Banning Mercury Amalgam

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Abstract: The purpose of this report is to empower the Commissioner of Food and Drugs to ban the use of mercury amalgam in the United States. Mercury amalgam restorative material generally contains 50% mercury in a complex mixture of copper, tin, silver, and zinc. Mercury has been demonstrated to have damaging effects on the kidney, central nervous system, and cardiovascular system, and has been implicated in gingival tattoos. Realizing the dangers of mercury amalgam, Norway, Denmark, and Sweden have enacted legislation that has banned mercury amalgam in their countries. The American Dental Association has said for the past 150 years that the mercury in amalgam is safe and does not leak. However, no clinical studies were ever done and the Food and Drug Administration approved amalgam under a grandfather clause. Subsequent studies have shown this claim of safety not to be true. Six states in the United States have enacted legislation that requires that informed consent brochures be given to the patient in a dental office before dental restoration in undertaken. In the very least, the Food and Drug Administration should develop informed consent brochures that are used in every dental office in the United States.

Keywords: Mercury amalgam, ban, Norway, Sweden, informed consent brochure

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The purpose of this report is to empower the Commissioner of Food and Drugs to ban the use of mercury (Hg) amalgam in the United States. Amalgam restorative material generally contains 50% Hg in a complex mixture of copper, tin, silver, and zinc[1]. It has been well documented that this mixture continually emits Hg vapor, which is dramatically increased by chewing, eating, brushing, and drinking hot liquids. Hg has been

demonstrated to have damaging effects on the kidney, central nervous system (CNS), and cardiovascular system, and has been implicated in gingival tattoos. While Hg amalgams may result in detrimental exposure to the patient, they can also be dangerous in dental practices. This report has been subdivided into seven different sections that include: (1) Banning Mercury Amalgam in Norway and Sweden, (2) Experimental Studies Documenting the Detrimental Effects of Hg Amalgam, (3) Hg Amalgam and Multiple Sclerosis (MS), (4) Neurological Effects of Hg Amalgam, (5) Hg Vapor and Dental Offices, (6) Food and Drug Administration Reclassification of Hg Amalgam, (7) Informed Consent Brochures, (8) Environmental Impact, (9) Economic Impact, and finally (10) Liquid Mercury In Bottles.

Banning Mercury Amalgam in Norway, Denmark, and Sweden

In Europe, Norway[2] and Sweden[3] have enacted legislation that has banned Hg amalgam in their countries. In 2008, Norway's Minister of Environment Development Erik Solheim said: "Hg is among the most dangerous environmental toxins. Satisfactory alternatives to Hg in products are available, and it is therefore fitting to induce a ban." In 2008, Denmark also banned dental mercury amalgam. The Swedish Dental Material Commission released a report recommending that dental Hg amalgam be banned. Sweden banned the use of Hg on June 1, 2009. In the United States, a few state governments have enacted informed consent legislation for dental patients receiving dental restorations. These state legislations were enacted by Maine[4], California, Connecticut, and Vermont. In 2002, the Connecticut State legislature passed a law telling the Connecticut Department of Environmental Protection to develop best management practices for the handling of dental amalgam. The purpose of these best management practices is to ensure that Hg from dental amalgam does not threaten human health or the environment. As part of the revised Dental Office Best Management Practices, all Connecticut dental offices who use amalgam, must provide a copy of the brochure to their patients that helps to explain the advantages and disadvantages to human health and the environment of the use of Hg amalgam fillings and other filling materials used in dental procedures. In the Maine brochure, they make the following comment, "To be careful, Canada and several other countries in Europe recommend limits on the use of Hg amalgam. They advice that pregnant women should not have amalgam fillings placed in or removed from their teeth. Some of these countries issued the same warning for nursing women and people with

kidney problems. Some countries advice limits on using amalgam fillings in young children and people with braces. The US Public Health Service thinks such advice is not needed. They say amalgam fillings are safe for most people."

It is a sad tragedy that Hg is causing such health damage to many people. The American Dental Association has said for the past 150 years that the Hg in amalgam is safe and does not leak; however, no clinical studies were ever done and the Food and Drug Administration approved amalgam under a grandfather clause. Subsequent studies have shown this claim of safety not to be true. Over ten years ago, the Federation of American Societies for Experimental Biology Journal published a comprehensive scientific report on Hg exposure to the U.S. Population[5]. The authors of this Citizen's Petition recommend that the Food and Drug Administration require that informed consent brochures be given to all patients receiving silver-Hg amalgam restorative materials. The need for informed consent for dentists who use Hg amalgam restorative material has been published in 2007[6].

Experimental Studies Documenting the Detrimental Effects of Mercury Amalgam

Hg vapor is released from Hg amalgam into human mouth air after chewing, and becomes a source of Hg exposure, as revealed by whole-body image scan and tissue analysis. Hahn et al. demonstrated that when radioactive Hg was mixed with dental amalgam and placed in teeth of adult sheep, this isotope appeared in various organs and tissue spaces within 29 days[7]. Evidence of Hg update was determined by whole-body scanning and measurement of isotope in specific tissues. This whole-body image demonstrated three important uptake sites: lung, gastrointestinal, and jaw. Once absorbed, high concentrations of dental amalgam Hg rapidly localized in kidneys and liver. One year later, 1990, Hahn et al. studied whole-body imaging of the distribution of Hg released from dental fillings into monkey tissues. Their investigation demonstrated the bodily distribution of amalgam Hg in a monkey who's dentition, diet, feeding regimen, and chewing pattern closely resembled those of humans. When amalgam fillings, which normally contain 50% Hg, were made with a tracer of radioactive Hg and then placed into a monkey's teeth, the isotope appeared in high concentration in various organs and tissues within four weeks. Whole-body images of the monkey revealed that the highest levels of Hg were located in the kidney, gastrointestinal track, and jaw. The authors concluded that the dental

profession's advocacy of Hg amalgam as a stable tooth restorative material was not supported by these findings in monkeys[8]. In 1990, Vimy et al. studied the maternal-fetal distribution of radioactive mercury released from dental amalgam fillings in five adult and fetal sheep[9]. On the basis of this study, it was concluded that accumulation of amalgam Hg progresses in maternal and fetal tissue to a steady state with advancing gestation and is maintained. The authors concluded that dental amalgam usage as a tooth restorative material in pregnant woman and children should be reconsidered.

In another landmark study by Lorscheider's team of scientists, they reported that Hg amalgam fillings impared sheep kidney function[10]. On the basis of this study, the scientists concluded that amalgam Hg levels in kidney were sufficient to significantly decrease the rate of inulin clearance by nondefined mechanisms, and that electrolyte patters in the urine were consistent with impaired renal tubular reabsorption.

In another comprehensive experimental study by Lorscheider et al. they examined the effects of Hg exposure upon cell function in the brain and in the intestinal bacteria[11]. In rats, they demonstrated that ADP-ribosylation of tubulin and actin brain proteins was markedly inhibited, and that ionic Hg can thus alter a neurochemical reaction involved with maintaining neuron membrane structure. In monkeys, they showed that Hg, specifically from amalgam, will enrich the intestinal flora with Hg-resistant bacterial species which in turn also become resistant to antibiotics.

On the basis of their extensive research, Lorscheider and his colleagues wrote a compelling Editorial on the safety of Hg amalgam[12]. They concluded that current research on the pathophysiological effects of amalgam Hg has focused upon the immune system, renal system, oral and intestinal bacteria, reproductive system, and the central nervous system. Research evidence does not support the notion of amalgam safety.

In another revolutionary study about the dangers of Hg amalgam, Lorscheider and his team examined the neonatal uptake of Hg from milk in a pregnant sheep model where radioactive Hg tooth fillings were placed[13]. The findings of their studies indicate that placement and removal of Hg tooth fillings in pregnant and lactating humans will subject the fetus and neonates to unnecessary risk of Hg exposure.

Morgan et al. examined the disposition of inhaled mercury vapor in pregnant rats, as well as maternal toxicity and effects on developmental outcome[14]. The authors concluded that their data demonstrated that inhaled Hg vapor was distributed to all maternal and fetal tissues in a dose-dependent manner. Adverse affects of Hg on developmental outcome occurred only at a concentration that caused maternal toxicity.

Ramirez et al. reported a scientific study of the follow-up at two years of age after prenatal exposure to mercury[15]. On the basis of this study, the scientists concluded that prenatal Hg exposure was correlated with lower scores in neurodevelopmental screenings, but more so in the linguistic pathway.

Mercury Amalgam and Multiple Sclerosis

In 2008, Edlich and his associates reported in a peer reviewed publication about a patient with multiple sclerosis (MS) who had a large cavity in his left lower molar tooth no. 18 that had to be removed by an oral surgeon[16]. The oral surgeon told him that he would replace the carious tooth with a gold implant. The patient was not given an Informed Consent Brochure regarding dental restorative materials. The carious tooth was extracted, and replaced with a supposed gold crown implant. On his yearly dental examinations, one dentist took an X-ray of his dental implant and explained that the X-ray could not distinguish whether the implant contained gold or Hg. Consequently, the dentist referred him to a dental clinic in which the dental implant could be removed without Hg contamination of my neurologic system during extraction of the implant from the root canal. During the removal, the root canal had a black color. The crown and underlying tooth were sent to ALT BioSciences, Lexington, KY for analysis. The crown and underlying tooth confirmed the presence of Hg in the restoration. It has been well documented that Hg has damaging psychological and somatic effects on the CNS of patients with MS.

Neurological Effects of Mercury Amalgam

In 1978, Craelius[17] examined the comparative epidemiology of MS and dental caries. In his study, the geographical distribution and other epidemiological characteristics of MS are compared with those of dental caries. He found that the rates of death due to MS in Australian states are linearly related to the numbers of decayed, missing and filled teeth found in

individuals from those states. In the United States, a strong positive correlation also existed between MS death rates and dental caries indices.

In a report on the relationship between Hg and MS, the Hg content assayed by neutron activation in eight macroscopically normal areas (frontal lobe) of MS autopsy brains was compared with those of eight controlled samples[18]. No significant differences could be traced between the two groups concerning total Hg. However, the lipid-soluble Hg (preferably methyl Hg) expressed per cell unit (DNA) was found significantly decreased in MS. This data may be explained either by a washout of lipid-soluble Hg due to a break-down of the blood-brain barrier in MS or to abnormalities in methylation processes, probably related to vitamin B12 metabolism in MS.

Another report by Siblerud and Kienholz[19] investigated the hypothesis that Hg from silver dental fillings (amalgam) may be related to MS. They compared blood findings between MS subjects who had their amalgams removed to MS subjects with amalgams. MS subjects with amalgams were found to have significantly lower levels of red blood cells, hemoglobin, and hematocrit compared to MS subjects with amalgam removal. Thyroxine levels were also significantly lower in the MS amalgam group, and they had significantly lower levels of total T lymphocytes and T-8 (CD8) suppressor cells. Their MS amalgam group had significantly higher blood urea nitrogen and lower serum IgG. Hair Hg was significantly higher in the MS subjects compared to the non-MS control group. Their health questionnaire found that MS subjects with amalgams had significantly more (33.7%) exacerbations during the past 12 months compared to the MS volunteers with amalgam removal. The authors also examined epidemiological correlations between dental caries and MS as well as how Hg could be causing the pathological and physiological changes found in MS.

In a report by Escheverria et al. in 1998, they examined the neurobehavioral effects of dental Hg amalgam[20]. In their report, the authors indicated that potential toxicity from exposure to Hg vapor [Hg(o)] from dental amalgam fillings is the subject of current public health debate in many countries. They evaluated potential 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. The authors found new distinctions between subtle preclinical effects on symptoms, mood, motor function, and cognition that were associated with Hg body burden as compared to those associated with recent exposure. The pattern of results, comparable to findings previously reported among subjects with urinary Hg >50 μg/L, presented convincing new evidence of adverse behavioral effects associated with low Hg exposures within the range of that received by the general population.

In a study reported by Huggins and Levy in 1998, they described cerebrospinal fluid protein changes in four MS patients after removal of Hg amalgam restorations[21]. Patient selection was based on the patient having been diagnosed with MS by magnetic resonance imaging prior to the study. Eight 1.5 mL cerebrospinal fluid samples were obtained before and after removal of the Hg amalgam restorations by lumbar puncture and frozen at −20°C within 1 h. The specimens were stored on dry ice and transferred to the Haley Laboratory at the University of Kentucky Medical Center. Changes in the patterns and amounts of cerebrospinal fluid proteins were noted in cerebrospinal fluid specimens of MS patients after undergoing a multidiscipline treatment protocol. This protocol involved removal of all Hg amalgam restorations and then replacement by non-Hg composite restorations. To further protect each patient from Hg exposure, each patient was fitted with a rubber dam, which somewhat isolates the teeth during removal procedures, minimizing any inadvertent swallowing of amalgam. The dental operatories were equipped with negative ion generators, charcoal air filters, and high-suction evacuation capability from the oral cavity. Serum biocompatibility was performed on all patients to choose optimal replacement filling materials. Each patient's blood serum was exposed to the components of the composite dental materials available. Selection of a material was based on finding one that would not form an antigen antibody when challenged. The presence of a complexing reaction was based on changes in the optical density of serum as measured by a Dynatec MR 5000 optical density scanner. Intravenous vitamin C was administered at a rate of ~ 200 mg/min before, during, and after the dental procedure, usually taking about 3.5 h. The total dose ranged from 35 to 40 g per dental visit. Individual blood chemistries were the basis of nutritional selection for the amount of carbohydrate, protein, and fat for each patient's diet. Patients were advised to reduce sugar, alcohol, and caffeine in their diet. In addition, this treatment included medical, dental, psychological nursing, nutritional, and neuromuscular therapies. The cerebrospinal fluid samples from the four

patients taken before removal of the Hg amalgam restorations showed heavy photolabeling of multiple proteins. The gel of the cerebrospinal fluid specimen obtained 24–48 h after completion of the dental procedures showed an absence of labeling, except in the area of albumin. Some albumin labeling did appear lighter in the cerebrospinal fluid specimens taken after dental amalgam restorations.

Of special interest was the similarity of results obtained, considering the variable clinical status of the patients. Two of the patients were totally confined to a wheelchair. One patient used crutches as well as a wheelchair. The fourth patient walked unassisted, but fell frequently. Despite this clinical variability, there was remarkable reproducibility in the appearance of
the cerebrospinal fluid as shown by gel electrophoresis. The only limitation in this exciting study was that there was no long-term follow-up of their patients. In other words, were there any therapeutic implications to the removal of dental restorations in MS patients? The first author can provide some insight to the answer to this question. He had the privilege of meeting a woman with MS who was courageous enough to go to Colorado to participate in this comprehensive treatment program offered by Huggins. Before her treatment, which included removal of the Hg amalgam restorations in her teeth, she had complained of serious fatigue and weakness that interfered with her ability to pursue her vocation. After treatment by Huggins, she was able to return to her employment without feelings of fatigue and weakness. With guidance and advice from other clinicians skilled in naturopathic medicine, she can now easily manage challenges at work and has the ability to exercise regularly without fatigue.

It is important to emphasize that scientific studies have documented that Hg amalgam is a causal factor of other neurological diseases, like Alzheimer's Disease[22], amyotrophic lateral sclerosis[23] and Parkinson's Disease[24].

Mercury Vapor in Dental Offices

In 2009, Farahat et al. reported on the effect of occupational exposure to elemental Hg in the amalgam on thymulin hormone production among dental staff[25]. The results of their study were more evident in the group of nurses compared to the dentists. Their results demonstrated that dentists and dental nurses have significant exposure to Hg vapor and point to the negative impact of Hg on thymus gland function and confirm the implication

that nitric oxide pathway is a possible mechanism for this impact. In addition, the study raises attention to the importance of hygiene measures in reduction of exposure to Hg vapor released from dental amalgam.

Food and Drug Administration Reclassification of Mercury Amalgam

In the United States Court of Appeals of the District of Columbia Circuit, the Appellants Mom's Against Mercury, Connecticut Coalition for Environmental Justice, Oregonians for Life, California Citizens for Health Freedom, Kevin J. Biggers, Karen Johnson, Linda Brocato, R. Andrew Landerman, and Antia Vazquez Tibaul filed a petition for review of Regulatory Inaction by the FDA[26]. On Monday June 2, 2008, the lawsuit was settled with the FDA after it agreed to classify Hg fillings. During its negotiation session with the Appellants, the FDA indicated that it would change its Web site on Hg fillings. The FDA no longer claims that no science exists about the safety of Hg amalgam or that other countries have acted for environmental reasons only. On its Web site, the FDA now states the following, "Dental amalgams contain Hg which may have neurotoxic effects on the nervous system of developing children and fetus." They also state that "Pregnant women and persons who may have a health condition that makes them more sensitive to Hg exposure, including individuals with existing high levels of Hg bioburden, should not avoid seeking dental care, but should discuss options with their health practitioner." The FDA decision to classify Hg fillings is a reflection of the Legislations enacted in Europe and Canada that highlight the neurotoxic effects of Hg fillings.

In 2007, Aminzadeh and Etminan published a systematic review and meta-analysis of the association of dental amalgam and MS[27]. The authors pointed out amalgam restorations have long been controversial due to their Hg content. Allegations that the Hg may be linked to nervous disorders, such as Alzheimer's, chronic fatigue syndrome, and MS have fueled the calls for the removal of amalgam restorations from dentists' armamentarium. To explore and quantify the association between amalgam restorations and MS, the authors conducted a systematic review and meta-analysis of the literature. A systematic search in Medline (from 1966 to April 2006), EMBASE (2006, Week 16), and the Cochrane library (Issue 2, 2006) for English-language articles meeting specific definitions of MS and amalgam exposure was conducted by the author. Studies were also identified using the references of retrieved articles. Studies were independently reviewed by the

two authors, and disagreements were resolved by consensus. Studies were selected based on a priori of defined criteria. Odds ratios or relative risks were pooled using the random
effects model. Heterogeneity was assessed using Q statistics. The pooled odds ratios for the risk of MS among amalgam users were consistent, with a slight, nonstatistically significant increase between amalgam use and risk of MS. The authors recommended that future studies that take into consideration the amalgam restoration size and surface area along with the duration of exposure are needed in order to definitively rule out any link between amalgam and MS.

Informed Consent Brochures

All individuals in a democratic country would agree that the patient should receive Informed Consent Brochures about dental restorations that will be placed in his/her mouth. In 2007, Dr. Michael Fleming spoke eloquently on the Informed Consent process for patients receiving dental restorations. Dr. Fleming said that "I think the major thread, or the take-home message that I have, is that the Federal Government and the agencies need to force dentists to provide informed consent to the patient, and making sure that the patient is going to be well-informed, and making their appropriate decision toward the use of this material. Having said that, I don't know what would be the mechanism, whether ADA has to step forward, or the Federal Agencies. I leave it as a question open at this point. But something has to be done. I think it's very important to have informed consent and I think there should be a change in the labeling of these amalgams to, if you will, 'silver Hg,' or 'Hg silver amalgams,' so people really understand what is being put in their mouths. I think also, as other people have said, from what I can understand, these amalgams are going to go away, and go away fairly soon. So I would recommend also that women who are of child-bearing age, especially the pregnant women, and also children, really be especially counseled on getting these in their mouths"[28].

Environmental Impact

The paper by Hylander and Goodsite[29] puts a tentative monetary value on Hg-polluted food sources in the Arctic, where local, significant pollution sources are

limited, and relates this to costs for strategies avoiding Hg pollution and to remediation costs of contaminated sites in Sweden and Japan. The case studies are compiled to help policy makers and the public evaluate whether the benefits to the global environment from banning Hg and limiting its initial emission outweigh the benefits from its continued use or lack of control of Hg emissions. The cases they studied are relevant for point pollution sources globally and their remediation costs ranged between 2,500 and 1.1 million U.S. dollars for Hg isolated from the biosphere. Therefore, regulations discontinuing Hg uses combined with extensive flue gas cleaning for all powder plants and waste incinerators should be cost effective.

In 2010, the US Environmental Protection Agency (EPA) announce that it will regulate dental Hg. The EPA intends to propose a rule to reduce Hg waste from dental offices. Dental amalgams, or fillings containing Hg, account for 3.7 tons of Hg discharge from dental offices each year. Mercury waste results when old mercury fillings are replaced with new ones. Mercury and dental fillings are flushed into chair-side drains and enters the waste water system, making the way into the environment through discharges in rivers and lakes, incineration or land application of sewage sludge. The EPA indicates that Hg released through amalgam discharges can be safely managed and prevented. EPA expects to propose a rule next year, and finalize it in 2012. Dental offices will be able to use existing technology to meet the proposed requirements. Amalgam separators can separate out 95% of the Hg normally discharged to the local waste treatment plant. The separator captures the mercury, which is then recycled and reused. Until this rule is final, EPA encourages dental offices to install voluntarily amalgam separators. Twelve states and several municipalities already require the installation of amalgam separators in dental offices. Approximately 50% of Hg entering toxic waste treatment plants comes from dental amalgam waste. Once deposited, certain microorganisms can change elemental Hg into methylmercury, a highly toxic form that builds up in fish, shellfish, and animals that eat fish. Fish and shellfish are the main sources of methylmercury to humans. The EPA indicates that methylmercury can damage children's developing brains and nervous systems even before they are born.

Economic Impact

Banning the use of Hg in dentistry would save the lives of Americans[1]. The discovery that amalgam releases Hg during chewing had led to concerns about

the safety of this restorative material. It has been well documented that Hg amalgam continually emits Hg vapor, which is dramatically increased by chewing, eating, brushing, and drinking hot liquids. Hg has demonstrated to have damaging nonspecific psychological and somatic effects as well as specific pathological effects on the kidney and CNS (MS, autism, Alzheimer's disease) and has been implicated in adverse effects on the cardiovascular system. It must be emphasized that this amalgam also results in a muscosal tattoo adjacent to the restorative material.

Liquid Mercury in a Bottle

Henry Schein, Inc., Melville, NY, sells a half pound of Hg in a bottle to any consumer. The company receives the Hg from DF Goldsmith Chemical & Metal Corp., Evanston, IL, who makes the half pound Hg liquid bottle and also sells it to the consumer. DF Goldsmith Chemical & Metal Corp. makes the product by collecting any Hg containing products. Even though both companies know that the liquid Hg bottle contains very toxic material, the companies make them available to the consumer without warning of the toxicity of the product.

In contrast, the FDA lists a 50 pound bag of cornstarch in its device classification as a class III device[30]. The FDA does not allow the companies that produce the cornstarch powder to sell the product to any consumer, healthcare worker, or hospital. The FDA allows the companies to ship the product to Asia to be used to coat examination and surgical gloves. It is important to reiterate that the bag of cornstarch powder is listed as a class III device. The sale of a half pound bottle of Hg to the consumer by the two companies is further evidence that the FDA is irresponsible, and allows Hg to be distributed to consumers throughout the country, even though it is considered to be a very toxic product by the manufacturer and Henry Schein, Inc. The sale of bottles of liquid Hg to the consumer in our country is strong evidence that Hg must be banned in the United States immediately by the FDA.

A Need for Reorganization of the Center for Devices and Radiological Health

I and eleven co-authors submitted a Citizen's Petition to ban the deadly cornstarch powder on medical gloves to the Center for Devices and Radiological Health on September 24, 2008. Since the submission of this Petition, Mr. Gadiock of Regulatory Affairs of the FDA and I have not found one single article that indicates that cornstarch on medical gloves is safe. On September 3, 2010, I

was notified by Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health, that the committee meeting about our Petition has made a final decision. He told me that he could not disclose this decision or the time-line for implementation. He further indicated that I should not contact or have telephone conference calls with any members of the FDA. It's important to point out that Germany and the United Kingdom banned cornstarch on medical gloves more than ten years ago. I am deeply concerned that the Center for Devices and Radiological Health will replicate their decision making process with the dangerous silver Hg amalgam and the liquid Hg in a bottle[31].

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