration.

Other investigations have examined the mercury hypersensitivity from dental amalgam in patients with and without oral lichen planus lesions.51-53 These studies showed that patient groups having oral lichen planus had a much higher incidence of mercury patch?test reactivity (16?62%) than did control groups (3?8%). Removal of the mercury fillings resulted in amelioration of the oral symptoms.

Governmental regulatory action concerning mercury fillings.
In 1987, the government of Sweden commissioned an "expert panel" to evaluate the available evidence regarding mercury filling safety. The panel concluded that mercury fillings were "unsuitable from a toxicological point of view". Based on this panels advice, the Swedish Socialstyrelsen announced that steps would be taken to eliminate dental amalgam usage and recommended that comprehensive mercury filling treatment on pregnant women should be stopped to prevent mercury damage to the fetus.54 Shortly thereafter, the German Ministry of Health (Bundesgesundheitsamt, BDA) issued an similar advisory.55 In October of 1989, the Swedish Director of Chemical Inspection (KEMI), responsible for environmental protection, declared that amalgam would be banned.56 In January of 1992, the German Ministry of Health (BDA) informed manufacturers of its intention to ban the production of amalgam.57 The BDA

removed low copper non-gamma-2-amalgam from the market and published a pamphlet recommending avoiding mercury filling use in individuals with kidney disease, children to age 6, and pregnant women.58 In August of 1992, the Swedish government suggested a timetable to phase out mercury fillings. Environmental concerns were used as the official reason for amalgam discontinuation, but the government did acknowledge the toxicological risk to patients and stated that mercury fillings should no longer be used in children by July 1993, in adolescent to age 19 by July 1995, and in all Swedish citizens by 1997.59 The Austrian Minister of Health announced that the use of mercury fillings in children would be banned in 1996 and discontinued in all Austrians by the year 2000.60 In 1994, the Swedish Dental Association acknowledged that its leadership had previously been incorrect in their position regarding mercury filling safety. They now support a discontinuation of mercury use in dentistry.61 Other industrialized countries, for what ever reason, appear to be side stepping the issue.

Conclusions.
As one might expect, the dental profession has not responded well to these data. Some national dental associations have attempted to influence public and governmental opinion by endorsing quasi academic symposia pervaded with amalgam advocates. These gatherings are non-consensus meetings often under government auspices, where the moderators responsible for drawing the conclusions are typically inclined toward the prevailing dental orthodoxy and the conclusions reached often blatantly disregard the experimental data presented.62 Most damning to the dental profession is that they have not advanced any reputable experimental evidence of their own to support their belief in mercury filling safety.

The medical research evidence has been clear for some time. Dental amalgam - mercury fillings - constitute a significant source of chronic exposure to mercury in the general population. This exposure is unnecessary and can not be justified by risk/benefit analysis. While incriminating medical research continues to be published, the dental profession persists in placing itself in the untenable predicament of advocating an anecdotal position of mercury filling safety. The mercury filling advocates can be criticized for their shortage of supporting research evidence; however, so can many mercury filling opponents, who irresponsibly go far beyond the limits of the experimental data, by suggesting that miraculous cures will occur after removal of the fillings. Still, the mercury exposure from dental silver amalgam is toxicologically significant and research into its possible effects is at an early stage. Perhaps a 1000 years from now, historians will look back and draw comparisons between the chronic lead poisoning of the Roman Empire and the insidious mercury poisoning from our toxic teeth.

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Dear Mr. Butcher:

I am a dentist, member of the IAOMT, and a friend of Mike Ziff and Boyd Haley, et. al.

I have written a review article entitled, "the case against amalgam," which contains the key points of the scientific literature that questions amalgam safety. It is supposed to be available soon on the IAOMT website, but there have been delays, and I thought I ought to make it available to you. You probably already have all this information, but perhaps this source can summarize it for you.

I hope attachments are ok - if not, I can mail you a hard copy.

By the way, I did mail a copy to Lawrence Pacheco in the office of my congressman, Mark Udall of Colorado, and I think Mr. Udall should be willing to come on board with HR 4163.

Thanks for your attention,

Stephen M. Koral, DMD

The Case Against Amalgam

The Case Against Amalgam 1
Amalgam releases significant quantities of mercury. 2
Mercury distributes to tissues around the body. 4
Maternal - fetal transfer of mercury 7
Adverse physiological changes due to exposure to amalgam mercury. 9
Risk assessment. 9
Immune System: 10
Renal System: 11
Intestinal Flora: 12
Are we dentists harming ourselves? 13
The unique neurotoxicity of mercury, and the Alzheimer's connection. 14
Neurite growth inhibition on video. 16
The anecdotes 17

The history of amalgam is, of course, familiar. The alchemists of China and Europe were fascinated with mercury, the only metal that is liquid at room temperature, and which would evaporate with mild heat. They knew that liquid mercury could dissolve powders of other metals, such as tin, copper or silver. European methods for using a paste of silver shavings dissolved in mercury as dental restorations were introduced to America by the Crowcour brothers about 1830. Problems with excessive expansion in early amalgam were solved in time by adding the other, now customary metals – tin, zinc, and copper. The formula and technique for using amalgam has remained virtually unchanged for the past one hundred years.

The "first amalgam war" started almost immediately. The toxic effects of mercury, including dementia and loss of motor control, were common knowledge in the post–Napoleonic era, and many dentists objected to the obvious disadvantage of using such a dangerous material in people's mouths. In 1845, the American Society of Dental Surgeons asked its members to sign a pledge never to use it. The economics were compelling, though, as they remain today. At a time when the only other feasible restorative material was gold, amalgam looked to be the restorative material for the masses. Then, as today, patients did not show signs of acute poisoning as they left the dentist's office, so there did not appear to be a problem. As the use of amalgam grew, the American Society of Dental Surgeons fell apart, and in 1859, the pro–amalgam faction formed the American Dental Association, the same organization that leads the dental profession in the USA to this day, and remains steadfast in its defense of amalgam.

The "second amalgam war" was provoked in the 1920's by Professor Alfred E. Stock, a leading chemist at the Kaiser Wilhelm Institute in Germany. Adverse effects on his own health from mercury in the lab led him to question the supposed safety of mercury from dental amalgam. His research concluding that there were adverse health effects was published in leading scholarly journals of the day. It touched off a debate that raged through the 1930's without a clear resolution, only to fade away in the storm of World War II.

We are currently in the advanced stages of the third amalgam war. The argument was reopened in the late 1970's, as modern methods of detecting the presence of trace amounts of mercury were introduced, including mass spectrophotometry and the Jerome mercury vapor detector. We have accumulated a formidable body of evidence establishing the chain of toxic events: 1) amalgam releases significant amounts of mercury; 2) the mercury distributes to tissues around the body, and is the biggest source of mercury body burden; 3) the mercury from amalgam crosses the placenta and into breast milk, resulting in significant pre- and post-partum exposures for infants; and 4) adverse physiological changes occur from that exposure on the immune, renal, reproductive and central nervous systems, as well as the oral and intestinal flora.

The most succinct review of this topic is: Lorscheider, FL, Vimy, MJ, Summers, AO. *Mercury exposure from "silver" tooth fillings: emerging evidence questions a traditional dental paradigm.* FASEB J. 9: 504-508 (1995). FASEB is the Federation of American Societies for Experimental Biology, and their journal is one of the world's highest rated scientific sources. They have published a number of important papers on this issue. We can link the reader to the abstract of the Lorscheider et. al. review (http://www.fasebj.org/cgi/content/abstract/9/7/504) , but it is such a key paper we encourage everyone interested to obtain a full text copy.

Organized dentistry could examine the emerging evidence and decide that it is time to change their minds about the traditional dental paradigm, although it appears more likely that they'll soldier on in denial. The four percent of dentists who think of biocompatibility first have long since abandoned amalgam, and the greater number who have joined the "esthetic dentistry" movement have, by and large, moved away from it as well. About 27% of US dentists are reported in 2001 to be practicing mercury free.[1] Will our profession accept a future of scientific progress and handle the legacy of amalgam in an enlightened way, or will we go down like DDT and asbestos, like big tobacco and nuclear waste?

This brief review will touch on the high points, the blockbusters in the case against amalgam. There is a vast literature on the subject, which can be accessed on *IAOMT References,* www.bioprobe.com , and www.altcorp.com/amalgampage.htm.

Amalgam releases significant quantities of mercury.

What kind of metal is amalgam? All the information about an intermetallic matrix of gamma and mu phases only serves to obscure the fact that the mercury is not all reacted. Figure 1 is a photomicrograph of a polished metallurgic sample of amalgam which has been pressed on by a micro-probe.[2] Where the probe touched the surface, droplets of free liquid mercury are squeezed out into view. This process does not require heating the sample, as some have objected; it was repeated down to the temperature of liquid nitrogen.[3]

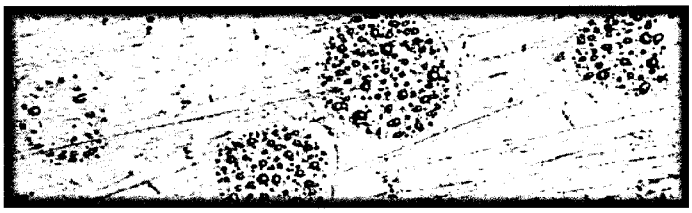

Figure 1 – Microscopic beads of liquid mercury expressed from the surface of amalgam metallurgical sample, following pressure from a microprobe. (from Masi, 1994)

The clearest, most gut wrenching way to comprehend that amalgam contains free mercury was discovered by IAOMT member Roger Eichmann, DDS. His demonstration is on the attached video clip. An extracted tooth containing an old amalgam filling is held in the light of a miner's blacklight, which is nothing but a fluorescent tube without phosphors – a pure mercury vapor discharge lamp. By the principles of atomic absorption spectrophotometry, the only cold vapor that could absorb the wavelength of mercury emission light and cast a shadow would be that of mercury itself. The filling in the clip has been rubbed with an eraser, to simulate the type of mild heating one would expect from chewing, grinding the teeth, or drinking hot liquids. Click on the button, and watch the steady emission of mercury vapor, like smoke from a smoldering fire.

show smoking tooth

This graphically dramatic process was hinted at by the fact that old amalgams contain significantly less mercury than new ones.[4 5] It was quantified in the human mouth by Svare, et. al., Gay et. al., Vimy and Lorscheider, and others.[6 7 8 9 10] By using a Jerome Mercury Vapor Detector and other methods, these groups were able to measure the mercury content of the air in the mouths of people with or without amalgams, before and after chewing. The baseline mouth air of people with amalgams contains more mercury than that of people without amalgams. After ten minutes of chewing gum, the mercury concentration in mouth air does not change in subjects without amalgams, while for those with amalgam fillings it increases 8 – 10 fold, and remains elevated for at least 90 minutes.

Vimy and Lorscheider derived an average absorbed mercury dose of 10 μg per day from amalgam fillings from their measurements of mouth air.[9] Other groups have reported varying estimates. On the low end, Mackert[11] and Berglund et. al.[12], by applying assumptions and inferences concerning how much mouth air is actually inhaled, arrived at average daily doses for subjects with twelve or more amalgam surfaces, of 1.83 and 1.7 μg, respectively (not zero). The question of inhaling the mouth air should be moot, though, because elemental mercury vapor is lipophilic, and is absorbed easily through cell membranes and mucosal barriers. On the high end, Patterson et. al.[13] reported absorbed doses of as much as 27 μg per day. Skare and Engqvist,[14] by metabolic methods, arrived at a figure of 12 μg per day for a group of subjects with an average of 47 amalgam surfaces.

The current best accepted reference on absorbed dose of mercury from amalgam fillings comes from the World Health Organization proceedings of 1991 [15], which was the report of a meeting of toxicologists and environmental health specialists (few dentists and no industry lobbyists, the opposite of the 1997 WHO meeting!). The conclusion of that group was that the average person in the industrial world with an average number of amalgam fillings, and no occupational exposure to mercury would absorb between 3 – 17 μg per day, with an average of 10 μg, from the fillings; 2.3 μg from all dietary sources; and 0.3 μg from all other environmental sources.

Mercury distributes to tissues around the body.

One of KO Frykholm's experiments in his landmark 1957 study [16] of mercury in amalgam involved giving eight volunteers four new fillings each, labeled with radioactive ^{203}Hg. He was able to detect excretion of the radioactive mercury in urine for seven days, and in feces for thirteen days. From this he concluded that the release of mercury from the fillings, while not zero, was self limiting, and should therefore be no problem for the exposed people. The "no problem" conclusion was not supported by toxicology, and there was no discussion of the possible retention in the body of some of that radioactive mercury. Nevertheless, this study has been relied upon by supporters of amalgam ever since, as proof that there is "no problem."

In the late 1980's, Murray Vimy, Fritz Lorscheider and their group undertook to use radioactive mercury to examine the question of tissue retention of mercury from amalgams fillings, in a series of experiments supported by the IAOMT. Vimy, a founding member of the IAOMT, is a general dentist in Calgary, Alberta, and Lorscheider, now retired, was a professor of physiology at the University of Calgary Medical School. They enlisted the help of the medical school's extensive animal program, and placed twelve occlusal fillings tagged with radioactive ^{203}Hg in the mouth of a sheep. The fillings were over-carved, not left high in the occlusion, as some have alleged, and the operators were careful to rinse all amalgam particles from the animal's mouth after placement. After twenty nine days, the sheep was killed, and the coronal portions of the teeth containing the radioactive fillings were removed. The sheep was placed in a full body gamma ray scanner, and the picture in figure 2 was the result.[17]

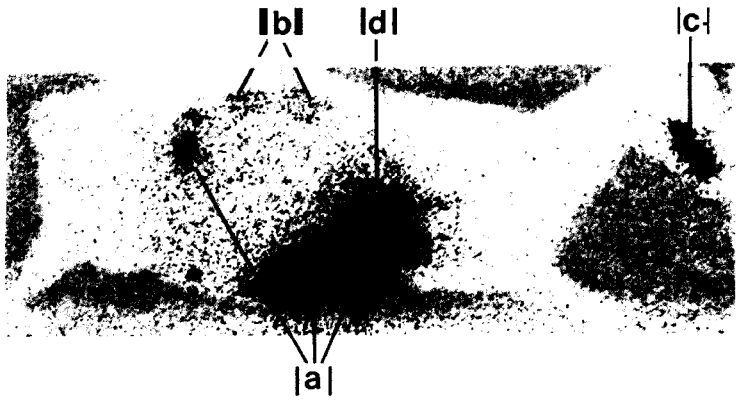

Figure 2 – Full body scan of a sheep 29 days after placement of 12 occlusal amalgams labeled with ^{203}Hg. The fillings were removed prior to the scan. (a) digestive tract. (b) kidneys. (c) gums and alveolar bone. (d) liver, partially obscured by the digestive tract. (From Hahn, et. al., 1989)

The graphic results are dramatic. Figure 2 is a full body gamma scan of the experimental sheep, showing translocation of radioactive mercury from the amalgam fillings into several organs. The teeth had been extracted prior to scanning, and the high concentration of radioactivity in the mouth region demonstrates movement of mercury into the jawbone from the fillings. The table below shows tissue concentrations of mercury that disseminated around the sheep's body. Control numbers would have been zero – all this mercury derived from the amalgam fillings, because the numbers were calculated from counts of radioactivity. In this experiment, the organ that accumulated the greatest amount of mercury was the kidneys, 7438 nanograms per gram of tissue (ng/g). The urine concentration was only 4.7 ng/g , demonstrating the inadequacy of plain urine samples as an indicator of mercury storage in internal organs. The order of magnitude of mercury accumulation in liver and kidney was confirmed by further studies using radioactive fillings in sheep.[18]

Tissue	ng Hg/g
Whole blood	9.0
Urine	4.7
Skeletal muscle (gluteus)	10.1
Fat (mesentery)	0.9
Cortical maxillary bone	3.6
Tooth alveolar bone	318.2
Gum mucosa	323.7
Mouth papilla	19.7

Tongue	13.0
Parotid gland	7.8
Ethmoturbinal (nasal) bone	10.7
Stomach	929.0
Small intestine	28.0
Large intestine	63.1
Colon	43.1
Bile	19.3
Feces	4489.3
Heart muscle (ventricle)	13.1
Lung	30.8
Tracheal lining	121.8
Kidney	7438.0
Liver	772.1
Spleen	48.3
Frontal cortex	18.9
Occipital cortex	3.5
Thalamus	14.9
Cerebrospinal fluid	2.3
Pituitary gland	44.4
Thyroid	44.2
Adrenal	37.8
Pancreas	45.7
Ovary	26.7

The dental establishment reacted with characteristic speed and determination. The "sheep experiment" was criticized for using an experimental animal that ate and chewed very differently from humans, and for not controlling for environmental factors, such as mercury in the diet. Of course, the experiment was not designed to look for mercury, but rather for radioactivity. There is no radioactive ^{203}Hg in nature, so any of it found could only have come from the fillings. The authors responded to the first criticism by saying that the sheep represents the "exacerbated case." If spread of mercury from amalgam could not be found in such a chewing machine as a sheep, the case would be closed, and the controversy over.

The same experiment was repeated using a monkey, which would eat much the same food and chew in much the same way as humans. The results, of course, were virtually identical to those found with the sheep.[19] Within twenty eight days, the radioactive mercury had spread around the monkey's body, yielding tissue concentrations that were highly similar to the sheep's. The monkey experiment was confirmed by Danscher, et. al.[20] in Denmark. Figure 3 is the full body scan of the experimental monkey. Again, the teeth were sectioned and the coronal fillings removed prior to the scan.

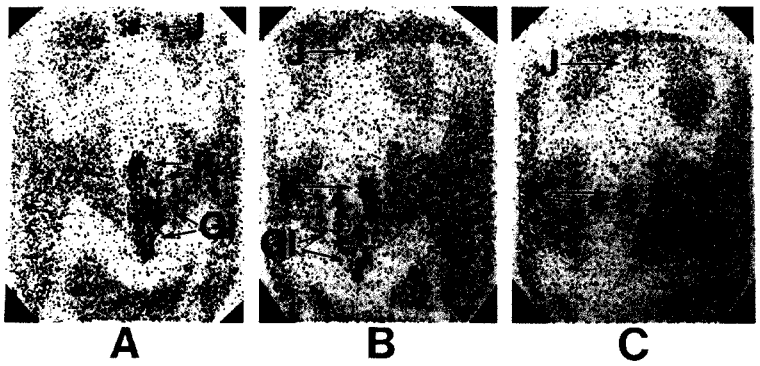

Figure 3 – Full body scan of a monkey 28 days after the placement of 16 occlusal fillings, labeled with ^{203}Hg, showing radioactivity in the jaws, kidneys and GI tract. (A) ventral view. (B) dorsal view. (C) dorsal view with the GI tract removed, clearly showing radioactive mercury accumulation in the kidneys. (From Hahn, et. al., 1990)

How is this "junk science," as it has been characterized in the dental press?

There is a large body of scientific literature that shows that amalgam–derived mercury spreads around the body, and that amalgam typically provides the greatest portion of the mercury to be found in the human body. Several autopsy studies showed a correlation between the mercury concentration in various tissues and organs of the human cadavers and the number of fillings or surfaces of amalgam present.[21 22 23 24 25] Blood levels of mercury correspond to amalgam exposure.[26 27 28] Subjects with amalgam excrete higher amounts of mercury in the feces.[29 30] Mercury in urine, blood, and feces declines after amalgam removal.[31 32 33]

Aposhian et. al.,[34] investigating the use of DMPS (2,3 dimercapto propane 1 sulfonic acid) as a chelating agent to remove toxic metals from the body, gave the drug to a group of subjects with amalgam fillings, and a control group of subjects who had never had amalgams. Urinary excretion of mercury in the non-amalgam group increased from 0.27 μg to 5.1 μg over a nine hour period, while among the amalgam subjects it went from 0.7 μg to 17.2 μg. They concluded that two thirds of the mercury excreted in the urine must derive from the amalgam fillings. They also reported a highly significant correlation between amalgam score and urinary excretion of mercury two hours after DMPS administration. Other labs report similar results.[35 36]

Maternal – fetal transfer of mercury.

Babies, with their still-developing nervous systems, are known to be more sensitive to the effects of mercury exposure than adults. Pediatric authorities say: "The developing fetus and young children are thought to be disproportionately affected by

mercury exposure, because many aspects of development, particularly brain maturation, can be disturbed by the presence of mercury. Minimizing mercury exposure is, therefore, essential to optimal child health." And "Mercury in all of its forms is toxic to the fetus and children, and efforts should be made to reduce exposure to the extent possible to pregnant women and children as well as the general population."[37]

This was made tragically clear in the case of the Minamata Bay methyl mercury poisoning, in Japan in the 1960's, where children were born with profound developmental disturbances, while the adults suffered much less. There is a substantial experimental literature on the neuro–teratological effects of mercury, where both humans and animals exposed to low doses of mercury *in utero* and soon after birth show measurable deficits in intelligence, coordination, and other measures of neurological development [38 39 40 41 42 43 44] (and hundreds more). And now there is an added controversy about vaccines preserved with thimerosal, a form of ethyl mercury, possibly causing neurological damage in infants, including autism. [45] Does amalgam use in dentistry really provide the unborn with a prenatal body burden of mercury?

Two more experiments by Vimy, Lorscheider and associates at the University of Calgary Medical School, supported by the IAOMT, provide some insight into the issue of amalgam–derived mercury exposure to the fetus and infant. In the first, [46] five pregnant ewes, at about 112 days of gestation, were fit with indwelling catheters that allowed the researchers to collect serial samples of maternal and fetal blood, amniotic fluid, plus maternal feces and urine. Each sheep received twelve occlusal amalgam fillings labeled with radioactive ^{203}Hg, as did the sheep in the original study. The various body fluid samples were collected for sixteen days, after which the sheep were sacrificed at intervals and tissue samples were analyzed for radioactive mercury. They found that the amalgam–derived mercury appeared in maternal and fetal fluids within two days of amalgam placement. Radioactive mercury was found in all post-mortem tissues studied. Tissue concentrations achieved steady state levels after about a month, levels that were maintained throughout the 140 day course of the experiment. The fact that tissue concentrations did not decline with time, as they would have with an acute, one time dose, implies that there was an ongoing exposure from the radioactive amalgam fillings. As before, the mothers concentrated the most mercury in the kidneys and liver, while the fetuses concentrated it in the liver and pituitary gland. Mercury concentration in the fetal blood was actually higher than in the maternal blood.

In the second study,[47] pregnant ewes received radioactive amalgams as before, and then nursed either their own lambs or foster lambs that had not been exposed to radioactive mercury in the womb. In the womb, the fetal lambs accumulated more mercury in the liver, while after birth the kidneys became the primary site of accumulation. Measurable quantities of radioactive mercury appeared in the tissues of both amalgam–bred lambs and those only nursed by amalgam–bearing ewes.

These studies are consistent with the work of other groups. For example, previous animal studies have shown that when the mother is exposed to Hg^0, the form of mercury that is emitted from amalgam, fetal tissues take up more mercury than when the mother is exposed to Hg^{2+}.[48] Drasch, et. al.[49] studied autopsy samples from human stillbirths and early post natal deaths. They found that the mercury concentration in the

infants' kidneys, liver and cerebral cortex correlated significantly with the mother's amalgam scores. Two labs also found that mercury concentration in human breast milk correlated significantly with the mothers' amalgam scores.[50 51]

Adverse physiological changes due to exposure to amalgam mercury.

So – all this exposure information is one thing, but as we have heard for years, "the dose makes the poison," and "no one has found dental amalgam to have caused any human disease, except for very rare allergic reactions." Very, very, very rare.

Well, it's not exactly true. It is true that in the huge body of information on mercury toxicity the greatest number of papers concern acute doses. Relatively few experiments have been done on chronic trace level exposure to elemental mercury vapor, and fewer still made use of amalgam as the mercury source. But there are some very provocative indications in the literature. A picture emerges, not of overt disease, but of many subtle (and some not so subtle) biochemical and physiological events that together constitute the pathophysiology of chronic low level mercury poisoning from exposure to dental amalgam. Certainly there are many suggestions that chronic exposure to mercury can contribute to big–name diseases. [see www.bioprobe.org for a bibliography, or read *The Toxic Time Bomb,* available on that site] But that concept is not necessary to warrant caution in using mercury. After all, who would wait for proof that lead or arsenic caused a "disease" before avoiding these known poisons?

Risk assessment.

In the early 1990's, Health Canada was sued by a group of consumer activists over a law requiring an evaluation of safety and effectiveness for all medical devices. They eventually forced the agency to apply that standard to dental amalgam. A staff specialist in medical risk assessment, G. Mark Richardson, was assigned the task of evaluating the available literature on mercury and amalgam, and to make recommendations concerning the health impacts of amalgam use in Canada.[52 53]

Richardson made detailed recalculations of mercury exposure from amalgams based upon the reported literature, and detailed recalculations of the level of mercury vapor exposure that would lead to "subclinical impairment of neurological and cognitive functions," based on the industrial hygiene literature. His general assessment was, in essence, that somewhere within the known range of mercury exposure from amalgam, there begins the known range of mercury exposure that produces neurological consequences. Based on his examination of the neurological data, he proposed a tolerable daily intake (TDI) of .014 μg Hg^0/kg-day, which was exceeded in all age groups by the average daily exposure from amalgam in Canada. In order not to exceed the proposed TDI, the maximum number of amalgam fillings allowed would have to be:

Ages 3 – 11	0 – 1
12 – 19	1 – 3

20 – 59	2 – 4
60 +	2 - 4

If the US EPA non–occupational "reference concentration" of 0.3 μg Hg/m^3 in air were to be used, 9 – 11 amalgam fillings would be acceptable in an adult. On the other hand, the US Agency for Toxic Substances and Disease Registry (ATSDR) published a minimal risk level (MRL) for non–occupational exposure of .014 μg Hg^0/m^3 in air. If this standard were used, even one amalgam would expose the individual to more mercury than would be allowed by Richardson's proposed TDI.

Richardson concluded that, "no clear threshold for subclinical neurological and cognitive function impairment is evident from published studies of the CNS effects of Hg vapor." In other words, no known safe level. Further, "the continued unconditional and unlimited use of amalgam as a dental restorative material, the placing of up to 25 amalgam fillings in one individual, is not supported by the available risk information."

The Canadian Dental Association called this report "unscientific," but later retracted that statement. Health Canada did not support a total ban on amalgam use, but, in 1996, did issue some restrictive recommendations: [54]

- Avoid using mercury to restore children's teeth.
- Avoid placing or removing amalgam in the teeth of pregnant women.
- Avoid using dental amalgams in patients suffering from kidney ailments.
- Use methods and equipment to reduce the risks of exposure to mercury vapor to protect their patients and their staff. [This is the subject of a later chapter in this on-line book.]
- Avoid using amalgams in patients who risk suffering from allergic hypersensitivity (5 to 15% of the population).
- On the advice of a physician, remove amalgams from a patient who has become sensitive.
- Avoid placing amalgam in contact with other metal appliances in the mouth (orthodontic appliances, etc).
- Fully inform patients of the risks and benefits involved.
- Recognize the patient's right to refuse treatment using a "specific material."

Immune System:

The "allergic hypersensitivity" to mercury issue is interesting. It is not very, very rare, as certain dental authorities would have us believe. The North American Contact Dermatitis Group, in 1972, determined that 5 - 8% of the US population demonstrates allergy to mercury by skin patch testing. [55] By using antibody – antigen flocculation tests on blood serum, the number is over 90%.[56] Djerassi and Berova [57] patch tested 180 subjects with amalgam fillings, and found that 16.1% of those without allergic disease, and 22.5% of those with allergic disease, tested positive for mercury allergy. Of sixty subjects without amalgam fillings, none tested positive for mercury allergy. In a study of

29 patients with oral lichen planus, 62% were positive for mercury allergy. [58] And at Baylor College of Dentistry, of 171 dental students patch tested, 32% were positive for mercury allergy. The percentage of positive tests correlated with the students' own amalgam scores, and with the length of time they had been in dental school. [59]

Mercury exposure is know to induce autoimmune reactions in susceptible animals,[60 61 62] and one investigation shows the same for amalgam. Hultman et. al.[63] implanted gelatin coated particles of either finished amalgam or unmixed silver alloy in the peritoneal cavity of mice known to be genetically susceptible to mercury–induced autoimmune reactions. Over the course of the experiment, both groups displayed their characteristic reactions of hyperimmuno-globulinemia, serum autoantibodies targeting nucleolar proteins, and systemic immune complex deposits. The authors ascribed the reactions in the alloy–only group to the silver component.

Think of the outbred human population, with its plethora of autoimmune diseases. We dentists have developed no method of screening our patients for contact dermatitis or for their susceptibility to metal–sensitive autoimmune responses. Knowing these mechanisms exist, how many such problems are we creating by using mercury – or nickel, for that matter?

Renal System:

Mercury, we now know, concentrates in the kidneys, and experimental evidence shows that it can inhibit kidney function. [64] But can mercury deriving from the presence of amalgam fillings have a direct effect upon kidney function? Once again in Calgary, six sheep received amalgam fillings, although they were not radioactive this time. Two control sheep received glass ionomer fillings. Renal clearance tests were performed before the fillings were placed and again at thirty and sixty days following. All six of the experimental sheep had a statistically significant decrease in their inulin clearance at both thirty and sixty days relative to the controls, with an average decline of 54%, $p < .01$. (see figure 4) They also had a significant increase in urinary sodium, and a decrease in urinary albumin as compared to the controls. The kidney tissue showed no structural change upon microscopic examination.[65] Molin, et. al.[66] reported that urinary albumin increased in humans one year after removal of amalgams. Mercury is known to concentrate in the proximal tubules, which are the primary site of sodium reuptake, so it makes sense that urinary sodium excretion increased if the mercury is inhibiting the function of those cells.

Although these effects could be described as "subclinical," in that overt disease was not caused, it demonstrates how much stress is placed upon the kidneys by the presence of amalgam, and suggests how patients with kidney malfunction may be endangered by amalgam fillings.

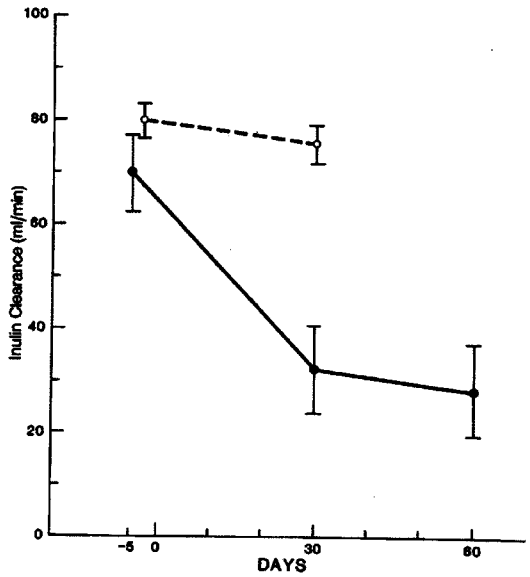

Figure 4 – Plasma inulin clearance (+/- SEM) of six sheep with twelve occlusal amalgam fillings (solid line) and two controls with glass ionomer fillings (dashed line). (from Boyd, et. al., 1991)

Intestinal Flora:

Anne Summers and her group in the Department of Microbiology, University of Georgia, were investigating resistance to antibiotics among intestinal bacteria when they discovered an unexpectedly high percentage of resistance in the flora of individuals who had had no recent exposure to antibiotics. They found that the genes for antibiotic resistance in these bugs were linked, on plasmids, to a gene for resistance to mercury toxicity. Therefore, subjects with a high percentage of mercury resistant bacteria in their intestines were significantly more likely to have bacteria with multiple antibiotic resistance as well. It was ecological pressure for mercury resistance that seemed to be maintaining the high prevalence of resistance in these gut flora samples. But where was the mercury coming from? [67]

To test the hypothesis that dental amalgam could provide enough mercury exposure to drive this ecological selection, monkeys were given amalgam fillings. Their intestinal flora showed a marked increase in the proportion of mercury resistant bacteria, and the increase was maintained until the amalgams were removed. Most of the mercury resistant microbes also possessed resistance to one or more antibiotics. [68]

The implication of this finding for human medicine is unproven, but disturbing to contemplate. At least it shows again that amalgam, while perhaps not causing overt disease, has a detectable effect upon the homeostasis of the body that is not benign.

Are we dentists harming ourselves?

One of the mantras chanted in support of amalgam has been that dentists' health status is not different from that of the general population, despite the fact that we are exposed in our work to mercury. Perhaps, one might say, that's due to the mercury hygiene rules promulgated by the profession – don't touch mixed amalgam with the hands while you pack it into patients' teeth, store scrap amalgam in tightly closed containers under various liquids to prevent vapors from escaping in the office, dispose of it with licensed hazardous waste handlers, etc. Even so, there is some evidence that mercury–exposed dentists and staff do suffer various effects.

In one study, dentists with high baseline urinary mercury levels showed neuropsychological and motor control deficits.[69] In another, dentists and staff with high mercury levels, proven by DMPS challenge, had altered porphyrin metabolism, as well as neurobehavioral changes, including impairment of attention, motor and perceptual skills, and increased irritability.[70 71]

The urinary mercury levels of 4272 dentists were measured at random at dental conventions by Naleway,[72] et. al., between 1975 to 1983. They found that dentists *on average* did not have urinary mercury concentrations outside "acceptable limits" and came to the conclusion that there was no problem with their occupational exposure due to amalgam. However, the urinary concentrations correlated significantly ($p<.001$) with the number of amalgams each dentist placed per week, and the range was tremendous. The general population has a range of 0 – 5 μg Hg per liter of urine, while 10.9% of the dentists in this study had over 30 μg per liter, including 1.3% with over 100 μg per liter! If the proportionality of mercury in urine to total body burden, as shown by the sheep and the monkey studies, holds true for humans, the dentists who use the most amalgam are storing prodigious quantities of mercury in their bodies.

In a survey of 7,000 female dental assistants, a subgroup of 418 women who placed over 30 amalgams per week, and had poor mercury hygiene habits, had a fertility rate of 63% that of control women not exposed to mercury. [73] Many other studies point to a negative effect of mercury vapor exposure on reproductive outcomes. [74 75 76 77]

Depression and mood alteration is a known feature of chronic mercury toxicity.[78] Dare we speculate that occupational mercury exposure plays a part in the suicide rate of dentists, which is higher than the population average?

The unique neurotoxicity of mercury, and the Alzheimer's connection.

The scene shifts to the Sanders-Brown Center on Aging at the University of Kentucky, which has a very active program for the study of Alzheimer's disease (AD). Autopsy specimens of the AD brain show certain diagnostic lesions – deposition of amyloid protein plaques, and neurofibrillar tangles, remnants of degenerated axons. There are characteristic biochemical lesions as well, including phosphorylation of tau protein, depletion of intracellular glutathione and creatine kinase, excess production of glutamine synthetase, and disruption of tubulin formation. Most of the research that we hear about in the press in the last few years has concentrated on the amyloid plaques, although amyloid deposition is found in many diseases, in other organs. The neurofibrillar tangle is more unique to AD, but there hasn't been an experimental system with which to study it until recently.

Following one track, Markesbury, Ehmann, Vance, and associates published a series of papers in which they described a variety of trace mineral changes in AD brain as compared to controls from patients with other psychiatric diseases or normal brains. They consistently found elevated concentrations of mercury, in various regions and subcellular fractions in the AD brain samples. [79 80 81 82] Other labs found elevated mercury in the blood and cerebrospinal fluid of AD patients. [83 84]

An examination of the same topic that was published with great fanfare in the Journal of the American Dental Association, along with press releases heralding the exoneration of amalgam, showed no correlation between amalgam history and AD, nor differences in mercury concentration between AD brains and controls.[85] This is the only paper in existence that presents such a position, contradicting those mentioned above, and the other human autopsy studies quoted earlier.

Meanwhile, Boyd Haley, a protein biochemist and chairman of the chemistry department at the University of Kentucky, was working on the tubulin synthesis defect in AD with his associate Kurt Pendergrass and their group. Haley had developed a chemical probe for the active site of an enzyme that he called "photo-affinity labeling," which has since become a standard tool in biochemical research. The technique involves a photoreactive chemical bridge between the substrate molecule and a radioactive $^{32}PO_4$ group. In the test tube, the target enzyme is allowed to react with the prepared substrate, and then exposed to light. The light causes the photoreactive bridge to disintegrate, allowing the highly active $^{32}PO_4$ to staple itself to the protein. If the enzyme's active site is not available, blocked by a mercury atom or other inhibitor, the photo-labeling will not take place. To summarize – if the active site is open, the protein becomes radioactive. If the active site is blocked, the protein is there, but does not become radioactive.

Haley, Pendergrass and associates used this technique to work out the biochemical mechanism behind the tubulin synthesis defect in AD, and linked it firmly to mercury. Tubulin is a structural protein in all cells, forming the girders and beams of the cytoskeleton. It is a large polymer made up of dimeric units, each having an α and β subunit. In order for the two to join, the β-subunit must bind a GTP molecule. The researchers found that the β-tubulin from AD brain could not bind photolabelled $^{32}PO_4$-GTP. The protein was there, but the active site was blocked! [86]

Taking a hint from their colleagues at the Sanders Center, they investigated the possibility that toxic minerals could be blocking the GTP binding site on β-tubulin. The story is told in extensive detail on Haley and Pendergrass' website, www.altcorp.com/amalgampage.htm. To make a long story short, it turns out that the binding site on β-tubulin is uniquely blocked by mercury, at extremely low concentrations in the 10^{-7} M range. Cadmium has a smaller effect, by orders of magnitude, and aluminum and lead have no effect at all. Excess zinc had a slight effect, but greatly increased the inhibitory action of the low concentrations of mercury. [87 88 89]

The mercury story is making its way in the laboratory, if not yet in the press. Recently, Olivieri, et. al.[90] reported that adding a very low concentration of mercury, 36 x 10^{-9} M, to neuroblastoma cells in tissue culture caused them to exhibit all the biochemical lesions of AD – inhibited tubulin synthesis, drop in intracellular glutathione, excretion of phosphorylated tau protein, and finally, excretion of β-amyloid. If most contemporary researchers think that amyloid is the cause of AD, here we have vanishingly small quantities of mercury causing amyloid in turn. The authors of this study suggest that mercury is the ultimate cause of these events.

Closer to our world, research shows that this test tube phenomenon can be induced in living animals. Mercury chloride has been shown to get into rat brains and inhibit the binding of GTP to β-tubulin,[91] and the same for elemental mercury vapor. Rats breathing 300 μg Hg^0 per cubic meter of air, a concentration that has been found in the mouths of people with lots of amalgam, for just four hours a day for fourteen days, had 75% inhibition of the photolabeling of β-tubulin with $^{32}PO_4$–GTP.[92 93] Did the rats become demented? That question was not asked. Perhaps this was a subclinical effect, one that did not cause overt disease. But is it not an effect we would wish to avoid?

The mercury story correlates with an epidemiological feature of AD. The age of onset of AD in the population is associated with the genetic variation of apolipoprotein–E, a "housekeeping" protein in the brain and cerebrospinal fluid. Its usual function appears to be transport of cholesterol. However, it comes in three genotypes, apo-E2, apo-E3, and apo-E4. Those individuals with apo-E2/2 almost never get AD, while those with apo-E4/4 tend to have early onset of the disease. Apo-E3 is intermediate. What's the difference among the genotypes? At amino acid position 112 and 158, apo-E2 has two of the sulfhydryl containing cysteine molecules. Apo-E3 has arginine at position 158, and apo-E4 has arginine at both places. In other words, apo-E2 has the most capacity to bind and remove divalent toxic metal atoms such as mercury as it moves from the brain into the cerebrospinal fluid, and out into the blood. Apo-E3 has less, and apo-E4 has none, at least by this mechanism.[94]

Dentists, we can be certain, have never screened patients for their apo-E genotype before exposing them to mercury in fillings.

Neurite growth inhibition on video.

What is it about Calgary? One of the few labs in the world that has the capacity to maintain growing neurons in tissue culture is at the University of Calgary Medical School. Very recently, a group there, supported in part by the IAOMT, published a paper and an accompanying video that shows how very low concentrations of mercury chloride, at 10^{-7} M again, causes the tubulin in the growth cones of young neurites to fall apart. [95] The subject cells were the large Pedal A neurons from the central ring ganglia of the snail *Lymnaea stagnalis*. The amino acid sequence of tubulin is at least 97% the same throughout the animal kingdom, so there is no difficulty comparing snail tubulin with human. Figure 5 is a series of still photographs from this experiment, which shows first the intact growth cone. Then the mercury solution is applied with a micropipette. Finally, seventeen minutes later, the growth cone has degenerated, leaving behind a tangle of neurofibrillar protein, reminiscent of those seen in AD brains. In another trial, growth-phase neurons in a culture medium containing 10^{-7} M mercury chloride failed to initiate growth cones. Other elements, aluminum, lead, cadmium and manganese were tried, but they produced neither effect.

The authors state: "Hg ions markedly disrupted membrane structure and linear growth rates of imaged neurites in 77% of all nerve growth cones. When growth cones were stained with antibodies specific for both tubulin and actin, it was the tubulin/microtubule structure that disintegrated following Hg exposure."

The complete paper is available on-line at this URL:
http://ipsapp002.lwwonline.com/J=1860&I=88&A=21&U=1&T=0

If you have a fast internet connection, you can view the video of this experiment at: http://movies.commons.ucalgary.ca/mercury/.

It is a miracle of nature and evolution that we are so elaborately protected from diseases and toxins. We have, in the case of mercury and the other divalent metal toxins, essential metabolic systems such as reduced glutathione, metallothionines, and apolipoprotein-E which double as protective elements. But, as we have seen in the case of apo-E, there are genetic variations and polymorphisms that inevitably leave some individuals more vulnerable to assault. We dentists may never have a perfect understanding of biocompatibility. We may always be forced into biological compromises with our need to implant synthetic materials in our patients' mouths. But let us at least minimize that risk where the science is firm. Amalgam has got to go. And if the mercury–Alzheimer's disease connection holds up, our profession is going to need some heavy rain gear.

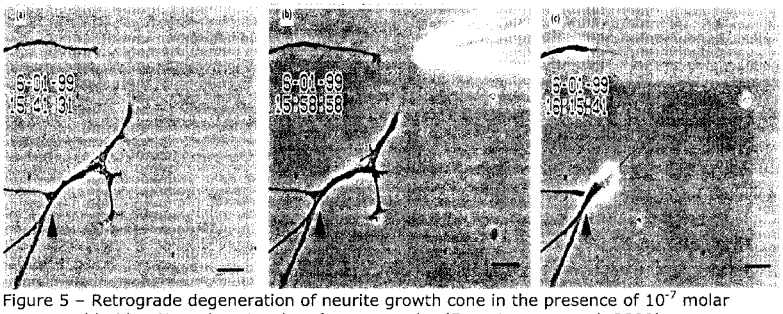

Figure 5 – Retrograde degeneration of neurite growth cone in the presence of 10^{-7} molar mercury chloride. Note the triangle reference mark. (From Leong, et. al. 2000)

The anecdotes

The world and the world wide web are full of anecdotes from people who claim their health improved once their amalgam fillings were replaced with other materials. These are real people with real life experiences, though their stories do not constitute scientific cause and effect evidence. Nevertheless, the scientific method requires that we observe natural phenomena, so as to gather ideas which we can try to develop into testable hypotheses. Where there's smoke there just might be fire.

The following is a summary of the subjective reports of 1569 patients who participated in six different surveys of health effects of replacing amalgam fillings. [96]

Symptom Reported	Percentage of patients claiming substantial relief
Allergy	89 %
Anxiety	93
Bad temper	89
Bloating	88
Blood pressure problems	54
Chest pains	87
Depression	91
Dizziness	88
Fatigue	86
Gastrointestinal problems	83
Gum problems	94
Headaches	87
Migraine	87
Insomnia	78
Irregular heartbeat	87
Irritability	90
Lack of concentration	80
Lack of energy	97

Memory loss	73
Metallic taste	95
Multiple sclerosis	76
Muscle tremor	83
Nervousness	83
Numbness	82
Skin disturbances	81
Sore throat	86
Tachycardia	70
Thyroid problems	79
Oral ulcers	86
Urinary tract problems	76
Vision problems	63

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Windhamcombined

From: Bernard Windham [mailto:berniew1@earthlink.net]

Subject: For submission to the Congressional Record, November 4, 2002 hearing on Mercury in Dental Amalgam: An Examination of the Science

Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform,

Studies document high mercury exposures from dental amalgam fillings and fish and common adverse neurological and cardiovascular effects

1. The largest source of mercury in most people is from dental amalgam fillings and exposures are commonly more than the federal health guideline for mercury due to mercury's high volatilization rate at room temperature and oral galvanism and EMF effects on mixed metals in the mouth. (1,2,3)

2. Approximately 50 percent of Florida lakes and rivers have fish consumption warnings due to high mercury levels and 20 % of all U.S. lakes have similar warnings. The majority of Gulf Coast saltwater predator fish species have levels of mercury documented to cause adverse effects. The majority who eat such fish at least once per week have been found to have dangerous levels of mercury. (4)

3. Dental amalgam is a larger source of methyl mercury than fish in many people, due to the high exposure from dental fillings and the methylation of elemental and inorganic mercury to methyl mercury by bacteria and other means in the body. Mercury exposures are cumulative and also synergistic with other toxic metals and other toxic substances for which exposures are common. (5,12)

4. Infants usually get higher mercury exposures than their mother's from prenatal exposures across the placenta from their mother and from breast milk. Mom's dental amalgam, fish, and mercury thimerosal used in vaccines are all significant sources of exposure for the fetus and infants. Mercury and other toxic metal exposures are the most common cause of children's neurological conditions like autism, ADHD, dyslexia, excema, etc. that have been rapidly increasing over the last decade. (6,7)

5. Studies have documented the mechanisms by which mercury commonly causes neurological and autoimmune conditions. Mercury has been shown to be highly cytotoxic, neurotoxic, and immunotoxic. Mercury has been found to bioaccumulate in the brain, central nervous system(CNS), heart, and hormonal glands and cause damage to nerve cells, blood cells, DNA, etc. and to block the function of the hormonal system and enzymatic processes of the body's cellular metabolic system. (8,9,10,13)

6. Medical studies have documented that mercury accumulates in the heart and has common adverse effects on the cardiovascular and circulatory system. (11)

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2. Summary of medical studies, Government studies, and Medical Lab clinical test results on exposure to mercury from amalgam fillings, B.Windham(Ed.) www.home.earthlink.net/~berniew1/damspr1.html

3. Oral galvanism and EMF: the Battery in Your Mouth, B. Windham(Ed.), Summary of peer-reviewed medical and dental studies, www.home.earthlink.net/~berniew1/galv.html

4. Mercury levels in freshwater and Gulf Coast saltwater fish and people who eat them, B. Windham(Ed.) Summary of government studies and tests, fish consumption warnings, mercury tests on people, and health standards;

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www.home.earthlink.net/~berniew1/damspr12.html

6. Developmental effects of mercury on children, Stejskal, V & Windham B; review of over 100 peer-reviewed medical studies, www.home.earthlink.net/~berniew1/fetaln.html

7. Cognitive and Behavioral Effects of Toxic Metal Exposure on Children, B. Windham(Ed.), Review of over 200 peer-reviewed medical studies on neurological effects of mercury and toxic metal exposure;
www.home.earthlink.net/~berniew1/indexk.html

8. Mercury''s endocrine disrupting effects on hormonal function(pituitary, thyroid,thymus, hypothallamous, reproductive system), B.Windham(Ed.), Review of peer-reviewed medical studies, www.home.earthlink.net/~berniew1/damspr8.html

9. Mercury''s neurological and autoimmune
effects(MS,FM,ALS,Parkinson''s,Alzheimer''s,Arthritis,ADD, Lupus, Depression, etc.)
www.home.earthlink.net/~berniew1/damspr9.html

10. Exposure levels and Mechanisms by which mercury causes over 30 chronic health conditions, and over 50,000 clinical cases of recovery from those conditions after reduction in mercury exposure and detoxification, B. Windham(Ed.) Review of over 2000 peer-reviewed medical and Gov''t studies,
www.home.earthlink.net/~berniew1/amalg6.html

11. Accumulation of mercury and mercury related plaques in the heart and circulatory system and adverse health effects. B. Windham(Ed.), Review of over 100 peer-review medical studies, www.home.earthlink.net/~berniew1/cardio.html

12. Amalgam dental fillings are the largest source of mercury in sewers and sewer sludge, which have high levels of mercury resulting in high levels of mercury in water bodies, fish, crops, and rain. DAMS, Inc.
www.home.earthlink.net/~berniew1/damspr2f.html

13. MELISA Medical Lab, MELISA blood immune reactivity test, www.melisa.org

The Mercury Connection to Allergies and Immune Reactive Conditions: allergies, asthma, eczema, diabetes, autism, etc. in children and chronic fatigue, Fibromyalgia, lupus, psoriasis, oral lichen planus, multiple sclerosis in adults. Review of over 1000 peer-reviewed medical studies and thousands of clinical cases found the following:

1. There has been a large increase in the incidence of allergic and immune reactive conditions such as allergies, asthma, eczema, diabetes, autism, etc. among children and in chronic fatigue, Fibromyalgia, lupus, psoriasis, oral lichen planus, multiple sclerosis, etc. among adults. (FS1, FS2, FS3, FS4, FS9, FS10)
2. Medical and clinical studies document that a high percentage of people are allergic or immune reactive to mercury to varying degrees, and that many millions are adversely affected by such immune reactive conditions, including many disabled by related autoimmune conditions. (FS1, FS3, FS9, FS10)
3. Clinical immune reactivity tests by medical labs document that high percentages of those with immune reactive conditions or chronic conditions are significantly immune reactive to mercury or other toxic metals. (FS1, FS9, FS10)
4. Peer-reviewed medical studies and clinical records document that many thousands of children and adults with mercury related immune reactive conditions have recovered or significantly improved after reducing exposures and proper treatment for mercury toxicity.
(FS1, FS2, FS9, FS10)
5. Studies researching the cause of the rapid of the rapid rise in children's immune

reactive and neurological conditions identified the high levels of mercury exposure from earlier and more frequent vaccinations that use mercury thimerosal as a preservative; along with significant prenatal and postnatal mercury exposure to infants from mother's amalgam fillings and breast milk. (FS1, FS3, FS4, FS5, FS6, FS9, FS10)
6. Medical studies, Government Scientific Panels, and thousands of clinical tests by medical labs have documented that amalgam dental fillings are the largest source of mercury exposure in most people, and that exposures from amalgam fillings commonly exceed Government Health Standards for mercury. (FS5, FS9)
7. Medical studies have documented the mechanisms such as immune reactivity by which mercury causes over 30 chronic health conditions, and many thousands of cases of recovery
or significant improvement after amalgam replacement or mercury detoxification. (FS9, FS10, FS1, FS2)

8. Mercury from amalgam fillings crosses a pregnant mother's placenta and accumulates in the fetus at levels significantly higher than in the mother's blood, and infants are also exposed to significant levels of mercury from mother's milk in those who have several amalgam fillings. (FS6, FS5, FS8, FS9)
9. The reasons for high levels of exposure to mercury in those with amalgam fillings include the volatility of mercury at room temperature, oral galvanic currents between mixed metals such as amalgam fillings and metal crowns, and currents induced by electromagnetic fields. This results in high levels of mercury in oral air, saliva, and then to other parts of the body. (FS8, FS7, FS5)
10. Mercury is extremely cytotoxic(kills cells), neurotoxic(kills and damages neurons), endocrine disrupting(accumulates and damages the hormonal glands and hormone function including reproductive effects and effects on IQ of children), and immunotoxic(kills cells and damages the immune system and immune function). Mercury is the most toxic substance people commonly come in contact with and so toxic that the drinking water standard is 2 parts per billion. Exposure from amalgam fillings or vaccinations are commonly much higher than government health standards. (FS9)
11. There are similar immune reactive and neurotoxic effects from other toxic exposures such as arsenic, lead, cadmium, nickel, pesticides, organochlorine and organophosphate chemicals, etc. The effects of mercury and other such toxic exposures are additive or synergistic. (FS9, FS10)

FS1. Immune reactive conditions: the mercury connection to allergies, asthma, eczema, chronic fatigue, Fibromyalgia, lupus, arthritis, multiple sclerosis, etc. B.Windham(Ed.) www.home.earthlink.net/~berniew1/immunere.html
FS2, Autoimmune conditions: CFS, FM, MS, Parkinson's, ALS, Alzheimer's, Lupus, Chron's, Scleroderma: the connection to mercury immune reactivity and amalgam fillings; B. Windham(Ed.) www.home.earthlink.net/~berniew1/indexa.html
FS3. Children's neurological and immune reactive conditions: the mercury connection to autism, ADD, eczema, allergies,etc.; www.home.earthlink.net/~berniew1/kidshg.html
FS4. Effect of Mercury and Other Toxic Metal Exposure on Cognitive and Behavioral Problems
of Children- including ADD, dyslexia, learning disabilities, juvenile delinquency, and crime; B. Windham(Ed.) www.home.earthlink.net/~berniew1.tmlbn.html
FS5. Common Mercury Exposure Levels from Amalgam Fillings High and Government Health Standards Commonly Exceeded, www.home.earthlink.net/~berniew1/amalno1.html
FS6. Transfer of Mercury from Mother's Amalgams and Breast Milk to the Fetus and Developmental Effects of Mercury on Infants,
www.home.earthlink.net/~berniew1/fetaln.html
FS7. Adverse Oral Health Problems related to Amalgam Fillings, B. Winhdam(Ed.) www.home.earthlink.net/~berniew1/periodon.html
FS8. The battery in your mouth: oral galvanic currents and metals in the mouth, and interactions with EMF , B.Windham(Ed.) www.home.earthlink.net/~berniew1/galv.html
FS9. Mercury exposure levels and health effects from amalgam fillings and results of replacement of amalgam filings. Over 2000 medical study references(most in NIH Medline) documenting common high mercury exposures from amalgam, and that vapor from amalgam is the most dangerous form of mercury to the fetus, and approx. 60,000 clinical cases of amalgam replacement followed by doctors;

FS10. V.D.M.Stejskal, Dept. Of Clinical Chemistry, Karolinska Institute, Stockholm, Sweden, LYMPHOCYTE IMMUNO-STIMULATION ASSAY -MELISA" & VDM Stejskal et al, "MELISA: tool for the study of metal allergy", Toxicology in Vitro, 8(5):991-1000, 1994; & V.D.M.Stejskal et al, "Mercury-specific Lymphocytes: an indication of mercury allergy in man", J. Of Clinical Immunology, 1996, Vol 16(1);31-40; & Sterzl I, Prochazkova J, Stejaskal VDM et al, Mercury and nickel allergy: risk factors in fatigue and autoimmunity. Neuroendocrinology Letters 1999; 20:221-228; www.melisa.org

Health Effects from Electromagnetic Fields(EMF) Exposure: the Mercury Connection

1. Reviewers for a comprehensive EMF risk assessment by the California Dept. of Health Services have determined that it is highly likely that EMF causes some forms of cancer, along with chronic neurological conditions like ALS, Alzheimer's, Depression, etc.

2. Medical and epidemiological studies have found strong evidence that EMF exposure causes some forms of cancer, along with neurological conditions like ALS, Alzheimer's Disease, Depression, etc.

3. One mechanism by which EMF causes these immune and neurological conditions is the fact that EMF has been found to cause significant increases in release of mercury into the body of those with amalgam dental fillings; and mercury has been documented to cause all of these immune and neurolgical conditions.

4. Amalgam dental fillings have been documented to be the largest source of mercury in most people who have amalgam fillings, with common mercury exposures more than Government health guidelines.

5. Most people get significant exposures to Electromagnetic Fields(EMF) from computer monitors, televisions, microwaves, other appliances, and power lines. These exposures have been found to significantly increase release and excretion of mercury in those with amalgam fillings.

Documentation:

In a long term comprehensive electromagnetic fields(EMF) risk assessment study by the California Dept. of Health Services, all reviewers concluded that it is highly likely that EMF causes some forms of cancer, along with chronic neurological conditions like ALS(Lou Gerhig's disease) and depression. They also found a significant likelihood that EMF causes cardiovascular problems and increased suicide(1). People are commonly exposed to electromagnetic fields from computer monitors, microwaves, televisions, other appliances, and power lines.

Actually there is strong evidence in the medical literature already supporting these conclusions and documenting mechanisms by which the effects occur. The evidence is based on the fact that chronic mercury exposure has been documented to cause all of these conditions (12-16), and EMF exposure has been documented to cause significant release of mercury into the body, including the brain and Central Nervous System, from those who have amalgam(2). Studies have found persons with chronic exposure to electromagnetic fields(EMF) to have higher levels of mercury exposure and excretion(2,9).</SPAN><SPAN STYLE="font-family: Times New Roman"></SPAN> Electromagnetic fields are known to induce current in metals and would increase the documented effects of galvanism(9,12-16). Amalgam has also been documented to be the largest source of mercury exposure in most people who have amalgam fillings(12,16).

EMF is also documented in animal and human studies to cause cellular calcium efflux and affect calcium homeostasis(3,4), which may be a factor in the reduction of melatonin levels caused by EMF exposure in animal and human studies(4,5). In studies on chicks this had significant adverse effects on viability of embryos and chicks. Melatonin is known to be protective against mercury and free radical activity, as well as regulating the circadian rhythm cycle and sleep cycle. EMF exposure lowers

melatonin production and disrupts the sleep cycle(5,8c). Another study provides evidence for an association between occupational electromagnetic fields and suicide(10). The authors indicate that a plausible mechanism related to melatonin and depression provides a direction for additional laboratory research as well as epidemiological evaluation. Occupational exposure to higher levels of EMF have also been found in many studies to result in much higher risk of chronic degenerative neurological conditions such as ALS(6), Alzheimer's Disease(7), Depression(11), as well as Leukemia and Cancer(8,6e).

Since EMF causes increased mercury exposure in those with amalgam, and mercury is also known to cause these conditions(13-16), it is not clear the relative importance of the factors since the studies were not controlled for mercury levels or number of amalgam fillings. But many suffering symptoms from EMF exposure/sensitivity have improved after amalgam filling replacement(4d,16).

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(B.Windham(Ed.), over 2000 peer-reviewed medical studies reviewed and referenced),

Mechanisms Documented by Which Mercury from Amalgam Dental Fillings and Vaccinations is a Cause or Major Factor in Over 30 Chronic Health Conditions1. Over 2000 peer-reviewed or Government studies have been compiled which document the mechanisms by which mercury from amalgam fillings is released in significant amounts and causes over 30 chronic health conditons. (1,6,7,8,9,5)

2. Over 60,000 clinical cases of recovery or significant improvement after amalgam replacement as followed and compiled by doctors have been documented. (3,1)

The conditions for which mechanisms of causality were documented and for which recoveries were documented include:

(a) autoimmune problems such as arthritis, MS, Lou Gehrig's Disease(ALS), Parkinson's/ muscle tremor, Alzheimer's, muscular & joint pain /fibromyalgia, chron's disease, lupus, scleroderma, Chronic Fatigue Syndrome(CFS), endometriosis , diabetes (6,1,5,3)

(b) neurological and mood disorders including memory disorders, depression , schizophrenia , insomnia, anger, anxiety & mental confusion, neuropathy/paresthesia, tinnitus, dizziness/vertigo,

headaches/ migraines, epilepsy, ADD, dyslexia, learning disabilities, hearing loss, (7,9,10,1,3)

(c) periodontal diseases such as gingivitis, oral lichen planus, amalgam tattoos, metal mouth, halitosis, oral keratosis(pre cancer); (8,4,1,3)

(d) immune system conditions such as allergies asthma, multiple chemical sensitivities, eczema, psoriasis, other skin conditions; cancer(breast,etc./ leukemia),susceptibility to infections, antibiotic resistant infection, sinus problems (6,7,1,3)

(e) cardiovascular conditions including tachycardia, angina, arteriosclerosis, other heart conditions, hypertension, and other blood conditions (1,3)

(f) hormonal problems such as hypothyroidism, adrenal problems, chronic chills, Hashimoto's Disease, alopecia/hair loss, urinary/ prostrate problems, (9,1,6,3)

(g) reproductive problems such as infertility, reduced sperm counts, PMS, spontaneous abortions, birth defects, children with learning disabilities and low IQ, etc. (2,7,1,3)

(h) chronic eye conditions: inflammation/iritis/ astigmatism/myopia /cataracts/macula degeneration , color blindedness, vision disturbances, etc. (1,3)

(i) stomach/digestive problems including leaky gut, malabsorption of essential minerals and essential fatty acids, blocked cellular enzymatic processes related to the ATPASE energy function and sulfur oxidation. (1,7,3)

(j) Allergies and Immune Reactive Conditions: allergies, asthma, eczema, diabetes, autism, etc. in children (7,5,12,1)

Mercury is the most toxic substance people commonly come in contact with and in the

top 3 of toxics causing large numbers of adverse health effects(EPA/ATSDR, 1).

Large numbers of medical and clinical studies, hundreds of thousands of tests by medical labs, Scientific Panels, and Government Agencies have confirmed that amalgam dental fillings are the largest source of mercury in most people(11,1). Studies have also confirmed that other forms of mercury are methylated in the body to methyl mercury by bacteria, etc. and amalgam is the largest source of methyl mercury in most people, even more than fish(11). Studies have also confirmed that exposures from amalgam are commonly more than the EPA/ATSDR mercury health guidelines(1). The reason for the high exposure levels from amalgam are mercury's high volatility that means it is constantly vaporizing, along with galvanic electric currents caused by mixed metals and EMF in the mouth that drive mercury and other metals into the body. These are easily measured which has been widely documented. (4,1)

Mercury's extreme cytotoxicity and neurotoxicity is a major factor in the neurological conditions, along with its inhibition of basic enzymatic cellular processes and effects on essential minerals and nutrients in cells(1). Mercury is also documented to cause imbalances in neurotransmitters related to mood

disorders(1,10,7). A direct mechanism involving mercury's inhibition of cellular enzymatic processes by binding with the hydroxyl radical(SH) in amino acids appears to be a major part of the connection to allergic/immune reactive conditions such as autism, schizophrenia, lupus, eczema and psoriasis, scleroderma, and allergies(5,7,1). Immune reactivity to mercury has been documented by immune reactivity tests to be a major factor in many of the autoimmune conditions. (12,7,6,1)

The studies also document that mercury from amalgam or other sources such as fish crosses a woman's placenta readily and accumulates to levels in the fetus at levels usually higher than in the mother(2). And that mercury in the mother is transferred at significant levels to a breast feeding infant. The fact that children have been exposed to levels of highly toxic mercury thimerosal in vaccinations well beyond Government health guidelines for mercury is also well documented(7). Studies document that such mercury exposures can cause developmental conditions and disorders such as autism, ADD, dyslexia, learning disabilities, eczema, etc. (2,7)

There are extensive documented cases where removal of amalgam fillings led to cure or significant improvement of these serious health problems. Over 60,000 such clinical cases are compiled in the documentation as followed and compiled by doctors. The over 60,000 cases of cure or significant improvements were not isolated cases of cures; the clinical studies indicated a large majority of most such type cases treated showed significant improvement. (3,1)

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60,000 clinical cases of amalgam replacement followed by doctors

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Chairman Dan Burton, Rep. Diane Watson, and Members of the Committee on Government Reform

"Dental Amalgam Fillings" are the Number One Source of Mercury in People and Exposure Exceeds Government Health Standards for Inorganic mercury(vapor) Bernard Windham(Ed.) - Chemical Engineer

Government agencies and medical studies have found that the number one source of mercury in people is from dental amalgam fillings(ref 2-20,26,27). Exposure from fillings amounts to from 50 to 90 percent of exposure, with the average being about 80 % of total exposure(5-9,12-15,19,20,26,27). The studies found that mercury amalgams are unstable due to mercury's low vapor pressure and galvanic action(24), leaking mercury vapor continuously into the lungs and saliva at levels exceeding health standards. The amount of mercury released by a gold alloy bridge over amalgam over a 10 year period was measured to be approx. 101 milligrams(mg)(60% of total) or 30 micrograms(ug) per day(21b), and other studies have found similar results for amalgam fillings(21a).

Mercury exposure of most people with fillings was found to exceed government health standards and levels found to cause adverse health effects(see below).

The tolerable daily exposure level for mercury developed in a report for Health Canada is .014 micrograms/kilogram body weight(ug/kg) or approximately 1 ug/day for average adult(2). The U.S. EPA Health Standard for elemental mercury exposure(vapor) is 0.3 micrograms per cubic meter of air(1). The U.S. ATSDR health standard(MRL) for mercury vapor is 0.2 ug/ M3 of air, and the MRL for methyl mercury is 0.3 ug/kg body weight/day(4). For the average adult breathing 20 M3 of air per day, this amounts to an exposure of 4 or 6 ug/day for the 2 elemental mercury standards. The EPA health guideline for methyl mercury is 0.1 ug/kg body weight per day or 7 ug for the average adult(1).

The range of mercury exposure levels found in people with amalgam fillings by

the World Health Organization Scientific Panel on Mercury was 3 to 70 micrograms per day(3), with other medical studies finding up to 500 ug/day in gum chewers or people who grind their teeth(6,11,16,17,18) or some with large numbers of fillings. The average amount absorbed was above 10 ug/day (ref. 3-18). The average mercury exposure for a Canadian adult with amalgam fillings was found in the Health Canada study to be 9 ug/day(2). In a large German study with 20,000 tested subjects at a University Medical Clinic, the average exposure from fillings was over 10 ug/day and over 50 % of all those with 6 or more amalgam fillings had daily exposure exceeding the EPA health guideline(6).

Note that the amount of mercury excreted in feces, as opposed to absorbed, is much higher than most of these estimates of mercury absorbed by the body. Daily excretion

through feces amounted to from 30 to 190 ug of mercury, being more variable than other paths(7). Other studies had similar findings(9,12,17-19) . Most with several amalgams had daily fecal excretion levels over 50 ug/day. The reference average level of mercury in feces(dry weight) for those tested at Doctors Data Lab with amalgam fillings is .26 mg/kg, compared to the reference average level for those without amalgam fillings of .02 mg/kg(27). (13 times that of the population w/o amalgam). Other labs found similar results(27). This level of mercury gives a daily excretion of over 30 micrograms per day. There is also evidence that amalgam is also the largest source of methyl mercury in most people with amalgam, based on studies and medical lab tests of those who have amalgam replaced(26,27,12). Mercury vapor and inorganic mercury have been documented to be methylated to methyl mercury by mouth and intestinal bacteria, along with candida albicans and other methyl donars(28), so that even people who don't eat fish but do have several amalgam fillings have high levels of methyl mercury in saliva and blood.

Studies have consistently found modern high copper non gamma-two amalgams have greater release of mercury vapor than conventional silver amalgams (21-23,25). Recent studies have concluded that because of the high mercury release levels of modern amalgams, mercury poisoning from amalgam fillings is widespread throughout the population"(17,22,18,6).

Common levels found in persons with amalgam fillings are over 10 times the Health Canada TDE, and more than the EPA health standard for mercury vapor. Thus persons with amalgam fillings have levels of intraoral mercury vapor and body exposure levels higher than the level considered to have significant health risk.

The studies found that Total mercury intake is proportional to the number and extent of amalgam surfaces, but other factors such as chewing gum and drinking hot liquids influence the intake significantly increasing exposure as much as 500%.).

A World Health Organzation Scientific Panel concluded that a safe level of mercury exposure below which no adverse effects occur has never been established(3)

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Oral galvanism and Electromagnetic Fields(EMF): factors along with mercury's high volatility and extreme toxicity in significant exposure levels and oral effects from amalgam fillings.

Having dissimilar metals in the teeth(e.g.-amalgam, or gold and mercury, or stainless steel and mercury) causes galvanic action, electrical currents, and much higher mercury vapor levels and levels in oral tissues. (1-11,30) The amount of mercury released by a gold alloy bridge over amalgam over a 10 year period was measured to be approx. 101 milligrams(mg)(60% of total) or 30 micrograms(ug) per day(7), and other studies have found similar results(4). Average mercury levels in gum tissue near amalgam fillings are about 200 ppm, and are the result of flow of mercury into the mucous membrane because of galvanic currents with the mucous membrane serving as cathode and amalgam metals as anode(1-4). Concentrations of mercury in oral mucosa for a population of patients with 6 or more amalgam fillings taken during oral surgery were 20 times the level of controls(14), and levels in root tips of 41 ppm(5). Amalgam also releases significant amounts of silver, tin, and copper which also have toxic effects, with organic tin compounds formed in the body being even more neurotoxic than inorganic mercury. Mercury and other metals accumulate in the oral cavity in fibroblasts, macrophages, and multinuclear giant cells of connective tissue, in blood vessel walls, along nerve sheath fibres, in basement-membranes of mucosal epithelium, striated muscle fibres, along collagen bundles and elastic tissue, in acini of salivary glands, and in tooth roots and jaw bones(5,11). Such mercury including that in the commonly formed amalgam tattoos moves to other parts of the body over time in significant amounts and more rapidly than the other metals. Macrophages remove mercury by phagocytosis and the mercury moves to other parts of the body through the blood and along nerves(5).

Amalgam fillings produce electrical currents which increase mercury vapor release and may have other harmful effects(1-14,38). These currents are measured in micro amps, with some measured at over 4 micro amps. The central nervous system operates on signals in the range of nano-amps, which is 1000 times less than a micro amp(38). Negatively charged fillings or crowns push electrons into the oral cavity since saliva is a good electrolyte and cause higher mercury vapor losses(11,1-6). Patients with autoimmune condtions like MS, or epilepsy, depression, etc. are often found to have a lot of high negative current fillings(11). The Huggins total dental revision(TDR) protocol calls for teeth with the highest negative charge to be

replaced first(11). Other protocols for amalgam removal are available from international dental associations like IAOMT(45) and mercury poisoned patients organizations like DAMS(46). For these reasons it is important that no new gold dental work be placed in the mouth until at least 6 months after replacement.

Some studies have also found persons with chronic exposure to electromagnetic fields(EMF) to have higher levels of mercury exposure and excretion(33c,38). Magnetic fields are known to induce current in metals and would increase the effects of galvanism. EMF is also documented in animal and human studies to cause cellular calcium efflux and affect calcium homeostasis (39,40), which may be a factor in the reduction of melatonin levels caused by EMF exposure in animal and human studies(40,41). In studies on chicks this had significant adverse effects on viability of embryos and chicks. Melatonin is known to be protective against mercury and free radical activity, as well as regulating the circadium rhythym cycle and sleep cycle. EMF

exposure lowers melatonin production and disrupts the sleep cycle(41). Since mercury is known to have some of these same effects and EMF exposure increases mercury exposure in those with amalgam, it is not clear in humans the relative role of the causality mechanisms. Occupational exposure to higher levels of EMF have also been found in many studies to result in much higher risk of chronic degenerative neurological conditions such as ALS(42), Alzheimer's Disease (43,33c), as well as Leukemia and Cancer(44,33c). Since EMF causes increased mercury exposure in those with amalgam, and mercury is also known to cause these conditions, again it is not clear the relative importance of the factors since the studies were not controlled for mercury levels or number of amalgam fillings.

Studies have shown that mercury in the gums such as from root caps for root canaled teeth or "amalgam tattoos" result in chronic inflammation, in addtion to migration to other parts of the body(5,10,15). Mercury, tin, and silver from amalgam fillings can be seen in the tissues as amalgam "tattoos", which have been found to accumulate in the oral mucosa as granules along collagen bundles, blood vessels, nerve sheaths, elastic fibers, membranes, striated muscle fibers, and acini of minor salivary glands(5,10). Dark granules are also present intracellularly within macrophasges, multinucleated giant cells, endothelial cells, and fibroblasts. There is in most cases chronic inflammatory response or macrophagic reaction the the metals(5,30), usually in the form of a foreign body granuloma with multinucleated giant cells of the foreign body and Langhans types. Mercury levels are often over 1000 ppm near a gold cap on an amalgam filling due to higher currents when gold is in contact with amalgam (8,9,11,12,13). Similar levels as high as 5000 ppm have been found by German oral surgeons in jaw bone under large fillings or gold crowns(37). These levels are among the highest levels ever measured in tissues of living organisms, exceeding the highest levels found in chronically exposed chloralkali workers, those who died in Minamata, or animals that died from mercury poisoning(29). The FDA/EPA Action Level for mercury in fish or food is 1 ppm. Warnings are given at 0.5 ppm. Some of the oral effects of mercury that have been documented include gingivitis, oral lesions, pain and discomfort, burning mouth, "metal mouth", chronic inflamatory response, lichen planus, autoimmune response, oral cancer, trigeminal neuralgia, etc.(4,5,11,15,19,22,23,25,26,30-35)

The component mix in amalgams has also been found to be an important factor in mercury vapor emissions. The level of mercury and copper released from high copper amalgam is as much as 50 times that of low copper amalgams(16). Studies have consistently found modern high copper non gamma-two amalgams have greater release of mercury vapor than conventional silver amalgams (17-21). While the non gamma-two amalgams were developed to be less corrosive and less prone to marginal fractures than conventional silver amalgams, they have been found to be unstable in a different mechanism when subjected to wear/polishing/ chewing/ brushing: they form droplets of mercury on the surface of the amalgams(3,23,24). This has been found to be a factor in the much higher release of mercury vapor by the modern non gamma-two amalgams. Recent studies have concluded that because of the high mercury release levels of modern amalgams, mercury levels higher than Government health guidelines are being transferred to the lungs, blood, brain, CNS, kidneys, liver, etc. of large

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numbers of people with amalgam fillings and widespread neurological, immune system, and endocrine system effects are occuring(25,26,27,28).

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Mercury Vapor Causes Neurological Developmental and Behavioral Effects at Lower Levels than Other Forms of Mercury.

1. Mercury vapor is lipid soluble and has an affinity for red blood cells and Central Nervous System(CNS) cells.

2. Only a few micrograms of mercury severely disturb cellular function and inhibits nerve growth. Prenatal or neonatal exposures have been found to have life long effects on nerve function and susceptibility to toxic effects.

3. Elemental mercury vapor is more rapidly transmitted throughout the body than other forms of mercury and has more toxic effects on the CNS and other parts of the body.

4. The half life of mercury vapor in the blood is less than 10 seconds, so mercury from amalgam passes rapidly into cells in organs throughout the body. Thus blood is known to not be a good way to test for mercury exposure from amalgam. Likewise, urine though better, also is mostly correlated with recent exposure and becomes less reliable as more accumulates and damage occurs.

5. Exposure to mercury vapor causes rapid transmittal across the blood-brain barrier and through the placenta of pregnant women to the fetus and significant developmental effects.

6. Developmental learning and behavioral effects have been found from mercury vapor at much lower levels than for exposure to methyl mercury.

7. More people have immune reactions to mercury vapor/inorganic mercury than to methyl mercury. Immune reactions to mercury are documented to cause autoimmunity and autoimmune conditions like chronic fatigue syndrome(CFS), fibromyalgia, lupus, mutiple sclerosis(MS), rheumatoid arthritis, ALS, etc.

8. Mercury vapor and inorganic mercury are methylated in the body to methyl mercury by bacteria, yeast, and other methyl donars.

9. Dental amalgam fillings are the largest source of both inorganic and methyl mercury in most people with amalgam.

Documentation:

There is a lot of controversy about the toxic effects significance of the various types of mercury people are exposed to: vapor, inorganic, organic(methyl) mercury. The American Dental Assoc., some at Gov't agencies, and other researchers have argued that methyl mercury is much more toxic than other forms, and mercury from fish thus a more important problem than vapor from fillings. However the pharmakinetics of mercury in the body is complex and the evidence seems contrary to that.

It is well documented that mercury from amalgam fillings is the number one source of both inorganic and methyl mercury in most people(506,etc.), since elemental and inorganic mercury in the body are methylized to methyl mercury by bacteria in the mouth and intestines, and by yeast and other methyl donars (51,53,54,225). Some people tested who do not eat fish have been found to have high levels of methyl mercury . An interesting finding is evidence that indicates that mercury vapor is 10 times more toxic to the fetal brain than methyl mercury. Developmental, learning, and behavioral effects have been found from mercury vapor at much lower levels than for exposure to methyl mercury(287,304,376c). Similarly for inhibition of some essential cellular processes(333,338,329). Richardson(paper for Swedish Scientific Panel FRN-1999) has estimated that about 20% of the population suffers a subclinical impairment of kidney or CNS function related to amalgam mercury.

Some references from the paper (www.home.earthlink.net/~berniew1/amalg6.html) on this are the following:

Mercury vapor is lipid soluble and has an affinity for red blood cells and CNS cells (21). Only a few micrograms of mercury severely disturb cellular function and inhibits nerve growth (175,147,226,255,305,149). Prenatal or neonatal exposures have been found to have life long effects on nerve function and susceptibility to toxic effects. Prenatal mercury vapor exposure that results in levels of only 4 parts per billion in newborn rat brains was found to cause decreases in nerve growth factor and other effects(305). Elemental mercury vapor is more rapidly transmitted throughout the body than most other forms of mercury and has more toxic effects on the CNS and other parts of the body according to the World Health Organization and other studies(38,183,265,282,287). Exposure to mercury vapor causes rapid transmittal across the blood-brain barrier and through the placenta of pregnant women to the fetus (38,85,113,146,162,262, 265, 281,287)-much more damage to the fetus than for maternal exposure to inorganic mercury(265,281,287,38) and significant developmental effects(305).

Levels for exposure to mercury vapor has been found to be approx 10 times that for maternal exposure to an equivalent dose of inorganic mercury(281,287), and developmental behavioral effects from vapor have been found at levels considerably below that required for similar effects by methyl mercury (20,49,119c,264,287,304,338,376c). The OSHA health standard level for mercury vapor in air is 50% lower than for organic mercury in air, as is the ATSDR MRL(217). More people have autoimmune reactions, related to chronic autoimmune conditions, to mercury vapor/inorganic mercury than to methyl mercury(60).

Mercury vapor passes through the blood rapidly(half-life in blood is 10 seconds(370)) and accumulates in other parts of the body such as the brain, kidneys, liver, thyroid gland, pituitary gland, etc. Thus blood test measures mostly recent exposure. Kidneys have a lot of hydroxyl(SH) groups which mercury binds to causing accumulation in the kidneys, and inhibiting excretion(503). As damage occurs to kidneys over time, mercury is less efficiently eliminated (11,36,57,183,216,260,503), so urine tests are not reliable for body burden after long term exposure. Significant levels are able to cross the blood brain barrier, placenta, and also cellular membranes into major organs such as the heart since the oxidation rate of HgO though relatively fast is slower than the time required by pumped blood to reach these organs(290,370). Thus the level in the brain and heart is higher after exposure to Hg vapor than for other forms(360,370)

Elemental mercury has a relatively high vapor pressure and vaporizes at room temperature. The rate of mercury volatilization is directly related to temperature so in the mouth it is even more volatile. The vapor saturation concentration in air of 20 milligrams of mercury per cubic meter of air is much higher than the safety limit. The ATSDR safety standard(MRL) for mercury is 0.2 micrograms of mercury per cubic meter of air.. Thus mercury readily vaporizes to above the MRL level and the mercury level in oral air of those with amalgam fillings usually exceeds the MRL.(15,18,83,95,137,176,217,319,335)

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