

From: HEALTHCARE WITHOUT HARM

Subj: "Docket No. 01N-0067 - Against FDA Rule"

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From: harvie@isfusa.org

To Whom It May Concern:

I am writing on behalf of HCWH to submit our report "Dentist the Menace"

http://www.noharm.org/library/docs/Dentist_the_Menace.pdf which documents the substantial impacts of dental mercury on environmental and public health.

Thank you for your attention to this matter.

Sincerely,

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Attached: *Dentist the Menace*

01N-0067

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DENTIST THE MENACE?

The Uncontrolled Release of Dental Mercury

JUNE 2002



Mercury
Policy Project



A C K N O W L E D G M E N T S

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NOTE: This educational report does not constitute legal or technical advice. Institutions and individuals facing waste disposal needs should, of course, consult legal and technical experts to determine appropriate disposal procedures.

Executive Summary

While there has been considerable public debate about the potential health effects of mercury fillings, little attention has been focused thus far on the disposal of waste dental mercury. Dental clinics remain largely unregulated for mercury disposal and extracted amalgam materials are often rinsed down the drain, usually to a municipal wastewater system (or septic system), deposited in biomedical waste containers destined for waste incineration, or placed in trash disposed in a municipal waste landfill or incinerator. By far, the largest single contributor of mercury to wastewater is from dental offices. While most other anthropogenic mercury uses—and their subsequent releases—have declined by 80 percent or more since the 1980s, this has not been the case in the dental sector. Today, dentists are the third largest user of mercury in the United States, consuming over 20 percent of the estimated 200 metric tons used in 2001—or over 40 metric tons of mercury—with most eventually released into the environment.

Mercury is a persistent, bioaccumulative toxin that poses a risk to human health, wildlife and the environment. While mercury is a naturally occurring metallic element, numerous human activities—including the use of dental fillings—contribute 70 percent of emissions into the environment. Levels of mercury in the environment have increased dramatically, with a twenty-fold increase over the past 270 years. Pregnant women and their developing fetuses, infants and young children are especially susceptible to the harmful neurological effects of mercury. A July 2000 National Academy of Sciences study found that at least 60,000 children are born at risk for adverse neurodevelopmental effects each year due to their mothers' exposure to methyl mercury. Further, data released from a Center for Disease Control and Prevention study in March 2001 indicates that at least one in ten women of childbearing age is exposed to mercury at levels above what is considered safe—translating into nearly 400,000 children born at risk of mercury exposure each year.

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 dentists in the Massachusetts Dental Society to remove and recycle mercury from amalgams. However, only a small percentage of dentists nationwide have taken the steps necessary to reduce use and release of this dangerous toxin. Up until recently this lack of action may, at least in part, be a result of the general focus primarily on voluntary mercury reduction initiatives at dental clinics by government agencies over the past decade or so.

Another significant factor is that the influential American Dental Association (ADA), as well as many state dental associations, has refrained from promoting, and even opposed mercury reduction efforts. Following the lead of the ADA, the U.S. dental establishment has consistently resisted efforts to reduce releases of mercury and follow suit with the rest of the health care establishment. The ADA refuses to encourage its members to assume responsibility for curtailing dental mercury pollution, opting instead to obstruct initiatives at the state and local levels. 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. In doing so, the ADA relies on questionable scientific assumptions that deny the serious impact of mercury releases and its build up in the environment.

Yet a growing number of governments now believe that dental mercury is a serious problem that needs to be addressed, and they are beginning to act. Many countries, especially in Western Europe and Canada—and a small, but growing number of local and state governments in the U.S.—now recognize dental mercury waste as a serious environmental pollutant and are enacting both voluntary guidelines and stringent policies to curtail its release. State and local governments are now finding that the establishment of some enforceable requirements, in addition to voluntary incentives, are providing the necessary impetus for dentists to change practices in the classic “carrot and stick” approach which has proved very successful in many other applications.

Clearly, the time has come for U.S. dental associations—as other health care industry associations are already doing—to embrace the fundamental credo of “first do no harm,” by taking responsibility to reduce amalgam use and mercury pollution.

Environmentally responsible dental clinics reduce the use of mercury where feasible, employ best management practices and operate amalgam separators to get the highest capture rates of dental mercury. This approach protects human health and the environment while requiring only a modest, compact, and available shift in clinical practices and expenses.

Recommendations

1. Disposal of dental amalgam into all waste streams should be prohibited and all dental mercury should be trapped, collected and recycled.
2. The reduced use and release of dental mercury should be fostered through voluntary incentives, technical assistance and mandates to encourage and/or require dentists to:
 - adhere to stringent best management practices
 - install amalgam separators to reduce mercury discharge by 95 percent or more
 - clean and replace mercury-laden pipes and plumbing fixtures
 - manage quantities of excess elemental mercury properly
 - submit annual reports on dental mercury reduction initiatives, including the quantities of mercury used and recycled.
3. An investigation should be conducted to determine environmental impacts and potential liability implications of dental mercury released into septic systems.
4. Mercury reduction and sampling requirements should be phased in over time for all municipal wastewater treatment plants.
5. The American Dental Association’s efforts to obstruct state and local initiatives to reduce dental mercury releases should be strongly opposed, including recent efforts to convince the Food and Drug Administration to preempt state legislation in this area.

SECTION I

INTRODUCTION

Dental amalgam has been used extensively as a restorative material in teeth for over 150 years. Amalgam is a metallic alloy consisting primarily of four metals—mercury, silver, copper and tin—with mercury comprising around 50 percent of the amalgam materials.¹ Despite the existence of increasingly attractive non-mercury fillings, U.S. dental associations continue to recommend the use of amalgam, citing its “nearly fool-proof ease of use, high clinical success, relatively low cost, and known performance.”² However, current practices result in significant quantities of mercury being released from dental clinics, contributing to the build up of this toxic heavy metal into the global environment.

Nationwide, the dental sector is now the third largest user of mercury. Approximately 100 million amalgams are placed in patients each year by 175,000 U.S. dentists,³ and around 70 percent of these are replacement fillings, according to the American Dental Association. Historically, U.S. dentist clinics purchased 2,767 metric tons of mercury or approxi-

mately 55 metric tons per year between 1941 and 1990.⁴ Since the 1980s, dental use of mercury has declined slightly due to the changeover from elemental mercury to prepackaged dental amalgam capsules and the increasing use of non-mercury fillings. Yet the percentage of total mercury used—and released—by dentists has increased significantly due to voluntary phase outs and the controls imposed on other industries. According to recent estimates, the dental sector used 41 metric tons of mercury in 1999⁵ and 44 metric tons in 2001⁶ (or 22 percent of the total 220 tons used last year) compared to 50 tons in 1985 (or 3 percent of the total 1,718 metric tons).⁷

Current projections anticipate that dental mercury use is expected to remain relatively stable, with perhaps a gradual decrease, in the coming years.⁸ The table presented below provides consumption data on major mercury uses between 1985 and 2001. The data shown for dental mercury use before 1999 are thought to be low due to under-reporting.⁹

CONSUMPTION OF REFINED MERCURY BETWEEN 1985 AND 2001
(METAL VALUES ARE IN METRIC TONS¹⁰)

	1985	1990	1992	1993	1994	1995	1996	2001 ¹¹
Chloralkali	235	247	209	180	135	154	136	46
Paint	169	22	0					
Laboratory	14	32	18	26	24			
Other Chemical/Allied Products			18	18	25			
Electric Lighting	40	33	55	38	27	30	29	28
Wiring devices and switches	95	70	69	83	79	84	49	60
Batteries	952	106	16	10	6	<0.5		
Measuring instruments	79	108	52	65	53	43	41	22
Dental	50	44	37	35	24	32	31	44
Other Uses	84	58	148	103	110	93	86	
TOTAL	1718	720	622	558	483	436	372	200

SECTION II

Occurrence and Toxicity of Mercury

Mercury is a persistent, bioaccumulative toxin that even in minute quantities poses a risk to human health, wildlife and the environment. It is one of the most toxic non-radioactive elements¹² and is a volatile heavy metal that can be rapidly released into the atmosphere. A potent neurotoxin, mercury causes damage to the central nervous system, immune system, liver and kidneys of humans,¹³ and is particularly dangerous for fetuses, infants and young children. Results from the first nationally representative sample of mercury in human blood and hair, taken in March 2001 by the Center for Disease Control and Prevention, indicate that at least one in ten women of childbearing age is exposed to mercury levels above which harm could occur.¹⁴ This translates into 390,000 children born each year at risk for neurodevelopmental deficits due to maternal exposure to mercury. Numerous species of wildlife and fish are also at risk from the pervasive occurrence of this toxic substance in the environment.¹⁵

While mercury is a naturally occurring metallic element, anthropogenic uses account for approximately 70 percent of all mercury emissions into the environment. In the last 270 years, industrial practices have led to a twenty-fold increase in levels of mercury in the environment.¹⁶ Elemental mercury and mercuric compounds are resistant to many of the natural environmental processes that otherwise break down, alter and dilute toxins.¹⁷ As a result, mercury persists indefinitely in the environment and cycles between the air, freshwater and saltwater, and soil/sediments. In water and soil, mercury is transformed into its most toxic form, methyl mercury by the natural biochemical process of methylation.¹⁸ Methyl mercury is highly soluble and therefore is mobile, incorporating easily into living tissues. Over time, methyl mercury bioaccumulates in the tissues of fish and wildlife, becoming increasingly concentrated in species higher on the food chain.¹⁹

Increasingly, the dangers posed by mercury contamination to public health are prompting national, state and local authorities to warn people to avoid ingesting foods likely to contain mercury. In July 2000, a National Academy of Sciences study found that "...over 60,000 children are born each year at risk for adverse neurodevelopmental effects due to in utero exposure to MeHg (methyl mercury)."²⁰ Six months later, the Food and Drug Administration issued new fish consumption advisories for pregnant women not to eat certain ocean fish due to high levels of methyl mercury.²¹ To date, public health advisories have been issued in 41 states warning people to limit their consumption of both freshwater and saltwater fish. Some states are cautioning pregnant women and children to avoid consuming certain fish altogether and at least ten states have issued statewide advisories recommending limits on the intake of fish obtained from *any* pond, lake or river within their borders due to extensive mercury contamination.²²

SECTION III

Dental Mercury Disposal Routes

The largest single source of dental mercury released into the environment comes from the removal of existing amalgams from patients during dental procedures (replacment fillings, crowns, extractions, etc). Extracted amalgam materials are either rinsed down the drain—usually to a municipal wastewater system (or septic system) where it can build up in sewage sludge—deposited in biomedical waste containers destined for waste incineration or autoclaves, or placed in the trash that is later disposed in municipal waste landfills or incinerators. It is estimated when an amalgam is prepared for a filling, 10 percent²³ is leftover and is often simply discarded. The “over-pack” portion is either drawn into the dental clinic’s waste vacuum system or is expelled by the patient into a chairside cuspidor.²⁴ But the majority of dental mercury waste is discarded into wastewater systems.²⁵

Dental Mercury Waste Disposal into Wastewater

Studies by EPA and numerous municipalities²⁶ document that most municipal wastewater treatment plants have high levels of mercury with significant contributions from dental clinics.²⁷ Recently, the Association of Metropolitan Sewerage Agencies (AMSA) evaluated seven major municipal wastewater treatment plants (WWTPs) to determine and quantify sources of mercury coming into these 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.²⁸

While municipalities undertaking similar studies have found comparable percentages of mercury coming from dental offices, estimates of the tonnage of dental mercury discharge into wastewater vary greatly per year, according to the table below.

Study	Date	Tons Per Year
Coilas ³³	1994	23.5
Drummond ³⁴	1995	24.6
Arenholt-Bindslev And Larsen ³⁵	1996	12
Water Env. Fed. ³⁶	1999	12
Canadian ³⁷	2001	24.7 ³⁸
AMSA ³⁹	2002	2.6

Yet there is little debate that municipal wastewater treatment systems are not designed to treat hazardous waste or reduce mercury loadings to the environment. Consequently, all mercury in the influent wastewater remains unattenuated in municipal treatment plants, and either settles out in the grit chamber or residuals (sludge, or “biosolids”), or passes through the system to be discharged into a downstream lake, river or ocean along with the “treated” effluent. Moreover, conditions at certain points within the wastewater treatment process are perhaps favorable for promoting methylation of mercury within the wastewater or sludge.⁴⁰ This has the effect of converting a portion of the influent mercury into its more toxic, organic form (methyl mercury), which is also highly soluble and able to pass through the facility to the receiving water body.

City	Mercury load from dental offices
Duluth, Minnesota	36% ²⁹
Seattle, Washington	40-60% ³⁰
Palo Alto, California	83% ³¹
Greater Boston Area, Massachusetts	13-76% ³²

Mercury amalgam particles that drop out of wastewater in the grit chamber (the initial coarse settling chamber at the front end of a treatment plant), are most commonly landfilled along with all other filtered materials. The residual sludge, which is the primary byproduct of the treatment process, is frequently incinerated. Incineration releases the mercury directly into the atmosphere as mercury vapor. Studies conducted at the metropolitan wastewater treatment plant in Minneapolis-St. Paul indicate that as much as 95 percent of the mercury load to the treatment plants is released to the atmosphere during sludge incineration,⁴¹ with the balance discharged to the Mississippi River.⁴²

When not landfilled or incinerated, "biosolids" are used in fertilizers or other soil additives. Agricultural sludge application can lead to mercury contaminated soil and groundwater, as well as direct volatilization to the atmosphere. Regulations for land application of sludge in the U.S. are far less restrictive for mercury and other heavy metals than many other countries.⁴³ This practice has not been thoroughly studied and is further hindered by the fact that both state and federal agencies responsible for regulating sludge-spreading are also often responsible for promoting it.

Mercury in Traps, Drains, and Sewer Pipes

Following years of use, the plumbing in dental offices can become significantly laden with dental amalgam. Studies show that high levels of mercury are accumulating in sewer pipes from dental offices, presenting potential liability concerns to land owners.⁴⁴ Amalgam particles trapped in dental office plumbing and drainage pipes have been found to provide a continuing source of dissolved mercury to wastewater over time.⁴⁵ The slow dissolution of mercury amalgam in dental office plumbing, as well as in the municipal sewer system, serves as a long-term source of mercury to the receiving facility and is eventually released to the environment.⁴⁶

Mercury in Septic Systems

Where no publicly operated treatment works exist, dental clinics frequently rely on septic systems for wastewater disposal. Similar to municipal treatment plants, the potential for methylation exists in the anoxic environment of a septic tank,⁴⁷ which can lead to the production and discharge of methyl mercury at private disposal fields. At these locations, the mercury path to the environment is more direct and the soils and groundwater surrounding the drain

fields of these systems can become contaminated with mercury.⁴⁸ Significant levels of mercury contamination have been detected both within septic tanks as well as adjacent to, and downgradient from, disposal fields receiving wastewater from dental clinics.⁴⁹ The drain fields of septic systems receiving dental wastewater have the potential to serve as point sources of mercury contamination to the underlying and adjacent soils and groundwater, and may potentially convey environmental liability on to the property owner, and/or wastewater generator.⁵⁰

Other typical disposal routes for waste dental mercury

Solid Waste

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. The mercury in amalgam disposed in a landfill may break down over time and co-mingle with landfill leachate. Depending on the landfill, mercury may enter groundwater, contaminate underlying soils, volatilize into the vapor phase and dissipate to the atmosphere or, when landfill leachate is sent to a wastewater treatment plant, be taken up in sewage sludge that is either re-landfilled or distributed. Also, formulation and release of methane gas from landfilled mercury may contribute to production of mercury emissions within the landfill.⁵¹

Biomedical waste/Incineration

Waste dental mercury is often disposed into the biomedical waste container. A recent survey found that 25 to 30 percent of dentists place their contact amalgam wastes into biomedical "red bags" that are often incinerated.⁵² Medical waste is a special type of regulated waste due to the potential presence of bacteria and pathogens, which is separated and handled differently from other solid wastes. If any amalgam has come in contact with the mouth or has been removed from or with teeth, it is considered "contact amalgam" and is often discarded into biomedical waste. So-called "red-bag" waste is often sent to a medical waste incinerator, where the mercury is vaporized into the atmosphere. Some handlers of biomedical waste sterilize it with high temperature and pressure steam in a process known as "autoclaving." Oftentimes, these facilities operate with no emission controls or standards, which result in mercury vapor releases, and discharge of effluent to the local wastewater system

following sterilization. Ultimately the mercury-bearing residuals from this process are landfilled.⁵³

Recycling

While actual numbers are hard to come by, a small but increasing number of dental clinics are beginning to have their mercury recycled. Where collection systems are in place, approximately 60 percent of all mercury-bearing amalgam waste is captured in coarse filters at chair side,⁵⁴ and 95 percent or more of the mercury can be cost-effectively captured when an amalgam separator is added to the system. These programs are, in general, effective and require only a modest shift in practices, and add a very minor increase in operating expense. According to recent estimates, an amalgam separator unit capable of removing both particulates and dissolved mercury can be operated for between \$47.95-\$100 per month.⁵⁵ Currently, there are many firms across the U.S. offering services to collect and recycle mercury from dental clinics. In addition, there are 11 amalgam separators available in the U.S. that were recently tested by American Dental Association and found to exceed testing standards.⁵⁶ Similarly, a recent study of several amalgam separators by the Minnesota Dental Association and the Metropolitan Council of Environmental Services reached similar conclusions.⁵⁷ Yet it is estimated that less than one percent of dentists have amalgam separator units in operation today.⁵⁸

Storage

Prior to receiving pre-encapsulated amalgams, dentists used to make their own mercury fillings and some still have large stocks stored in their offices. (Few, if any dentists today make their own fillings.) While some states and locales have hosted "clean sweeps" to collect excess elemental mercury from dentists, based on the quantities collected thus far it is likely that large quantities of elemental dental mercury remain uncollected and represent a significant risk of being mismanaged or improperly disposed.

Human Wastes

Amalgam have been determined to be the primary source of mercury in human waste.⁵⁹ After releases from dental offices, human wastes are the next greatest contributor of dental mercury to waste water treatment plants (WWTPs).⁶⁰ In addition, amalgam fillings are responsible for additional environmental releases of mercury at the end of life. Each cremation in the U.S. accounts for, on average, one gram of mercury, due to vaporization of mercury contained in dental amalgam fillings.⁶¹

SECTION IV

Challenges to Reducing Dental Mercury Releases

Numerous opportunities are now available for dental clinics to reduce overall mercury use, as well as contain and capture waste amalgam prior to discharging it into the wastewater system. Some local governments have successfully worked with their dental community to foster effective voluntary mercury reduction initiatives, yet these cases remain the exception rather than the rule. To date, dental mercury waste mismanagement is primarily due to the following:

- ▶ lack of general awareness among dentists that their waste mercury is a serious pollutant that should be managed properly;
- ▶ lack of the regulatory control by most government agencies;
- ▶ lack of support from the American Dental Association (ADA) and state dental associations for dentists to take the necessary steps to reduce mercury releases; and
- ▶ lack of governmental resources for the level of staff outreach to the dental community that voluntary initiatives require in order to be effective.

Lack of Regulatory Control for Dental Mercury Releases

Currently, there are few regulations governing the use, control or discharge of mercury from dental uses. Once amalgam materials are delivered to dental clinics, there are no recording or manifest requirements designed to record the quantities of mercury used and recycled, or to track disposal routes.

The problem with mercury in wastewater was first identified when municipal WWTPs experienced mercury spikes in samples of their treated effluent. This contaminated effluent was failing discharge limits for mercury established by the National Pollution Discharge Elimination System (NPDES). A NPDES permit includes discharge limits for individual environmental contaminants that are based on the human health criteria for each contaminant, and the

characteristics of the receiving waters into which the treated effluent is released. As such, it is up to the municipal sewer authority to keep track of industries and commercial enterprises that discharge wastewater into their systems to ensure that a commercial entity is in compliance with the discharge limits. Yet municipal wastewater authorities often lack effective enforcement mechanisms and few have chosen to regulate dental mercury under NPDES or any other requirements. Currently less than 10 percent of major WWTP facilities even have a mercury sampling requirement in their NPDES permits.⁶² An even smaller percentage of the 63,000 minor WWTPs (serving less than 1 million population) have a mercury limit in their discharge permits.

Voluntary Approaches to Reducing Dental Mercury Releases

Much information now exists on how to operate an environmentally responsible dental office, and this information, including Best Management Practices (BMPs), has been distributed in many states. BMPs are designed to be economically achievable measures and/or actions to control and reduce or eliminate the discharge of pollutants to the environment.

BMPs have been developed by individual state waste management or pollution prevention authorities or nongovernmental organizations in conjunction with the state dental association and, to this point, are generally voluntary, rather than mandatory.⁶³ These guidelines outline sound methods for collection and proper management of mercury and other wastes, and provide information on resources, techniques and equipment. Voluntary approaches for reducing dental mercury releases usually begins with employment of BMPs, and are then followed by other steps, including the installation of amalgam separators. Chairside traps, vacuum filters, and air-water separators are readily available and all can be used to more effectively limit the uncontrolled discharge of mercury amalgam.⁶⁴

In certain locales, government-initiated voluntarily programs for dental clinics to reduce pollution have resulted in documented reductions of mercury releases. Yet, throughout the Nation, government resources for sustained staff outreach and assistance are generally not available for successfully promoting voluntary initiatives to the local dental community.

ADA's Lack of Support for Reducing Dental Mercury Releases

Perhaps the biggest hurdle to removing mercury from dental waste streams is to obtain the cooperation of both individual state dental associations and the American Dental Association (ADA).⁶⁵ Despite overwhelming evidence to the contrary, 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,"⁶⁶ but other times remaining completely silent on the question of environmental impacts, such as in its *Statement on Dental Amalgam*.⁶⁷

The ADA's unwillingness to acknowledge the extent of the mercury problem within the dental industry is also reflected at the state levels. Although state level dental associations have at times appeared ready to support the dental mercury reforms, they have also frequently rejected the potency of the issue. In Seattle, for instance, dentists questioned the environmental impact of amalgam, and claimed amalgam separators were "untested, expensive and not readily available,"⁶⁸ although they have been widely tested, and even according to ADA's testing, are cost effective and readily available.⁶⁹ In its most recent statement on the issue, the ADA pledged support for a Food & Drug Administration initiative to preempt or override any and all state laws intended to regulate the dental industry and reduce its use of mercury.⁷⁰

Indeed, ADA and the greater dental industry insist on obscuring substantiated scientific evidence in order to advance their objection to reforming the use of mercury in dental applications, floating a host of flawed arguments designed to reject outright the pos-

sibility of regulation. The ADA, for example, asserts that incineration is the only means by which mercury is released to the environment, thus categorically denying evidence of the presence of mercury in wastewater. It argues that mercury is stable while in the general waste stream, and only emits mercury to the environment when burned as sludge or solid waste. This reasoning is then used as the primary justification for recommending only the prevention of amalgam waste incineration, relegating further evaluation of minimization of the amalgam-derived mercury discharged from vacuum systems to secondary consideration.⁷¹ The ADA goes so far as to argue that amalgamated mercury waste poses no environmental risk, asserting that it is a "scientific fact that mercury in dental amalgam chemically combines with other ingredients, including silver, to form a biologically inactive substance."⁷² ADA maintains that mercury in dental amalgam does not leach under toxicity characteristic leaching procedure (TCLP) testing and therefore, it should not be considered a hazardous waste under federal regulations.⁷³ Finally, ADA, state dental associations and their members consistently refer to amalgams as "silver fillings" even though, on average, the silver actually only comprises 25 percent of an amalgam filling.⁷⁴

All of these contentions, arguments, and positions by the ADA and state dental associations 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. Non-mercury alternatives have been viable and readily available for some time,⁷⁵ and for many applications are already used extensively in the U.S. and other countries. However, 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 composites⁷⁶—make the dental industry wary of accepting responsibility for the transition away from mercury amalgams and for reducing their mercury releases. But clearly, the inconvenience of using non-mercury fillings wherever feasible, and the small additional charges associated with utilizing new technologies for the capture and recycling of mercury, is far outweighed by the environmental benefits.

SECTION V

A Broader Perspective

While dental mercury use and release continues relatively unabated in this country, there are a growing number of new initiatives in the U.S.—and especially abroad—to reduce dental mercury pollution. As described below, voluntary guidelines by themselves are oftentimes not as effective without the addition of some regulatory “teeth.”

The Case for Coupling Voluntary Initiatives With Dental Mercury Regulations

Based on the case studies presented below, it appears that a combination of voluntary and mandatory initiatives have been most successful in convincing dentists to take the necessary steps to reduce their mercury pollution.

Seattle, Washington

In 1990, Seattle began to quantify the dental contribution of mercury in wastewater entering their treatment plants. By 1994, enough information had been collected to justify proposing a rule requiring the installation of amalgam separators in all dental offices. In response to intense opposition by dentists, this rule was tabled in 1995 in favor of aggressive educational outreach with the goal of changing the prevailing practices and spurring voluntary adoption of amalgam separation technology.⁷⁷ After five years of intensive outreach and cash incentives, and more than 400 office visits by both county and dental society officials, less than 3% of dental offices had purchased amalgam separators, and less than 40% of dentists collected and recycled mercury-bearing wastes.⁷⁸ After a decade, the voluntary approach was deemed unsuccessful and regulatory intervention was determined necessary. This involved requirements for installation of amalgam separators, with a phase-in period that extends to July of 2003. In the most recent phase of the project, city officials have encountered little resistance from the local dental society.⁷⁹

Wichita, Kansas

The City Pretreatment Staff has worked with the dental community to develop BMPs for managing mercury discharges. Implemented in June 1, 2001, phase 1 of the program required use of a technology greater than the traditional chairside trap and vacuum filter—at minimum, a modified chairside trap with either decreased pore size or a modified design that allows for some sedimentation. If mercury levels have not decreased significantly after completion of Phase 1, then Phase 2 will be implemented, requiring Best Available Technology to reduce mercury levels by 90% or more by June 1, 2003. Although initially the program is voluntary, dentists who do not comply will be fined \$2000 with additional fees for quarterly sampling and fines for exceeding a discharge limit of 0.0007 mg/L.⁸⁰

Boston, Massachusetts

In 1995, Greater Boston area hospitals were responsible for contributing 22 pounds of mercury to the WWTP. Yet by the year 2001 their contribution was one pound— primarily due to Massachusetts Water Resources Authority regulation and enforcement. However, during that same time period, dental facilities escaped environmental regulation. In 1995, their load to the WWTP was approximately 36 pounds and in the year 2001 their contribution of mercury to the WWTP was still around 36 pounds per year—no reduction! Clearly, this creates an unlevel playing field between the hospitals forced to comply with the regulations and the dental facilities who are not.⁸¹

Billerica, Massachusetts

A review was undertaken by Solmetex, an amalgam separator manufacturer, in 2000 at a dental clinic to determine the average amount of mercury discharged per day with and without an amalgam separator in a clinic housing four dentists and six hygienists. At the beginning of the study, the dental clinic had no chairside traps, leaving only the screen mesh pump filter to remove mercury particles. Influent and effluent samples were taken over 74 days from February 2000 to September 2000. Prior to separator installation, each dentist discharged an average of 570 mg/day. After an amalgam separator was installed, tests indicated a 99% removal rate.

State of New Hampshire

In May 2002, the New Hampshire legislature passed first-in-the-nation legislation requiring state rules “for dental offices relative to the use of environmentally appropriate disposal equipment or methods” to trap dental mercury—despite opposition from the ADA.⁸² The New Hampshire Department of Environmental Services supported the legislation, calling “...for better management of mercury amalgam waste, promoting the increased use of alternative fillings and phasing out the use of amalgam over time.”⁸³ Similar to a law adopted in Maine in 2001, the New Hampshire law also requires dental offices to provide information “...regarding the risks and benefits of dental mercury, including mercury amalgams.” It also requires the health department to “provide information ...about the risks and benefits of dental restorative materials including the use of amalgam in children under the age of 6.”⁸⁴

State of Connecticut

Legislation passed by the Connecticut legislature in 2002 requires vocational dental education or training schools to develop and implement a plan approved by the environmental commissioner that assures best management practices are used to prevent discharge of mercury into the environment, and to properly manage and recycle elemental mercury and amalgam. The law also requires the plan to provide for an education program for dental students regarding the hazards of mercury and best management practices.⁸⁵

Dental Mercury Reduction Initiatives in Other Countries

Over the past decade or so, many other countries have taken concrete steps to reduce dental mercury use and pollution. For example, the fact that sludge with elevated mercury content had to be treated as a hazardous waste led several European governments to ban certain types of amalgam disposal and require dental pollution prevention practices. In Scandinavia in the early 1980s, publicly owned treatment facility sludge used for fertilizer by farmers was found to have extremely high levels of mercury. Consequently, the farmers discontinued using the pellets, which forced facilities to trace the source of mercury and eliminate it from their influent. Subsequent research uncovered that the largest generators and dischargers of mercury were dental clinics.

Starting in 1992, Scandinavian countries, as well as Germany, Switzerland, Austria and Holland, either required the use of advanced amalgam separation equipment, or regulated dental mercury in some manner.⁸⁶ Today most regulations in Europe require 95 percent removal (by mass) of waste amalgam prior to discharge, with this standard applied downstream from the initial filters that easily remove the largest particles.

The table on the following page illustrates the steps that many countries have taken to reduce dental mercury use and pollution. The information comes primarily from a compilation by the United Nations Environment Program for their draft *Global Mercury Assessment*.⁸⁷

OTHER COUNTRIES' DENTAL MERCURY REDUCTION INITIATIVES

Country	Regulation/Initiative
The Netherlands	For several years, there has been an agreement between the national organization of dental surgery and the public authorities to collect amalgam separately from the sewage system with at least 95% efficiency. ⁸⁸
Sweden	A voluntary agreement since 1979 requires that all dental clinics are equipped with amalgam separators. ⁸⁹ Between 1990 and 1995, the concentration of mercury in the city of Stockholm's WWTP sludge decreased by 33%, ⁹⁰ which is approaching the percentage of mercury believed by Swedish authorities to originate from dental clinics (50%). Beginning in January 1999 the Swedish Parliament abolished compensation for amalgam fillings with the ultimate aim of a total ban of the use of dental amalgam, in part, to reduce environmental release. ⁹¹
Canada	A recently adopted Canada-wide Standard is the application of "best management practices" to achieve a 95% national reduction in dental mercury releases to the environment by 2005, from a base year of 2000. Best management practices are defined as including the use of an ISO certified amalgam trap, or equivalent, and appropriate management of waste so that mercury does not enter the environment. ⁹² The Sewer Use Bylaw in Victoria, BC requires installation of amalgam separators in all dental offices by July 1, 2001. If dentists do not comply, they are required to collect and transport the wastewater from the dental operation for off-site management. ⁹³ Victoria's BMPs include guidelines for collection, storage and recycling of mercury. In addition, Montreal and Toronto have imposed stricter new emissions standards to reduce dental mercury releases by 90 percent or more. As a result of recent initiatives, more amalgam separators are being installed in Canada than in the U.S., ⁹⁴ even though Canada's population is much smaller than the U.S.
Denmark	Results from wastewater sludge studies in Denmark indicate a dramatic reduction in mercury (50 - 80%) following mandatory installation of amalgam separators in dental clinics. ⁹⁵ Dental amalgam is allowed only in molar teeth, where the filling is worn, until further notice, thereby significantly reducing both mercury use and, over time, releases. Denmark is ready to ban the remaining use of dental amalgam, whenever the Danish National Board of Health is satisfied that the non-mercury alternatives have full substitution capabilities. ⁹⁶
France	1998 regulations regarding elimination of amalgam waste from the dental sector's complemented by a 2000 decision by the Agence Francaise de Securite Sanitaire et des Produits de sante that imposes the use of pre-dosed capsules of amalgam. In addition, an amalgam separator is required and waste water pipes should be cleaned when the equipment is installed. Finally, an agreement is required for disposal of amalgam waste in an appropriate facility. ⁹⁷
New Zealand	In 2001 the New Zealand Dental Board adopted guidelines on dental amalgam waste and wastewater discharges. The guide describes a code of practice for the use, storage, collection and disposal of mercury. It recommends that amalgam scrap should be collected, stored and sent for recycling. The guidelines state that amalgam scrap should not be disposed of in any medical waste to be incinerated, systems to reduce amalgam discharge to wastewater should be installed, and by regulation, amalgam separators meeting the ISO 11143 standard (an established stringent standard for dental mercury reduction) should be installed. ⁹⁸
Switzerland	According to the Swiss government, because of increasingly popular non-mercury alternatives, use of amalgam tooth fillings has been strongly reduced. There is also reportedly an increased use of mercury separators in dentists' offices. ⁹⁹

SECTION VI

Summary

Amalgam use and release by the dental establishment is a significant and persistent source of mercury pollution in the U.S. and must be curtailed. Many other industries, sectors, institutions and government agencies have been actively pursuing ways to reduce their reliance on mercury. In 1998, for example, the American Hospital Association entered into an agreement with EPA committing to the virtual elimination of mercury from hospital waste streams by 2005. In so doing, the health care industry recognized that its fundamental credo of “first do no harm” must extend to the toxic materials and contaminants used in treatments and equipment.

But U.S. dental associations, following the lead of the American Dental Association, have consistently resisted efforts to reduce releases of mercury and follow suit with the rest of the health care establishment. The ADA refuses to encourage its members to assume responsibility for curtailing dental mercury pollution, opting instead to obstruct initiatives at the state and local levels. Consistent with its position, the ADA is now currently supporting a regulatory effort by the Food & Drug Administration that would effectively preempt and reverse significant legislative advances made at the state level. In doing so, the ADA relies on questionable scientific assumptions that deny the serious impact from mercury used and eventually released into the environment, despite a preponderance of evidence contradicting these claims.

Yet in instances where dentists have showed a willingness to support mercury reduction initiatives—both abroad as well as within a growing number of local communities across the U.S—they have clearly demonstrated the relative ease and low expense with which effective pollution prevention practices and technology can be applied to existing practices. Environmentally responsible dental clinics employ best management practices together with amalgam separators to get the highest capture rates of dental mercury. This approach is economical, compact in design, available, and protective of human health and the environment. For example, it costs Massachusetts Dental Society members only \$50 per month¹⁰⁰ to operate the amalgam separator equipment needed to trap and collect waste mercury, a price that is redeemed exponentially by the long term benefits to human health, wildlife and the environment.

SECTION VII

Recommendations

1. Disposal of dental amalgam into all waste streams should be prohibited and all dental mercury should be trapped, collected and recycled.
2. Policies should be adopted to foster the reduced use and release of dental mercury through a combination of voluntary incentives, technical assistance and mandatory requirements to encourage dentists to:
 - ▶ Adhere to stringent best management practices to control discharge of mercury.
 - ▶ Install amalgam separators to reduce discharge of amalgam particles (and in some cases dissolved mercury) by 95 percent or more, and follow strict protocols to ensure units are maintained to manufacturer's specifications.
 - ▶ Clean and, as needed, replace mercury-laden pipes and plumbing fixtures.
 - ▶ Properly manage significant quantities of excess elemental mercury.
 - ▶ Submit annual reports on quantities of mercury used and recycled, and an evaluation of the performance of BMPs, amalgam separators and removal of mercury in discharge pipes.
3. An investigation should be conducted to determine environmental impacts and potential liability implications of dental mercury released into private septic systems.
4. Major municipal wastewater treatment plants (WWTPs) should have mercury reduction and sampling requirements in their National Pollution Discharge Elimination System permits. Similar requirements for minor WWTPs should be phased in.
5. The American Dental Association's efforts to obstruct state and local initiatives to reduce dental mercury releases should be strongly opposed, including recent efforts to convince the Food and Drug Administration to preempt state legislation in this area.

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PROFESSIONAL RESPONSE

**AGAINST
the FDA Proposed Rule on
Mercury Dental Fillings**

(these are only a sampling of letters submitted)

Docket No. 01N-0067

**More than 700 letters have been submitted to the FDA opposing
the Rule to reclassify dental amalgams and mercury as
proposed in FDA docket number 01N-0067.**

FROM: DR. BOYD HALEY, PhD, CHAIR AND PROFESSOR, CHEMISTRY DEPT. UNIV. OF KENTUCKY

5/16/02

Dear FDA officials:

Re: Proposed FDA Rule docket number 01N-0067

The purpose of this e-mail is to express my strong objections against the FDA proposal to reclassify dental amalgams and mercury as proposed in FDA docket number 01N-0067.

I am a professor of chemistry and chair of a major research department at the University of Kentucky. I have had extensive research experience in biochemistry and cell biology, lately emphasizing in my research the effects of toxic heavy metals on central nervous system proteins and cells. I have had technicians measure the amount of mercury emitting from a dental amalgam of one spill just recently. They confirmed earlier reports that the amount is in the micrograms per cm² per day which is much higher than that estimated by certain supporters of amalgam usage. Also, I avidly read all of the literature on mercury exposures and toxicity, evidently something the FDA officials in charge carefully avoid doing. Otherwise, they would not take the stand that there is "no research supporting the contention that amalgams do the body damage." Just because most individuals can survive the level of mercury from dental amalgams does not justify exposing these individuals to this toxicant.

Further, the science published in academic journals is strongly against the exposure to mercury even at very low levels, especially for the very young and expectant mothers. It is well known that amalgams are the major contribution of mercury that is found in the bodies of USA citizens and that mercury is one of the most toxic of substances. This would be enough evidence for rationale, reasonable people to make them want to stop placing amalgams in the mouths of our children and young mothers. To avoid mercury exposure the government warns against eating fish on one hand and then, on the other hand, supports the use of a material that releases 24 hours per day toxic mercury vapor.

Finally, it is addition of mercury, and only mercury, that can generate in normal biological test systems most of the aberrant biochemistry observed in Alzheimer's diseased brain as well as three of the most widely accepted pathological hallmarks of this disease. The odds against this being an artifact, without involvement of mercury in Alzheimer's disease is extremely unlikely. Recommending the placement grams of neurotoxic mercury into the mouths of potential Alzheimer's disease victims is totally unjustified and heartless. Therefore, I strongly recommend against this proposed rule and further request that a committee of qualified scientists and research physicians be formed, independent of the dental branch of the FDA, to evaluate the safety of dental amalgam.

Sincerely,

Boyd E. Haley,
Ph.D. Chemistry/Biochemistry

Boyd E. Haley 859-257-7082
Professor and Chair
Dept. of Chemistry
University of Kentucky

HOLISTIC DENTAL ASSOCIATION

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September 14, 2002

Food & Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061-HFA-305
Rockville, MD 20852

Dear Sirs:

This letter is in response to:

Docket # 01N-0067 – AGAINST the FDA Rule on Mercury Dental Fillings

The Holistic Dental Association, founded in 1978, is a national organization of dental healthcare professionals whose members believe that the accepted concepts in modern dentistry are, unfortunately, limited in scope, do not recognize the physiologic effects, and unintentionally cause harm to a significant number of individuals. Virtually all HDA members do NOT place mercury (amalgam) fillings in their patient's mouths because of this potential risk.

It is difficult to understand how intelligent and educated healthcare professionals can ignore the large amount of existing science and clinical observations that cast doubt on the safety of mercury in amalgam fillings. Dentistry has alternatives to mercury fillings, and every dentist knows about them. And even though there is controversy about the use of mercury fillings, shouldn't the public be adequately and objectively informed and given the option of choosing what materials are used to restore their teeth? Most patients are uninformed about the materials used and the benefits/risks of each. The American Dental Association, to its credit, very recently produced an informational brochure about dental materials, but it is inadequate because it doesn't address the potential problems of toxicity and oral galvanism.

I am sure others have informed the FDA about the health issues of mercury, but I would like to reiterate some basic, but key facts:

1. There is overwhelming scientific evidence to support that mercury is a toxin. It is regulated as such, the exception being when used as a dental restorative material. It is classified as hazardous before placement in the mouth and after its removal from the mouth, but not while in the mouth. Where is the logic in this?
2. It is a proven fact that mercury is not chemically bound in amalgam fillings as was believed in the recent past, and therefore mercury vapor is constantly released into the mouth.
3. There is scientific research indicating a possible link between mercury and chronic illness.
4. Children and fetuses are highly susceptible to mercury toxicity.

Some references that support these statements:

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Web site: www.fplc.edu/risk/vol2/spring/royal.htm
Web site: vest@ab.gu.se/~bosse/Mercury/Mouth/Mail/gammalcontra.html
Web site: www.listserv.gmd.de/archives/amalgam.html

Book: *The Mercury in Your Mouth: The Truth About "Silver" Dental Fillings*
by Quicksilver Associates

Book: *Toxic Metal Syndrome* by Drs. H. Richard Casdorff & Morton Walker

Book: *It's All in Your Head* by Hal Huggins, DDS

Book: *Mercury Free* by James E. Hardy

Book: *Solving the Puzzle of Mystery Syndromes* by Mary Davis

Book: *Amalgam Illness: Diagnosis and Treatment* by Andrew Cutler

Book: *150 Years of Amalgam* by Fredrik Berglund, M.D., Ph.D.

Book: *ABC's of Mercury Poisoning from Dental Amalgam Fillings Handbook for Victims of Mercury Poisoning* by Mats Hanson, Ph.D.

Book: *Chronic Fatigue – Poisoned by the Mercury in Your Mouth?* by Annika and John McClintock and Christer Malmström DDS

Book: *Does Mercury From Dental Amalgams Influence Systemic Health?* by Gary A. Strong, D.D.S.

Book: *Infertility & Birth Defects - Is Mercury From Silver Dental Fillings A Hidden Cause?* by Sam Ziff and Dr. Michael F. Ziff.

Book: *Mercury Poisoning from Dental Amalgam - A Hazard to Human Brain* by Patrick Störtebecker, M.D., Ph.D.

Book: *Silver Dental Fillings - The Toxic Time Bomb* by Sam Ziff

Book: *The Missing Link? – A Persuasive New Look at Heart Disease as it Relates to Mercury* by Michael F. Ziff, D.D.S. and Sam Ziff.

Please realize this letter represents about 160 dentists and their staffs who deal with these problems firsthand, almost everyday. For us, it is not just an academic discussion or a debate of scientific research, it is up close and personal! I think it is accurate to say that those dentists, staffs, professional dental organizations, and educational institutions who argue the opposite point of view, or are silent on the issue, have little experience treating this type of patient and/or have not *personally* read the literature referenced.

The FDA takes great care in not approving products that pose a potential risk to the health of its citizens. All we ask is that you use the same objectivity and due diligence when deciding this issue.

Sincerely,

Ronald L. King, DDS
President, Holistic Dental Association
Member, Minnesota Board of Dentistry

FROM: PHIL DAHL, DDS

● Subj: Fw: Dock#01N-0067- Against the FDA Rule on Mercury Dental Fillings
Date: 9/17/2002 5:47:19 AM Pacific Standard Time

From: phil dahl
To: fdadockets@oc.fda.gov
Sent: Tuesday, September 17, 2002 8:40 AM
From: phildahltheteeth@tvli.net

Subject: Dock#01N-0067- Against the FDA Rule on Mercury Dental Fillings

Dear Sirs,

Place me on record as being in opposition to any statement that dental fillings containing mercury are safe. I have seen enough people harmed by those substances and if you continue in this course, they will show you a rath which I cannot.

Furthermore, since the scientific evidence is there and growing, you will not only become a political liability to anyone associated with you, you will be a laughing stock in the scientific community.

Sincerely,

● Philip Gerard Dahl, D.D.S.

●

FROM; MARC C. FLACK, D.D.S. F.A.G.D. A/F.I.A.O.M.T

Subj: Docket #01N-0067 - Against the FDA Rule on Mercury Dental Fillings

Date: 9/14/2002 10:48:05 PM Pacific Standard Time

From: mdflack@xmission.com

To: fdadockets@oc.fda.gov

Please respond to this attached letter.

Docket #01N-0067 - Against the FDA Rule on Mercury Dental Fillings

Dear Committee Members:

It is my understanding that the FDA is considering enacting a rule to cover up the risks of mercury present in dental fillings in the mouth. As a dentist that has been involved in and studied the science on this issue for nearly twenty years, I am convinced that you will be derelict in your duties to protect the American public if you rule in favor of implementing this ruling.

Please explain to me why there are no warnings available to consumers about the health hazards they may face due to the exposure of mercury amalgam fillings going into their teeth. Mercury is toxic in any form and I have found through testing with a Mercury Vapor Analyzer, that there is mercury coming off of nearly 100% of all amalgams that I have tested. Many times, the levels I have tested are well above exposure limits set by our government. Why is it toxic on my dental counter and has to be treated as a toxic hazardous waste, and it is supposedly non-toxic in a filling in the mouth. There is adequate research that points out the detrimental effects of mercury exposure from dental fillings. It appears to me that you are ignoring the science and that this rule you want to impose will only protect the ADA's position on safety, instead of protecting the American public.

The latest federal report on mercury by the Agency for Toxic Substances and Disease Registry appears to be totally ignored. Who is responsible to review and report this research to committees so they can make better decisions? As a dentist, I have seen first hand the toxic effects on many people as a result of getting mercury dental fillings. I deal with patients who are damaged by mercury on a daily basis in my practice. Mercury in dental fillings does leak out of the fillings for the life of the filling. Mercury is absorbed by the patient into tissues and organs where it causes damages. It may take years to express itself, but it does eventually. PLEASE do not enact this ruling - many will suffer if you do and it could be someone you that you know and love! Mercury from any source has no place in the human body. Please read the science and act responsibly for the good of the public.

I do expect a written reply to this letter.

Sincerely,

Marc D. Flack D.D.S. F.A.G.D. A/F.I.A.O.M.T
2417 E. Karren St
SLC, Utah 84124
Sept. 14, 2002

FROM: Deborah L. Pence DDS

Subj: Docket #01N-0067-AGAINST the FDA rule on Mercury Dental fillings

Date: 9/17/2002 12:27:08 PM Pacific Standard Time

From: debpence@mindspring.com

To: fdadockets@oc.fda.gov

Dear Sirs and Madams,

I am writing today to once again express my educated and earnest concerns about the mismanagement of the classification of Dental Amalgam.

I am a licensed dentist and former dental school instructor. My discovery of the current FDA stance on Dental Amalgam has created an intolerable level of skepticism about the independence of YOUR GOVERNMENTAL ORGANIZATION from the PRIVATE INTERESTS of the American Dental Association.

Is it true that in your classification of Dental Amalgam, the main component, MERCURY, IS EVALUATED AND CLASSIFIED SEPARATELY from the rest of the components of this dental device which dentist install (once mixed together) just inches from human brains?

If so, what purpose justifies this departure from common sense?

Does it help the individual practitioner to make informed choices on the behalf of the patients who trust him/her?

Would it sound cynical if I mention a broadly known fact?

Mercury is a neurotoxin.

Would it sound threatening if I mention a lesser known fact?

The FDA's dental division is staffed exclusively with ADA-indoctrinated recruits. These few facts demand yours and the public's immediate attention.

Sincerely,
Deborah L. Pence DDS

FROM; DR. STEVEN A. SWIDLER, DDS

Subj: Docket # 01N-0067 - AGAINST the FDA rule on Mercury Dental Fillings

Date: 9/16/2002 2:00:48 PM Pacific Standard Time

From: Steven A. Swidler DDS

To: fdadockets@oc.fda.gov

To Whom It May Concern:

Please register this e-mail as severely against the FDA rule on Mercury dental fillings.

Mercury is neurotoxic and we need not to be exposing anyone to fillings that are 50% mercury, vaporize measurably throughout the life of the filling and the waste is now creating such high wastewater reading of mercury traced to dental offices that separators must be placed in offices.

Existing science demonstrates unequivocally that mercury vapor from mercury containing amalgams cross the blood brain barrier, the placental barrier and through breast milk. A decision to allow these fillings as safe in the face of existing scientific proof will reflect directly back to it's originators as an infamous harm to the public.

Sincerely,

Dr. Steven A. Swidler DDS

FROM: JEFFREY A. NELSON, DC

Subj: Docket # 01N-0067 - AGAINST the FDA Rule on Mercury Dental Fillings
Date: 9/15/2002 9:02:34 AM Pacific Standard Time
From: leldc@optonline.net

TO: Food and Drug Administration
Dockets Management Branch,
5630 Fishers Lane, Room 1061- HFA-305
Rockville, MD, 20852

From: Jeffrey Nelson, DC
1946 NY Ave
Huntington Station NY 11746
jeff.nelson28@verizon.net

RE:Docket # 01N-0067 - AGAINST the FDA Rule on Mercury Dental Fillings

This letter is regarding the above captioned FDA proposed ruling.

I strongly urge you to consider the ramifications of this proposed classification by your office of dental mercury "silver" fillings. Objections to the reclassification of mercury in "silver"/amalgam dental fillings from Class I dental device to Class II are rampant nation and worldwide.

As you are aware, these fillings contain approximately 50% mercury, a commonly known neurotoxin and the most poisonous non-radioactive metal in the periodic table of elements. A nationwide public forum need be held in order to inform, as is one of the primary duties of the FDA, the public and scientific community and to evoke their input on this issue. The public also needs far more widespread notification and education, another primary function of the FDA, on your offices proposal to reclassify mercury's status.

Certainly, as popular as this critical issue has become, the last thing the FDA would want would be perceived as shutting such an important ruling, if not down our throats, then most assuredly at least into our teeth, without a reasonably publicized campaign. Consider how much publicity and legislation lead(Pb) has received over the past few decades—a metal that is only 11% as toxic as mercury(Hg). You could consume eight times as much lead and still not be a poisoned as 1/8 the same amount of mercury.

Thousands of pages of peer reviewed valid and unbiased scientific studies exist worldwide attesting to the fact that mercury vapor is released slowly from dental amalgam fillings especially every time someone chews. There are further unbiased and independent studies that show the dental health community reveal far greater mercury related symptomatology than the general public, much like the "hatter" industry did in the 19th century from mercury industrial exposure.

Mercury rarely cause "allergies," it is a poison—just slightly less toxic than arsenic(As). You are incorrect in assuming or stating that people don't become ill from it.

If mercury is banned from thermometers, advised against being consumed in seafood for gravid mothers, and newly or long time banned in nearly all publicly offered items, as well as handled as the toxic substance and waste that it is by the dental profession, why is the only safe place for it in our teeth?

Another recent major federal report on mercury by the Agency for Toxic Substances and Disease Registry cannot be ignored or explained away without embarrassment to your office. You have selected old data and have ignored the most current research. According to the EPA, amalgam/silver filling are classified as hazardous waste. What is it when it's in the patient's mouth? The American Medical Association in the New England Journal of Medicine, as early as 1990, recognized that the mercury, rather deceptively labeled as "silver" in dental fillings, is hazardous to one's health. With so much evidence to contradict the safety of mercury, a large percentage dentists are holding fast to their mercury tradition much in the same way that smokers hold fast to their defense of tobacco. There are striking similarities to those certain individuals that are seemingly cancer resistant in lieu of a lifetime of smoking. Certain individuals are more resistant to heavy metal sensitivities and therefore less symptomatic.

Your ruling is not strong enough and will protect ADA dentists but not the public. Those mercury dentists are injuring patients by not informing them that they are placing mercury in their teeth. Please make them prove mercury amalgam SAFE instead of accepting their long term and false smokescreen defense that mercury has never been proven unsafe. Mercury in compound with the various other amalgam heavy metals, is not stable and does release from compound in vapor form.

I urge you to not reclassify the mercury in dental amalgam in the filling from Class I to Class II. If you do reclassify it, make it Class III and PROVE to the American consumer that mercury is safe AND that their best health and environmental interests are being protected by the FDA.

I, like hundreds of thousands of others, have personally suffered from high mercury levels from high mercury levels from mercury amalgam fillings augmented with other exposures to mercury. I have suffered, in many insidious ways, from the adverse effects of this toxic metal that was, without my knowledge, placed into my mouth in my early years. We evolve and become increasingly educated as a race and populace. We have done so regarding dental mercury to the point of dentists no longer being able to bare hand mercury in their offices as was common practice only a few decades ago. You are urged to protect the public from further exposure to the most poisonous metal this side of plutonium.

There is no longer any need for mercury amalgams to be sold by the dental community. Mercury amalgams has run its course. Restricting or banning them, as has been done in several other countries, has and will spur on better and new alternatives to toxic heavy metal placement. The durability advantage to amalgams is close to being a moot point. The only remaining advantage to mercury fillings seems to be an economic one for those that persist with them. Even that is a dubious advantage at best. This is the beginning of the end of mercury in the public domain. Please make the first strong statement to that effect by classifying mercury amalgams Class III and demand social and environmental responsibility to those who produce and profit from it.

Yours,

Jeffrey A. Nelson, DC

FROM: Elisabet Carlsson, Master of Political Science, Sweden

Subj: ³Docket # 01N-0067 - AGAINST the FD A Rule on Mercury Dental Fillings²

Date: 9/15/2002 12:09:18 AM Pacific Standard Time

From: elisabet.carlsson@kurage.se

To: fdadockets@oc.fda.gov

To:
USA Food and Drug Administration
Dockets Management Branch,
5630 Fishers Lane, Room 1061- HFA-305
Rockville, MD, 20852, USA

From:
Elisabet Carlsson, Master of Political Science
elisabet.carlsson@kurage.se

Högbergsgatan 40 A
SE-118 26 Stockholm
Tel: +46(0)8-640 03 87
Fax: +46(0)8-640 03 88
Mobile: +46(0)70-791 25 07

Date: September 15, 2002

Dental amalgam which contains 50 percent Mercury is not only a threat to peoples health but also an environmental problem.

In Sweden the population is recommended not to eat fish from 30 000 lakes due to the high amount of Mercury in each of these lakes. That is why we are careful not to let out more of this poisonous metal into the environment.

Since there are no industries working with Mercury in the city of Stockholm any more dentistry is the big problem.

This is a poster prepared by Mr.Bernt Wistrand from Stockholm Water Company for an international conference in Berlin 2001.

I ask that the FDA consider the above material, and ask that you restrict or ban the use of dental amalgam in the USA, to protect the public health and the environment in order to protect future generations.

Thank you for considering my letter.

Sincerely,

Elisabet Carlsson

In 1997 the Swedish Council for Planning and Coordination of Research (FRN) was commissioned by the Swedish Government to shed some light over the issue of amalgam usage in dental implants. The result was published in a report called Amalgam and health - New perspectives on Risks. Report 999:1

In a literature and knowledge summary about Mercury in dental fillings - an Environmental medicine risk Assessment professor Masths Berlin says: "Mercury is a multi-potential cell toxin attacking the cell's primary processes, which creates preconditions for a broad spectrum of possible side-effects. The prevalence of side-effects from the mercury in amalgam on the nervous system, immune system and kidneys seems in total to be between 10% and 0,1%, probably about 1% which means around 50 000 cases with an uncertainty interval between 500 000 to 5 000 cases in the Swedish population. (8 million people) --- However, nothing has emerged to contradict the idea that the cessation of the exposure to mercury through the removal of all the amalgam can restore the patient's health with regard to effects induced by the mercury exposure. --- The risk that the brain's development during foetal stage and during early childhood can be inhibited by exposure to mercury from the mother's amalgam or the child's own amalgam fillings is significantly more serious."

Of course it is quite possible for the FDA to ignore material like this and to ignore the science, the reports from medical doctors, dentist and patients and still claim that there is no scientific proof that amalgam causes health problems in humans. But meanwhile, out there in the real world, people are suffering from the side effects of mercury which is one of the most toxic substances we know about. The patients has a very low quality of life which also effects the families. And the insurance system has to pay the prize. Sooner or later the public is going to ask why the FDA did not listen to the Citizens.

With hope for a new policy
Elisabet Carlsson

--

K U R A G E K B

Elisabet Carlsson
elisabet.carlsson@kurage.se

Högbergsgatan 40 A
SE-118 26 Stockholm
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From: Alan Noelck DDS

[mailto:hgfree@earthlink.net]

Sent: Saturday, September 14, 2002 9:06 PM

To: fdadockets@oc.fda.gov

Cc: brownchas@erols.com

Subject: "Docket # 01N-0067 - AGAINST the FDA Rule on Mercury Dental Fillings"

Food and Drug Administration

To whom it may concern:

Mercury is a poison. Dental Amalgam contains approximately 50% mercury. It is not stable. We are taught to handle the scrap that is not placed in the mouth as a toxic waste because mercury vapor is continually being released from the Amalgam BECAUSE IT IS NOT A STABLE COMPOUND. If it is toxic outside the mouth, how can it be safe in a persons mouth? Please review the research, not just the ADA's pro mercury research or their antidotal comments that it has been used for 150 or more years. Put it to the same stringent requirements that are now required to prove safety before a product reaches the market. Read the research published in peer reviewed scientific journals, not only the ADA publications.

As "Doctors" we are taught to be able to read and understand the research. We are taught to use our minds and evaluate what is best for our patients. What has happened to the ideal of "doing no harm" to our patients? Placing Mercury in someone's body is doing harm to them.

Please think with your minds. Evaluate all the evidence, and I am sure you will agree that Mercury (Amalgam) is toxic.

MERCURY DENTAL FILLINGS ARE UNSAFE.

Thank you for keeping an open mind and considering my point of view.

Respectfully'

Alan L. Noelck, D.D.S.

Rebecca L Griffiths, BS, DMD Mercury Toxicity Testimonial Letter

13 September 2002

To Whom It May Concern:

I am a practicing dentist, who matriculated from Temple University School of Dental Medicine in 1982. Prior to that, I received a bachelor degree in Biology with a minor in Chemistry, graduating cum laude in 1978. I am well educated in anatomy, neurology, physiology, microbiology, inorganic and organic chemistry, and physics. I also have an extremely logical and constantly questioning mind.

I started to become poisoned from mercury in my teen years (1970s), although the symptoms were not recognized by my healthcare providers at the time. I had had numerous mercury fillings placed into my teeth over the years, starting from about the age of three.

While attending dental school, I continued to have the same symptoms, only worsening in their intensity. Again undiagnosed, I continued to work with mercury fillings, now not only present in my own teeth, but I was handling it and placing it into and grinding it out of the teeth of my patients. As my exposure increased, so did my symptoms.

I hit "rock bottom" with my health in 1995 and began to seek care from holistic alternative healthcare practitioners who practiced "blended" medicine, with a focus on chemical toxicity. This was when I was advised to have the mercury removed from my teeth and to stop handling it in the workplace. I was shocked.

I was so brainwashed by the stances of the ADA and FDA on the harmlessness of mercury in the human body, that I continued to doubt what these holistic practitioners told me, even though I wanted an end to my symptoms badly. I suffered two more years and then finally I had the mercury fillings removed from the entire left side of my mouth one day, on the spur of the moment, with no detoxification procedures performed beforehand, because I still didn't believe that my fillings were the cause of my problems. So many respected allopathic healthcare practitioners and their organizations were still refuting this theory of mercury toxicity.

When I went home that evening, I developed flu-like symptoms, with lymph node enlargements in my neck and armpits, and a massive headache. My armpits hurt so badly that I didn't want to lower my arms from shoulder height. I couldn't focus enough to make dinner for my family. The following morning, I couldn't force myself to get out of bed to go to work and I was so mentally depressed that I was having vivid images of committing suicide. My physician, William Kracht, DO, an internist with a specialty in environmental medicine and practicing at Woodlands Medical Center, was contacted and I was taken to his office for an intravenous detoxification "cocktail" including a massive load of vitamins and minerals, to counteract the mercury poisoning. I was now a believer in the absolute neurotoxicity of mercury to humans.

There is no acceptable ppm level of mercury for humans. That is why there is no mercury ever present in humans, except for what is there from environmental exposure to this lethal neurotoxin.

The Occupational Safety and Health Administration and their guidelines that became mandatory in 1981 was a godsend to the dental profession. Finally, a government organization was put into existence and the main goal of that organization is worker safety in the workplace. OSHA mandated that no more leftover mercury filling material would be allowed in the ordinary trash that went to landfills. It was polluting the environment and contaminating fish and wildlife. Mercury filling material was classified as a hazardous substance.

Is it logical thought to assume that the only safe depository for mercury is in the human body, when even the Earth's ecosystem can't handle it???

Please pass a ruling that totally eliminates the use of mercury in filling materials and in any other dental devices, including dental alloys and plastics. Do not protect its continued use in the human body, when it has been recognized for years as an extreme neurotoxin.

Sincerely,

Rebecca L Griffiths, BS, DMD
AZ License 4480
PA License DS-022816-L
drrebecca@cox.net

From: Robert Kulacz DDS

[mailto:robert.kulacz@verizon.net]

Sent: Saturday, September 14, 2002 9:23 AM

To: 'fdadockets@oc.fda.gov'

Subject: Against mercury dental fillings

Dear FDA:

I am a dentist in New York. I am writing concerning the use of mercury amalgam in dentistry and the continued position held by the American Dental Association that amalgam poses no health risk. Mercury has been removed from medical products, from latex paint, and many other products. Mercury is an extremely potent toxin; toxic in even the smallest quantities. Mercury continually leaches out of mercury amalgam. Some people have large volumes of mercury amalgams in their mouths due to many large restorations. We have alternatives, why do we continue to place a hazardous material, one that must be disposed of as hazardous waste, into our bodies? It just does not make sense.

The only reasons that I can think of is that

1. The ADA and dentists fear lawsuits since they have proclaiming mercury amalgam to be safe
2. The insurance companies do not want to pay for removal of amalgam or the subsequent higher cost of alternative materials.
3. The insurance industry fears an abundance of disability claims.
4. Dentist would lose income since amalgam is much easier to place than alternative materials.

The issue is not that complicated. Mercury is toxic in small amounts. Mercury is continuously released from amalgam fillings. There is no safe level of mercury exposure. Mercury has been removed from products that give far less exposure. We have alternatives. Why are we still using it and advocating its safety?

The issue of amalgam safety cannot be closed without a thorough investigation by appropriate research scientists, not the ADA. Any other action is a violation of the public trust and clear evidence that science comes in second to politics.

Very truly yours,

Robert Kulacz, D.D.S.

To:
USA Food and Drug Administration
Dockets Management Branch,
630 Fishers Lane, Room 1061- HFA-305
Rockville, MD, 20852, USA

From:
Maryanne Rygg
Halden terrasse 9c
N-1367 Snarøya
Norway

Date: September 14, 2002

I am an American citizen who has lived in Norway for 26 years. During that time I became aware of the dental amalgam issue after becoming seriously ill with a chronic intestinal disease, and was diagnosed as having Mb. Crohn or a similar disease. After removing amalgam with adequate protection, and following my doctor's advice to take antioxidants and other food supplements, I have recovered. I have not taken medications for 5-6 years, and I have no symptoms of the disease at present. I have been hospitalized for this illness only once (12 years ago), and that was before I had my amalgam removed.

I am writing because I heard that the FDA is accepting public comments about dental amalgam until September 16, 2002.

I would like to make you aware of the status of dental amalgam in Norway. A study of dental materials was done by the Norwegian Board of Health in 1998. You may find the conclusions from this study in English at the website of the Norwegian Board of Health:
<http://www.helsetilsynet.no/trykksak/ik-2675/ik-2675.pdf>

As a follow-up to this study, an international conference was organized by the Norwegian Board of Health in May, 2000. The official report from this conference, in English, is posted at this website:
<http://www.bysant.com/helse/main.html>. At this conference the highly respected international mercury expert Maths Berlin said that the risk involved for future generations is by itself reason enough to prohibit the use of dental amalgam. I was there and heard his comments. You will find very much relevant information from experts in this report.

The Norwegian Directorate for Health and Social Welfare has followed up by writing new proposed guidelines for the use of dental materials in Norway. You will find the official English version of their press release at this site:
<http://www.shdir.no/index.db2?id=1522>

The entire text of the proposed guidelines may be found (in Norwegian) at this website:
<http://www.shdir.no/index.db2?id=1430> (as pdf files). Since I assume that it may be difficult for the FDA to read Norwegian, I enclose a file with my unofficial translation of these proposed guidelines. I assure you that my Norwegian is adequate to translate this document correctly. There is one table of technical terms which I have not translated, in addition to one technical term in the text of the document. I know that the Norwegian Directorate for Health and Social Welfare was in the process of making an official translation, but I do not know if this is finished. The person responsible for this work at the Directorate is Senior Adviser Liljan Smith Aandahl, and her e-mail address is: Liljan.Smith.Aandahl@shdir.no

The deadline for public comments on these proposed new guidelines for the use of dental materials in Norway is October 1, 2002. The Directorate expects the new guidelines to take effect on January 1, 2003.

I ask that the FDA consider the above material, and ask that you restrict or ban the use of dental amalgam in the USA, to protect the public health and to protect future generations.

Thank you for considering my letter.

Sincerely,
Maryanne Rygg (an American citizen)
Halden terrasse 9c
N-1367 Norway

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Participants in the group that handled 'Directive for dental filling materials' on the second day of the conference in May 2000, the national day, were:

Jon E. Dahl, NIOM, Secretary for the group
Jan Ask, Norwegian Dental Association
Kari Odland, Norwegian Dental Association
Maryanne Rygg, FTH (substitute for Dagfinn Reiersøl)
Christer Malmström, Swedish dentist (recommended by FTH)
Dag Ørstavik, NIOM
Asbjørn Jokstad, Faculty of Dentistry, University of Oslo
Gunhild Westerhus Strand, Faculty of Dentistry, University of Bergen
Magnar Torsvik, Chief County Dental Officer
Tore Ramstad, National Insurance Administration
Vibeke Qvist, School of Dentistry, Denmark
A representative from 3M (a producer) was also invited.

During autumn of that year a new revised draft was sent out for comments to the institutions and groups that had participated in compiling and revising the draft. Work in the groups was of course characterized by the considerable professional disagreement that prevails regarding amalgam. When the internal round of comments was over and the comments were to be worked into the drafts, the disagreement became even more pronounced, and NIOM's representative withdrew from further work with the 'Directive for the use of dental restorative materials'.

The Norwegian Board of Health decided that the health authorities themselves would compile a draft that expressed the health authorities' purpose for working out such directives, assessment of the factual basis that was generated through work with the study IK-2652, in the process of work with the directives and the comments received.

The directives, when they are finished, will replace the circular IK 51/91 published by the Norwegian Board of Health in 1991.

Target Group

Professional personnel in dental services: dentists and dental hygienists.

Goal

- The general population receives reliable, safe and good dental health services of good quality with materials that satisfy present-day demands
- The mercury burden of the population is reduced
- The amount of mercury released into nature is reduced

Use of the Directive

The directive shall guide dentists in their choice of dental restorative materials for various indications. The directive shall be used as a tool to reduce the use of amalgam in dental health services.

Factors when Choosing Materials

- The choice of material should be made based on a complete diagnosis including the patient's medical history and clinical, X-ray and other findings together with consideration of the likelihood of the degree to which the patient may be able to follow advice and recommendations. Preventive care should weigh heavily in the consideration. For operative treatment, the most conservative preparation techniques possible should be chosen.
- The dentist is responsible for the choice of dental material, according to the law regarding health personnel § 4. This choice should be made in consultation with the patient or parent/guardian. In the event of deviation from this directive in the choice of dental material, the reasons must be specified and the patient's informed consent entered in the dental journal.
- Only dental materials that bear the CE symbol shall be used. Pre-dosed packages are recommended. Indications, counter-indications and directions for use from the manufacturer shall be followed.
- The use of amalgam shall be limited as much as possible due to possible health and environmental damage. Amalgam, if it is to be used, must not come in contact with other metals. When a patient must be treated under anesthesia, amalgam may be used when broad indications are present.
- Filling therapy should be avoided as much as possible for pregnant women.
- New amalgam fillings should not be placed for persons with renal (kidney) ailments.
- Allergy for a particular material is a counter-indication for use of that material.
- A vacuum suction shall be used when removing previous fillings. For advice concerning removal of amalgam fillings, consult the website of the Norwegian Adverse Reaction Unit: www.uib.no/bivirkningsgruppen. Efforts should be made to reduce exposure to chemical substances under dental treatment for both patients and dental personnel.

Choice of Dental Material

Table 1. The table shows prevailing practice in much of the dental health services. The Directorate for Health and Social Welfare interprets this as an expression of good practice. (This table is presently not translated to English.)

Permanent teeth				
Location of caries	Standard material	Alternatives	Comments	Documentation
Fissurforsøgling	Plast resin (spesialmidler) Kompositt Glassionomersement	Resinmodifisert Glassionomersement		(1)
Okklusalt	Kompositt Posterior glassionomersement	Innlegg*	Alternativer kan vurderes ved store fyllinger	(2;3)
Approksimalt premolarer og molarer	Kompositt	Posterior glassionomersement** Innlegg* Amalgam	Glassionomer kan vurderes ved moderat belastning. Amalgam kan vurderes ved høy kariesaktivitet, store fyllinger og vanskelig tørlegging dersom andre alternativer er uaktuelle	(4-13)
Approksimalt fortenner og hjørnetenner	Kompositt	Glassionomersement Posterior Glassionomersement*		(14;14)
Hjørneoppbygging	Kompositt	Skallfasett*** Krone****		
Facialt og oralt	Kompositt Resinmodifisert glassionomersement Glassionomersement Polysyremodifisert kompositt (kompomer)		Velges etter kariesaktivitet og estetikk	
Baby teeth				
Alle flater	Posterior glassionomersement* Resinmodifisert glassionomersement	Polysyremodifisert kompositt (kompomer) Kompositt Stålkrone	Stålkrone ved store destruksjoner	(9;10;15-17)

*Innlegg av metall, keramisk materiale eller kompositt

**Posterior glassionomersement betyr nyere typer av konvensjonell glassionomersement der produsenten angir bruk i belastede flater.

***Skallfasett (skallfasade, skallkrone) av keramisk materiale eller kompositt

****Krone av metall og keram (MK), metall og kompositt eller av hel-keramisk materiale

As shown in the table, for several indications various materials may be **recommended standard materials**. This directive does not exclude choices that are not recommended, but the manufacturers description of indications are always the determining factor. If materials are chosen from the **alternatives**, an explanation must be given in the patient's journal.

Implementation and Evaluation

When finished, the directive will be printed and sent to all dentists and dental hygienists in Norway. The Directorate for Health and Social Welfare will provide information to the Chief Dental Officers in each county and will, if desired, participate in meetings of local chapters of the Norwegian Dental Association throughout the country.

A survey will be carried out during the autumn of 2002 to chart the amount of amalgam being used in the dental health services. For evaluation purposes, this will be repeated after five years.

Remaining Work

In order to meet the requirements set forth in the 'Directive for Directives', work will take place parallel to the gathering of public comments, to conduct new searches for documentation based on a specified search strategy. Both new material and references already included in this draft will be critically considered and subject to quality control. Inclusion and exclusion criteria for documentation that is used in the finished directive will be described.

The Directorate for Health and Social Welfare will as far as possible attempt to grade the knowledge base and classify the strength of recommendations as follows:

Knowledge base and documentation

The grading of the knowledge this directive is based upon shall, when the directive is complete, be done according to the following scale:

Level 1 (very good): A good, systematic review with at least one good study

Level 2 (good): At least one good study

Level 3 (deficient): No good studies

Classification of strength of recommendations

Strong: Based on very strong documentation; level 1

Moderate: Based on at least one good study; level 2

Weak: Based on deficient documentation; level 3

Background

Work on developing this directive was started by the Norwegian Board of Health. It is an assignment given by the Ministry of Health and Social Welfare financed by the State in its annual budget. In connection with reorganization of the central health administration agencies in Norway, this work was transferred to the Directorate for Health and Social Welfare. This directive is a result of follow-up work for the study entitled *The Use of Dental Filling Materials in Norway*, number IK-2652 in a study series by the Norwegian Board of Health (hereafter called 'the study'), presented to the Minister of Health in October 1998.

When work on the study was started in the autumn of 1997, it was important to take into consideration the criticism that was directed towards similar studies done in other countries. Those studies were criticized as being one-sided, dominated by odontologists, and because odontologists wrote about subjects that did not fall within their primary area of expertise.

The study was organized as a project, with a steering committee, supplemented by a quality assurer, a project group and a reference group. The important task of choosing contributors within various professions and sectors was given to the project group. The project group consisted of the (now former) leader for Forbundet Tenner og Helse (the Norwegian Dental Patient Association), an epidemiologist and a neuropathologist, in addition to the project leader.

The project group resolved that contributors would be chosen who were in a position to write on their own primary area of expertise and apply this specialized knowledge to the use of restorative materials in dentistry. To give the study added legitimacy, it was decided that such contributors should, as far as possible, be drawn from circles which had not been strongly involved in the previous debate surrounding the use of amalgam. This was in order to ensure access to persons with the relevant expertise who would be able to take a fresh and unbiased look at the matters at issue from their own specialized points of view. This was done because the amalgam issue has attracted more than just professional curiosity and a scientific approach from those who have participated. In this regard it can be appropriate to give a reminder of the Swedish project leader's warning to both sides in connection with the last Swedish study (18):

'During the work on the report, the FRN has been forced to notice a widespread tendency among researchers in the field of amalgam to set aside the scientific, critical approach. The Committee therefore urges both researchers in the field and financing and executive organizations to monitor the scientific quality of the work in a better way.'

Authors of the various chapters are personally responsible for the contents of their contributions to the study. The Norwegian Board of Health is responsible for Chapter 1, which contains its assessment and recommendations.

The Study consists of chapters within a broad range of subjects. The use of restorative dental materials was examined from a philosophical point of view in addition to the treatment of the subject by the media, and by the opinions and conclusions of the medical and odontological disciplines. The judicial and social economical aspects were also examined.

In contracts with the authors, it was not specified that they should describe the search process they had used to find documentation, and they were not asked to grade the strength of the documentation. Nor were they asked to explain the inclusion and exclusion criteria. Most of the authors have, however, done a broad search and used large amounts of documentation, which is included in the list of references for each chapter. These are available at www.helsetilsynet.no

Assessments

This directive builds upon assessments based on scientific articles and experience, new public health administration principles and rights and duties resulting from new laws.

Assessment based on scientific articles and experience

1. Dental fillings are in principle a form of prosthesis that replaces natural highly specialized tissue. It is very difficult to find materials that are good enough. The ideal dental filling material does not exist at present.

When a dental filling must be installed, it is important that the filling technique chosen is conservative and involves minimal removal of dental tissue (19;20).

2. Materials are now available that do not require removal of as much dental tissue to obtain retention as amalgam requires, and which are considerably more satisfactory from an esthetical point of view. They do not seem to represent an environmental problem either. **Glassionomer** cements and adhesive resin-based filling materials (composites) that bind to the dental tissue are more suitable for conservative preparations than amalgam (21).
3. Existing dental restorative materials have various technical, biological and esthetical properties and therefore have limited indications for use. Limited documentation is found from clinical studies that compare the properties of the newer materials. This is because the development of new materials is happening so quickly that time is too short to reap clinical experience with one material before another purportedly better version appears. In the nordic countries there are, in addition, considerable differences in choice of materials for equivalent indications (2;6;6;7;22;23;23). It is therefore difficult to give recommendations about filling materials that can be expected to apply for a long period of time. The recommendations given in Table 1 are based on top national health and environmental priorities, and certification provisions in the Agreement on the European Economic Area have been taken into account. Furthermore, they are based on recommendations from schools, newer publications, the producers' directions and experience from odontological practice (2;4;4;6;24-26).
4. When treating primary caries in permanent teeth, **glassionomer** and adhesive resin-based filling materials are a natural first choice (25). There is also a clear trend towards replacing amalgam with other dental restorative materials in the clinics practicing general dentistry (4). For baby teeth it has been generally accepted for a long period of time that appropriate enamel-colored fillings are the first choice, even though they do not endure as much bite pressure as amalgam (24;25).
5. When odontological indications exist for replacing an amalgam filling, preparations for amalgam already exist, and the argument that new materials save tooth substance are no longer applicable. In some cases where a large amalgam filling is to be replaced, a choice may be made between a new amalgam filling and a crown.
6. Only in cases where a long lifetime for the filling is important and short treatment time with few sessions is required, for example for patients who must be treated under anesthetics, may indication exist for the use of amalgam.
7. There is a certain amount of risk for adverse reactions involved in the use of all dental restorative materials. The prevalence is low however. During the past few years, the relative fraction of amalgam-related adverse effects has stabilized, and there has been no alarming increase for other materials, even though the use of these has increased. Where dental material reactivity testing ('patch testing') has been used to find possible allergic reactions, amalgam and plastic components were the substances which gave the lowest number of positive reactions for patients that were referred to the Norwegian Adverse Reaction Unit (Annual reports 1998, 1999, 2000). Most of the positive reactions were from gold/palladium and nickel. The clinical relevance of the dental material reactivity test is uncertain, but at present no better test has been found. It is difficult to give general recommendations for choosing one dental restorative material rather than another, based on the adverse effects profile of the various materials.
8. There is, however, reason to point out that for dental health personnel the handling of adhesive resin based filling materials (composites) before they are cured seems to involve the greatest risk for development of allergic responses (27).
9. Amalgam has been used in dentistry in Norway for more than 100 years, and is the restorative material that contributed most to eliminating edentulousness in Norway, because it was both inexpensive and easy to use. There is, however, extensive agreement that mercury from amalgam fillings makes up a substantial portion of the mercury to which the general public is exposed (28;29).

10. It is known that mercury in high doses leads to health damage such as disturbances in brain function, kidney function, the immune system and fetus development (28). There is no identified lower limit where sub-clinical injury in these areas can set in. No limit has been established for safe/harmless influence either (30). Sub-clinical effects have, however, been shown at doses equaling those which some persons can receive from amalgam fillings (31;31-35). In some publications, no relationship is found between illness and the number of amalgam fillings (36-39).
11. The amount of mercury vapor released from amalgam fillings increases when chewing, brushing teeth and with bruxism (grinding the teeth). There have been reports about persons who have had a high level of mercury in blood/urine due to intense chewing of gum while attempting to quit smoking (32;40-43). Considerably lower amounts of mercury have been found after removal of fillings from some of the same people.
12. During the last 10-15 years, documentation has become available showing that mercury from amalgam fillings is traced in locations in the human body where it is unwanted. It has been shown that the amount of mercury in the brains of deceased persons correlates with their number of amalgam fillings (44). Mercury passes through the placenta, and the mercury concentration in fetuses correlates with the number of amalgam fillings in their mothers (45). The amount of mercury in breast milk increases with increasing numbers of amalgam fillings in the mother (46). Those who bear amalgam fillings have more mercury in body fluids than persons without amalgam fillings (47).
13. Dentists and doctors in Norway are less concerned about health effects from amalgam than the general public (48). There are, however, some articles that indicate health effects on dental personnel (33;49-51).
14. It has been reported that a majority of those who assume that their health problems are due to amalgam fillings, experience an improvement in their health after removal of amalgam fillings, but this is a complex area where cause and effect mechanisms have not been clarified (52;53). A relationship between the mercury level in body fluids and symptoms has not been shown (54).
15. The possibility that mercury can be methylated in the human body makes it more difficult to determine the mercury burden from amalgam fillings (55;56).
16. No data has been presented that proves it likely that mercury impact from amalgam leads to illness for many persons. Risk studies have, however, indicated that for a minority of the population, a combination of increased sensitivity and genetic risk factor can lead to health damage resulting from mercury influence (57).
17. The margin of safety between the mercury burden some persons with amalgam fillings experience and the burden that can set off illness, is small. A Swedish expert group concluded as early as 1987 that amalgam, from a toxicological point of view, is unsuitable as a dental filling material (58).
18. Mercury from amalgam fillings is the only component of dental restorative materials that is considered as an actual environmental problem. The strong increase in the concentration of mercury in the food chain is especially a problem (59). Consideration of both public health and the environment requires that the use of heavy metals be held at the lowest possible level.
19. Although all dental clinics are now required to collect amalgam waste in special separators, the Norwegian Pollution Control Authority is still of the opinion that it is desirable to find more environmentally friendly dental materials than amalgam. In the Ministry of the Environment's 'Handlingsplan for helse- og miljøfarlige kjemikalier' (Action plan for chemicals that are a hazard to health and the environment) from 1999, strong action is recommended in working to reduce the release of or phase out environmental toxins. Mercury is among the most problematic environmental toxins (59).

Assessment regarding new public health administration principles

Public health perspective and the precautionary principle

Amalgam is one of the oldest filling materials we have, and it has periodically been controversial during the whole time it has been in use. It has been known for a long time that mercury is released from amalgam fillings, and during the last decades much documentation has appeared regarding absorption of mercury from amalgam in humans.

Mercury is among the most problematic environmental toxins. It has been documented that mercury from amalgam fillings contributes substantially to the total mercury exposure of the population (28). The documentation that exists at present is not accepted as evidence that mercury from amalgam fillings leads to health damage in patients without a clearly defined clinical picture, although many of them have experienced complete or partial improvement after removal of amalgam fillings. For precautionary reasons it is important that the exposure of the population to mercury is limited to the lowest possible level (59;60). It is therefore natural to replace amalgam with other dental restorative materials as far as possible, since good alternatives are available.

Newer materials can also possibly have unfortunate effects that we have not yet discovered. There is some documentation of undesirable conditions regarding tooth-colored materials (61). There is therefore reason to practice precautionary measures when new materials are introduced. In practice this will mean considering preventive measures, keeping a reasonably hesitant attitude towards filling therapy, and using conservative forms of preparation when a filling is required.

The Substitution Principle

The substitution principle entails that chemical substances which can result in damage to health or disruption of the environment, be considered replaced by less harmful substances. The alternatives to amalgam seem to represent less of a public health problem and a considerably less significant environmental problem than amalgam. In the law regarding control of products ('produktkontrollloven') §3a the duty of substitution is discussed. The Norwegian health administration is required to follow the substitution principle, which became law through passage of Ot. prp. nr. 40 (1998-99) through Innst.O.nr.70 (1998-99). The substitution principle entails that substances which can result in damage to health or disruption of the environment, be considered replaced by less harmful substances. The Directorate for Health and Social Welfare is of the opinion that this law also includes amalgam due to its high content of mercury.

Dentists today have several good alternatives to amalgam available. None of the alternatives can replace amalgam for all indications, but in sum they cover the entire breadth of indications. All of the restorative materials which may replace amalgam are, however, more expensive than amalgam.

Assessment of rights and duties resulting from new laws

Responsibility and Professional Justification

The dentist is responsible for the odontological treatment of a patient, including choice of dental restorative material. As health professionals, the dentist is obliged to perform in accordance with the requirements for professional justification and careful help that can be expected based on his/her qualifications, the character of the work and the situation in other respects, see the law on health personnel § 4. In addition, justifiable practice assumes that the patient has the right to participate, among other ways also in the choice between available and justifiable treatment methods, see the law about patient rights § 3-1. The dentist has a duty to inform required by the law on health personnel § 10.

Treatment in accordance with the requirement for justifiable practice means that each case must be considered separately. The choice of material must be based on medical history, the wishes of the patient, clinical, X-ray and any other findings, and a detailed diagnosis based on this information. When choosing treatment, the patient's capability to follow advice and guidance from dental personnel must also be considered. The

competence, skill and experience with various materials of the person performing the treatment, can be important for a successful result.

The use of pre-dosed packaging is recommended, because these reduce variation due to handling and reduce the danger of work related exposure for dental personnel. The producer's directions for indications, contraindications and handling of the material must be followed. When removing old fillings, a vacuum suction must be used in order to avoid unnecessary burden of harmful substances for the patient and personnel. For advice regarding removal of amalgam fillings, refer to the website of the Adverse Reaction Unit (Bivirkningsgruppen) at www.uib.no/bivirkningsgruppen.

An exact specification of which products have been used must be included in the patient's journal.

Informed Consent

In the law on patients' rights, the right of the patient or next of kin to participate and to receive information is specified. The patient's right to participate in decisions where several different treatments are considered professionally justifiable, is particularly emphasized. The patient is to receive, in advance, and as the dentist receives additional knowledge, information that is necessary to understand their condition and the contents of the help to be given, including information about possible risks or adverse effects. Information must be appropriate for the individual qualifications of the receiver such as age, experience and cultural and language background. The main contents of the information shall be recorded in the patient's journal. This is according to the law on patients' rights chapter 3 and journal regulations § 8j.

In practice this means that the patient/next-of-kin must be consulted when choosing restorative materials. It also means that the patient/next-of-kin shall be informed of the recommendations from the authorities. When information is given and conditions for informed consent are present, will keeping the appointment for treatment be understood as a tacit consent. Where there is an agreement to choose a treatment or a material that is not a standard choice, the reasons and the informed consent must be documented in the journal (journal regulations § 8i). The dentist has a right to, and under the circumstances a duty to refuse to carry out treatment that the dentist does not find professionally justifiable (law on health personnel § 4).

Conditions in other Scandinavian countries

Sweden

The government in Sweden has planned to ban amalgam. In the national budget proposal for 1999 (prop. 1998/99:1) it was announced that the government intended to do whatever was necessary to introduce a ban on the use of amalgam. It was to take effect at the latest from 2001. It appears, however, that the EU regulations and agreements entered into probably prevent a ban. In the budget proposal for 2001 (prop 2000/01:1) the government said that it would explore the possibility of banning amalgam out of consideration the environment.

Many of the 'landstingene' (state parliaments) have decided that amalgam shall not be used in dental care for children and youth.

In Sweden the general national insurance plan also covers dental care. No refund is given for amalgam fillings, while adhesive resin-based filling materials (composites) do qualify for refund. It is assumed that this has contributed to the phasing out of amalgam.

Finland

As early as 1993 STAKES in Finland sent out recommendations to reduce the use of amalgam in dental health services.

- In consideration of the environment, the use of amalgam as a dental filling material should be reduced
- Amalgam shall be used as a dental filling material only when other filling materials cannot be used
- Since it has not been revealed that amalgam fillings are harmful to health, there is no reason to routinely remove satisfactory amalgam fillings.

Denmark

Denmark has had a ban against the sale of mercury since 1994, but an exception has been made for the time being regarding mercury for dental amalgam.

Comprehensive assessment

This assessment builds upon knowledge and conclusions from the study *The Use of Dental Filling Materials in Norway* as well as upon newer research that has appeared after the study was completed. In its assessment, the Directorate for Health and Social Welfare has proceeded with the decision that was made by the Norwegian Board of Health in 1998; amalgam shall be phased out as a dental restorative material.

This directive is in accordance with recommendations from the environmental authorities (62). These recommendations are not in conflict with agreements that Norway has entered into under the Agreement on the European Economic Area (EEA-Agreement) (63;64).

Conclusion of the Directorate for Health and Social Welfare:

1. From a public health point of view, it is desirable to reduce mercury exposure in the population. The Directorate for Health and Social Welfare recommends that the use of amalgam as a dental filling material be reduced. This directive shall be used as a tool to that end.
2. This directive does not involve a ban against the use of amalgam, but dentists are encouraged to reduce the use of amalgam.
3. The directive does not imply any recommendation for removal of existing amalgam fillings on persons without symptoms.
4. Special and weighty reasons must exist for use of amalgam for children and youth. Informed consent must be documented in the patient's journal.
5. When odontological indications exist for replacing a filling in an adult, a material other than amalgam should be used. In a case where a patient, after thorough information from the dentist about all conditions pertaining to choice of material, still requests amalgam as a dental restorative material, this should nevertheless be accepted.
6. The Directorate for Health and Social Welfare is of the opinion that a quality-controlled knowledge base for use of dental restorative materials/odontological bio-materials should be established and routinely updated, so that advice given on choice of materials that dentists should use, will continually be improved.
7. The Directorate for Health and Social Welfare contributes with this directive to the 'Action plan for chemicals that are a hazard to health and the environment', written by the Ministry of the Environment in 1999.

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From: HEALTHCARE WITHOUT HARM

Subj: "Docket No. 01N-0067 - Against FDA Rule"
Date: 9/13/2002 10:27:08 AM Pacific Standard Time
From: harvie@isfusa.org

To Whom It May Concern:

I am writing on behalf of HCWH to submit our report "Dentist the Menace"
http://www.noharm.org/library/docs/Dentist_the_Menace.pdf which documents the substantial
impacts of dental mercury on environmental and public health.

Thank you for your attention to this matter.
Sincerely,

Jamie Harvie
Mercury Coordinator
Health Care Without Harm
Institute for a Sustainable Future
32 E. 1st Street, Suite 206
Duluth, MN
55802
218-525-7806
fax 218-720-4890

Attached: *Dentist the Menace*

FROM: ADRIAN CHANG

Subj: Docket No. 01N-0067 - Against The FDA Rule
Date: 9/9/2002 2:46:45 AM Pacific Standard Time
From: changjak@lava.net

To: fdadockets@oc.fda.gov

Food and Drug Administration
14101 Parklawn Building
5630 Fisher's Lane, Room 1061
Rockville, Md 20857
Attn: Dockets Management Branch (HFA-3E)

To Whom It May Concern (Food and Drug Administration):

It is my understanding that the FDA will announce that mercury amalgams are safe. I strongly disagree with your proposed action and suggest, for the health and safety of the taxpayers paying your salary, that you do more homework on this issue. Here is my testimony and I hope it will help in your research.

I and a family member have both suffered from mercury amalgam poisoning. About four years ago, I phoned the FDA to inquire about reporting this condition and was informed they do not have a form or mechanism for reporting this problem. I was shocked that many are suffering and yet there is no data collected. Also, a dentist would be placing himself/herself in financial and liability jeopardy if they admitted responsibility. Obviously, then the FDA and ADA can, with a clear conscience, make a statement that it is safe, with no reports of adverse effects. This is poor science and SO WRONG!

As a former nuclear engineer (retired from Pearl Harbor Naval Shipyard), I was trained very thoroughly on the dangerous and corrosive effects of mercury on nuclear system piping and components. Ask anyone in NAVSEA 08 of the U.S. Navy. When a family member became ill in 1997, my investigation led to mercury poisoning. If a health or technical professional reviews the hazard based on the quantity of the mercury in an amalgam, most of them would come to the conclusion it should not be a health problem. After all, I myself have some in my mouth that are over 45 years old and I am still alive. But, many of them do not have the electrical and metallurgical background necessary to understand what is happening to the material electrically which then affects the body.

During my research, I have found that the quality control specification for amalgams (See American Dental Assn Specification No. 1), was specifically revised in 1977 to allow more copper in the amalgam to make it easier for the dentist to install by providing a more homogenous amalgam. This action, with no scientific testing for adverse health effects, allowed the copper content to increase by as much as 500% depending on the brand and manufacturer. From an engineering viewpoint, this translates to an amalgam with much higher electrical conductivity (more copper with less tin), shorter service life (about 8 years vs 40+ years), and more release of mercury vapors. By this change alone, the published ADA statement that it is safe based on over 170 years of use is no longer valid if the material composition of the amalgam was significantly changed with no testing and no FDA approval. Perhaps, from 1977 to present, this could be one of the major contributing factors as to why so many health problems such as asthma, have been increasing nationwide. According to the Merck Manual of Medical Information (1997), between 1982 and 1992, the number of people with asthma increased by 42 percent. Today, it is an epidemic. A study to determine if there is a correlation based on

chronological sequence of events is definitely warranted, since mercury amalgam is one material that people are exposed to nationwide.

In my review of amalgam manufacturer's Material Safety Data Sheets and other accompanying literature for the material, I found that Caulk Dentsply had listed in their Directions For Use the following contraindications (my comment in parenthesis): "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 amalgams;
- For retrograde or endodontic filling;
- As a filling material for cast crown;
- In children 6 and under;
- In expectant mothers. (One amalgam manufacturer also included "mothers who are nursing" since it is already established that mercury will excrete into breast milk)

In addition to the above, some of their side effects/warning state: Exposure to mercury may cause irritation to skin, eyes, respiratory tract and mucous membrane. In individual cases, hypersensitivity reaction, 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.

After placement or removal of amalgam restorations, there is a temporary increase of the mercury concentration 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.

Removal of clinically acceptable amalgam restorations should be avoided to minimize mercury exposure, especially in expectant mothers.

The number of amalgam restorations for one patient should be kept to a minimum. (Poor guidance since dentists do not know what is minimum. My DDS said, to keep cost down, he installed as much as 10 in a child's mouth in one visit).

In their MSDS, they indicate that, in severe cases, hallucinations, loss of memory, and mental deterioration may occur. Vapor concentrations as low as 0.03 mg/cubic meter have induced psychiatric symptoms in humans. (The International Academy of Oral Medicine and Toxicology have found mercury vapors during removal of amalgams were about 1000 mg/cubic meter or higher.)"

During the process of removing my amalgams, out of curiosity, I had electrical measurements taken of my amalgams. As expected, there was a lot of electrical activity even though I had no gold in my mouth for galvanic reactions. What was interesting is that the "newer fillings" that were installed after 1977 had a much higher and unsatisfactory electrical current. In fact, based on my familiarity with electrical measurements as an electrical engineer, these newer fillings acted like a capacitor and had a longer discharge when the probe made contact to take the reading. When I had replaced my 3rd and 4th mercury amalgams, my memory significantly improved as quickly as the next day. The electrical levels in my mouth were reduced significantly. The leukoplakia condition in my mouth improved. The high electrical activity would have been worse if I had gold fillings due to galvanic reactions. Could electrical activity be contributing to the increase in leukoplakia and oral cancer? However, I do not recommend any of you to rush and remove your mercury amalgams without proper research because many dentists are not properly trained to remove amalgams without patient ingestion of any mercury vapors or particulates.

From an environmental viewpoint, most of the amalgams removed are currently being disposed of through the sewer system. Perhaps, this may be contributing to the buildup of mercury in our fish as it happened in Minamata Bay, Japan.

This concludes my testimony so that the FDA can no longer state that there are no reports of adverse effects from mercury amalgams. If you do, the government (and we taxpayers) will be assuming a huge liability since the FDA failed to test and approve the safety of mercury amalgams and excluded it by classifying it as a minor medical device. Also, according to OSHA laws, it is the manufacturer's responsibility to fully disclose the truth about all the health effects of the material they sell or accept liability consequences; not the U.S. government and definitely not the FDA. It should be the FDA's job to require proof of testing for safety, which obviously has been lacking in this area.

Recently, the mercury compound, thimerosal, has been banned from vaccinations. Mercury amalgams are now the last of mercury products which are still exposing people. By copy of this letter, Hawaii congressional representatives are requested to investigate this matter. I believe Hawaii is one of the few states that still uses a significant amount of mercury amalgams. At least, people should be provided the opportunity with informed consent if they still want to have mercury installed in their mouth.

Thank you all for your assistance in this matter and ALOHA FROM HAWAII.

Adrian Chang (Hawaii Coordinator for Dental Mercury Amalgam Syndrome Support Group)
216 Nomilo Street
Honolulu, Hawaii 96825
Ph 808-395-6198

Dr Dawn Ewing RDH, PhD, ND, DIM

Subj: "Docket No. 01N-0067- Against FDA rule"

Date: 6/28/2002 1:28:23 PM Pacific Standard Time

From: drdawn@drdawn.net

To: fdadockets@oc.fda.gov

I am a Doctor of Integrative Medicine and deal with individuals harmed from the toxic effects of "Silver Mercury Fillings". Symptoms can range include compromised immune systems, muscle tremors, loss of memory, fatigue, and much more.

Explain why you can not purchase a Mercury thermometer in the stores any more. Is someone afraid you might break it while in your mouth and swallow it? Do you realize that swallowing that mercury is safer than inhaling the mercury vapor generated by Silver Fillings as they are placed or removed? 24 hours a day 7 days a week as they are used to chew they create that vapor.

Someone does not have the citizens best interest in mind, if they did, we would abolish the use of Mercury in mouths! It is your duty to ban the use of Mercury fillings in the USA! We are behind other industrialized Nations in this matter.

I see children who have never had a silver filling placed but have high, measurable levels of mercury because it was passed through the placental barrier to the fetus from the mother, who had a whole mouth full of silver mercury fillings. Are you not aware that 50% of every one of those fillings is mercury? Mercury is a neurotoxin. Would you want a known neurotoxin in your new baby? No, of course not but the patient is not informed or they would never consent to the use of this as an option to fill teeth.

I urge you to do the job that was in the mind of Governmental officials when they created the FDA.
PROTECT THE PUBLIC!

Waiting impatiently,

Dr Dawn Ewing RDH, PhD, ND, DIM

Dr. Daniel A. Boudreaux

Subj: Docket No. 01N-0067-Against FDA Rule
Date: 6/23/2002 12:04:48 PM Pacific Standard Time
From: drdaniel@goforhealth.com

To: fdadockets@oc.fda.gov

CC: phil_gramm@gramm.senate.gov, kay_hutchison@hutchison.senate.gov, tx18@mail.house.gov, diane.watson@mail.house.gov, dan.burton@mail.house.gov

Hello:

I am a health care provider who has seen the negative effects that mercury amalgam fillings have had on some sensitive individuals. I have also seen the apparently political position taken by the American Dental Association regarding the use of these materials. Meanwhile, practically every other industrialized country in the world has banned the use of amalgam fillings containing mercury and other toxic metals.

Why is it so difficult for some to see that placing the most toxic metal on earth into living human tissues (teeth) is not a wise thing to do?

And now the FDA proposes to declare that these materials are safe!? Something is not right here.

I hope you will take a stand against this proposal, while allowing individual states to move forward with their own proposals as they see fit. If you are not familiar with this issue, I hope you and your staff will take the time to educate yourselves with information that is not influenced solely by the ADA and the FDA.

Thank you,

Dr. Daniel A. Boudreaux
Houston, Texas

FROM: Dr. Paul Gilbert, Mercury Free Dentistry

Subj: DOCKET # 01N-0067 AGAINST the FDA Rule

Date: 6/21/2002 11:45:11 AM Pacific Standard Time

From: drpgilbert@earthlink.net

To: fdadockets@oc.fda.gov , cc: dan.burton@mail.house.gov, diane.watson@mail.house.gov

Docket No. 01N-0067 - Against FDA Rule

June 20, 2002

Dear FDA

I am amazed that the FDA is considering a ruling that would minimize the risks of mercury in dental amalgam fillings. Mercury is the most toxic, non - radioactive element on earth. The FDA has eliminated (if there ever were any) all medical uses of lead, and other laws have banned its commercial use. This was done to eliminate exposure to lead - not because lead causes one or more diseases. 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 irrelevant. 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 besieged 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.

Classifying mercury as a Class II device 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. This defies both logic, and all that is currently known about the human physiology of mercury.

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 the public that congress mandated the FDA protect. If the FDA chooses to classify amalgam as a Class II device, especially with uniform language, which would take away what little protection is now afforded by state laws, a grass - roots backlash will likely be trigged, resulting in a congressional investigation of the FDA.

Classifying dental amalgam as a Class III device is the only appropriate 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, and that isn't even always so, as dental amalgam has been implanted in bone for decades, when it is used as a root end seal for surgical root canals (apicoectomies). When Amalgam is 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 will remain 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 FDA to be unbiased in its approach to classifying dental amalgam, and to place it in the only logical classification where it belongs - Class III.

Respectfully,
Dr. Paul Gilbert

FROM: William P. Glaros, DDS

Subj: docket number 01N-0067-Against the FDA rule
Date: 5/29/2002 12:35:21 AM Pacific Standard Time
From: wglaros@houston.rr.com

To: fdadockets@oc.fda.gov

Dear Sirs and Madams,

As a practicing dentist, a husband, a father, and a citizen, I write in opposition to Docket # 01N-0067.

Mercury has been removed from every product in our country that potentially exposes its hazards to the public: batteries, kid's shoes, prescription and non-prescription drugs to name a few. Mercury-silver fillings unquestionably expose people to the hazards of mercury.

From my perspective of choosing to discontinue placing mercury-silver fillings in 1984, I would want to ban its use.

Minimally, I strongly believe that every patient should be made aware that approximately 50% of a new mercury-silver filling is elemental mercury, that mercury vapor will be released in their mouth to be inhaled for the life of that filling, and that there are practical alternatives.

I am concerned that you, to date, appear to be ignoring current research, ignoring the latest report by the Agency for Toxic Substances and Disease Registry, ignoring your commitment ten years ago to classify mercury as it is used in dentistry, and ignoring individual states' rights. These are grievous concerns, and each is well within your control.

I beseech you to respond responsibly.

Yours for responsible health care,

William P. Glaros, DDS
17222 Red Oak Drive, Suite 101
Houston, TX 77090

Date: 5/17/2002 1:52:42 PM Pacific Standard Time To: fdadockets@oc.fda.gov

From: AndyCutler Docket Number 01N-0067 - submission in opposition to the proposed rule

Dockets Management Branch (HFA-305)
Food & Drug Administration,
5630 Fishers Lane, Room 1061
Rockville, Maryland, 20850

Dear FDA,

An unfortunate departure from your usual careful scrutiny and thoughtful analysis appears to have occurred in proposing this rule. I will discuss assorted problems with it and then briefly outline some of the scientific issues that are well established in the literature and readily predictable from multiple published studies. This information indicates that a different rule must be proposed. I will also discuss how current and ongoing research will allow good rulemaking on the issue of dental amalgams in the near future and why some think it is appropriate to defer any change in the current rule until data from these studies is available. Others read the current evidence of amalgam's toxicity as strong enough to promptly ban amalgam pending a demonstration of safety.

First let me introduce myself and discuss some issues that while not scientific in the formal sense are relevant to the appropriateness of rulemaking at this time.

I am Andrew Cutler. I have a BS in physics from the University of California and a PhD in chemistry from Princeton. I am a registered chemical engineer in Colorado and California, and am admitted to practice as an agent before the Patent and Trademark Office. I have 20 years of research experience and many journal publications in chemistry, engineering and materials science, and am now a researcher and author in the medical field. My current interest lies in understanding to what extent different "alternative medicine" approaches are consistent with known science.

One problem with your proposed regulation is it will lead to dentists not generally being able to tell consumers that mercury amalgam fillings are considered toxic hazards before placement and after removal. This is information many consumers and dentists consider relevant. Some states have also decided this is relevant enough to statutorily require specific disclosures. I do not believe it is appropriate for the FDA to regulate the speech of dentists, or disclosure requirements imposed by the sovereign states. I believe the generally accepted (and statutorily granted) regulatory powers of the FDA extend to what the manufacturers of drugs and devices may say about them, not what third parties may say about them. People depend on their health care providers for candid advice - it is not appropriate to interfere in any way in the doctor-patient relationship through the regulation of a medical device. I believe your regulation should be re-cast so it clearly states that it only applies to what the manufacturers and resellers of dental amalgam compositions may say about them. I believe the appropriate limits to how your regulations affect what dentists say and states require to be disclosed are that you may require a disclaimer that "the FDA has not reviewed this material" when people routinely make a specific statement about the purported safety or hazards of dental amalgam.

Another problem with your proposed regulation is that it may give some people the appearance of impropriety. I have no reason to believe there is any impropriety or any interest in impropriety on the part of the FDA with regards to this regulation. However, it is a generally accepted principle of administrative action that not only must impropriety and conflict of interest be avoided, but their appearance must also be avoided so that the utmost public trust may be maintained. By proposing a regulation that is very favorable to the position of the American Dental Association without public hearings you create a situation where some people might suspect that the ADA wrote the regulation to protect its interests rather than the FDA writing a regulation to protect the public. By conducting extensive public hearings, making a public report analyzing all comment offered and all available scientific and clinical information, and only then proposing a regulation you would reduce the appearance of impropriety and maintain public confidence in the integrity of your rule making process.

Your proposed regulation implies people don't have adverse health effects from dental amalgam. I believe you need to withdraw this regulation and have someone who knows something about dental amalgam write the next draft - the proposed rule is not consistent with the literature or your own records and past actions.

- o The FDA has received an exceptionally large number of adverse reaction reports regarding dental amalgam. Some of these include overwhelming documentation showing the patient to be intoxicated by mercury and the source to be amalgam.
- o The FDA approved a clinical trial of DMPS to treat mercury intoxication, primarily from dental amalgam. This trial was halted due to the large number of adverse reactions patients experienced due to the mobilization of mercury during

treatment.

- o There is no double blind placebo controlled trial of amalgam safety. In the hierarchy of evidence typically held forth by mainstream medicine, the most rigorous level of evidence available is the study by Stenman and Grans which demonstrates that many patients do in fact become mercury toxic from their amalgam fillings. Given this study the only 2 legitimate positions the FDA can take are to ban the use of amalgam pending a double blind placebo controlled trial demonstrating safety in thousands of subjects, or decline to regulate at this time.
- o The recently published study by Huggins and Levy on multiple sclerosis and amalgam removal also demonstrates amalgam causes a life threatening disease, and removing it improves a biochemical marker of the disease. This study is also at a higher level of proof than any study purporting to demonstrate amalgam is safe.
- o Your regulation gives no weight to the latest federal report - by ASTDR - on mercury, nor does it address why the EPA and FDA have substantially different permissible exposure guidelines for mercury in its various forms. The FDA should act consistently with other federal agencies, or explain in detail how they erred and allow public comment and debate before proposing regulations.
- o Amalgam toxicity is not a new issue. Stock's multitudinous publications in the 1930's are as compelling now as they were then. His findings have yet to be seriously addressed in the context of amalgam regulation.

It is my impression that the relevant advisory panel hasn't met for 8 years. Major advances have been made in the science of amalgam mercury effects in those 8 years. It would be appropriate for your advisory panel to meet and review the issue in light of recent results as well as past evidence not yet evaluated before you regulate in this area.

I will discuss available clinical and scientific information and what might be appropriate studies to conduct or evaluate in your proceedings to determine how to regulate dental amalgam. I hope this discussion is helpful to you.

The "safe limits" for mercury exposure were derived by occupational studies in the 1960's. There are two flaws with this approach. First, it studied men. Clinically, women present far more often than men with complaints traceable to mercury intoxication from their amalgam fillings. Secondly, it studied self-selected men. The men in the study had worked for an average of eight years in an occupation where high exposure to mercury was ubiquitous. It is reasonable to expect that those men more sensitive to the toxic effects of mercury found work elsewhere, leaving the study group deficient in the people who needed to be studied.

People's metabolism of mercury is varied and may be polymorphic. Some people retain it for much longer periods than others. In addition, the literature shows that most people have simple, one compartment kinetics with first order excretion for inorganic mercury. Yet those who present clinically with mercury intoxication from their amalgam fillings do NOT show simple first order excretion kinetics. They show complex kinetics representative of more than one compartment which leads to them having a much higher body burden of mercury at a given exposure rate than do those who have simple one compartment metabolism of mercury. In the published literature on the subject there are 2 or 3 subjects who appear from the data presented to be showing this effect, though it is not discussed in the relevant papers. Additionally, most studies are carried out with occupationally exposed individuals show more rapid excretion (which corresponds to a lower body burden at a given intake rate) than do those few studies on more representative populations. Due to this variability in the population it is not possible to generalize as is usually done that the average level of mercury exposure from dental amalgam must be safe because it is less than the exposure limit for toxic effects shown in industrial studies.

Complicating this matter further is the variability in mercury release from amalgam fillings. 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. Two of these individuals have serious chronic health problems.

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.

Clinically it is often observed that patients who blow into mercury vapor meters, or who have the air over their fillings sampled, have higher mercury vapor levels than are permissible for industrial exposure. This is particularly significant because industrial exposure limits assume exposure during a 40 hour work week, while those with high mercury vapor

levels due to their fillings are exposed 168 hours per week. There are some papers in the journal literature regarding the levels of mercury vapor measured in the oral cavity. This evidence alone calls into question the safety of amalgam as a dental restorative material.

Bjorkman and others showed that in normal subjects 72% of mercury excretion was via feces by way of the bile. Those with impaired bile flow thus are at greater risk of mercury intoxication at a given exposure level than the rest of the population is.

Enestrom and Hultman discuss the immunological effects of mercury from dental amalgam but failed to perform appropriate calculations to compare the body burdens expected in rodents and humans at a given exposure level and thus failed to draw the correct conclusion that mercury body burdens many humans carry due to their amalgam fillings cause adverse immunological consequences in both mice and rats. One of the very few studies of the immunological effects of amalgam in humans is reported in Uninformed Consent where a crossover trial showed white blood cell levels to decline significantly when amalgams were in place.

Engel showed improvement in the classic symptoms of mercury poisoning in 100 patients a year after amalgam removal, as did Lichtenberg in a separate study.

Ewers and Erbe showed that the activity of adenylyl cyclase was reduced by up to 50% at concentrations of mercury known to occur in human brain tissue due to amalgam exposure. Since cyclic AMP is the second messenger for so many diverse neurotransmitters this would reasonably be expected to have a profound impact on brain function and provides a biochemical explanation for why mercury intoxication causes a progression from subtle emotional changes and neurobehavioral impairments to frank personality disorder or psychosis in severe cases.

Marlowe showed in several papers that hair mercury levels were associated with emotional problems and reduced intelligence in children.

Siblerud showed in several papers that mercury exposure from dental amalgam caused adverse psychological, immune and physiological changes in human subjects.

Skare and Engqvist presented a flow diagram for mercury metabolism in an "average person." This could easily be extended to performing a mass balance and conducting sensitivity studies using models for exposure from amalgam, metabolism of mercury, and sensitivity to its toxic effects. All of the information to do this is available in the literature and it would be irresponsible to regulate without doing this so as to estimate the fraction of the population that would reasonably be expected to experience toxic effects from amalgam mercury under different scenarios so that studies could be designed in such a manner that they would actually demonstrate safety or harm to a high level of confidence. One problem in an area where both sides of the debate on amalgam safety agree that adverse reactions are not common is that any safety study must be large enough to exclude adverse reactions to the 95% confidence level - which requires a large study. E. g. to exclude an adverse reaction rate of 1% to the 95% confidence level requires a minimum study size of 298 subjects. To exclude an adverse reaction rate to the 0.1% level requires a minimum of 2,994 subjects. Some mass balance and sensitivity calculations are in order before studies are begun in order to ensure they will have enough statistical power to answer the question posed. After all, an adverse reaction rate of 0.1% is HUGE in a public health sense. 75% of all Americans have amalgam restorations in their mouths so this would be about 200,000 people. As you are no doubt more than well aware, the FDA, drug companies, and medical industry has been getting crucified in the press recently for drugs that caused 10-100 adverse reactions before the FDA acted.

Direct measurement of mercury in human tissues associates it with certain diseases. Zuichik and others found vastly elevated levels of mercury in cancerous thyroid nodules but not in benign ones. Frustaci and others found vastly elevated mercury levels in cardiac tissue from patients with idiopathic dilated cardiomyopathy but not other cardiac disease. Nakagawa found elevated hair mercury levels in patients with a number of health conditions. Since dental amalgam is the primary source of mercury exposure for the general population and certain serious, common conditions are associated with great elevations in mercury it is unreasonable to argue that dental amalgam does NOT pose a health hazard in the absence of rigorous safety studies which do not now exist and are not now being conducted. There are now seven journal papers showing an association between dental amalgam derived brain mercury and Alzheimer's disease. There is one showing no association. Since science relies on the reproducibility of experiments by others, it appears that the only scientifically tenable position is that there is a strong and possibly causal association between amalgam mercury exposure and Alzheimer's disease.

Given the dramatic demonstration by Huggins and Levy of multiple sclerosis responding to amalgam removal, follow up on their subjects, and a controlled trial with removal and non-removal groups are essential before concluding amalgam is safe. Such a controlled trial of amalgam removal in idiopathic dilated cardiomyopathy would also be appropriate since it has a poor prognosis with current treatments. Similarly for Alzheimer's disease.

Richardson and Allen used a monte carlo simulation of the health effects of mercury (but did not account for variation in exposure) which showed that the number of amalgam fillings people could tolerate even if there was no variation in mercury emission was lower than the number in many people's mouths. This led to some regulatory activity in Canada.

The most recent edition of Harrison's Textbook of Internal Medicine discusses the issue of mercury poisoning from dental amalgam fillings and new methods of diagnosing mercury poisoning in cases where urinary excretion and blood levels are below what used to be considered the toxic threshold. Cecil Textbook of Medicine also mentions that low blood and urine mercury levels do not exclude intoxication and that other methods of testing must be used. One would hope that FDA regulations were proposed by people on the cutting edge of research, not by those ignorant of textbook knowledge.

Amazingly enough, there do not appear to be direct measurements in the literature of the vapor pressure of mercury over the component phases of amalgam, over amalgam as prepared and placed clinically, or over amalgam aged either in the laboratory or in vivo. The literature on amalgam corrosion both by itself and in contact with other dental restoration materials is exceptionally poor. There are many people (outside the health care professions) who know how to do the relevant studies and could easily do them in short order if provided with clinically obtained material by collaborating dentists. Conducting these studies is essential before there can be a rational basis for any regulation other than a ban on amalgam use pending further studies.

Dr. Martin at the University of Washington dental school is conducting a study in Lisbon, Portugal where children are given either amalgam or composite fillings and different parameters measured over a 7 year period. The study is now 4 years old. The urinary mercury excretion of the 2 groups are now distinct. Data on porphyrin levels in urine are apparently not presently available even though the study is supposed to analyze all data each year to ensure it is called off if a problem is detected. However, information in previous publications by Echeverria, Woods and others (including Martin on some of the relevant papers) allows one to calculate the expected amounts of porphyrins in the urine of these 2 groups and as with the mercury, there are now expected to be 2 groups. Put another way, by measuring the mercury level or certain porphyrins in the urine of a child in this study, one could classify them into the amalgam or composite group with high certainty without needing to look in their mouths. The data from this study and from a similar one in Massachusetts needs to be reviewed before it is appropriate to issue new regulations regarding dental amalgam other than a ban on its use.

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.

You will find much further discussion of amalgam toxicity and related issues in Amalgam Illness: Diagnosis and Treatment on pages 14-24. In addition, you will find an enormous amount of literature apparently unknown to your regulation writer in Bernard Windham's annotated bibliography on mercury. It is incumbent on you to evaluate and respond to all relevant literature and available information before proposing regulations.

In sum, I personally believe the current evidence provides an overwhelming case for reclassifying amalgam as a class 3 device and prohibiting its sale pending studies with at least 10,000 subjects demonstrating its safety. Reasonable people may differ on this - for example, Dr. Martin of the University of Washington School of Dentistry does agree that the strongest available evidence (the paper by Stenman and Grans) shows amalgam to be a toxicity hazard, but he believes that regulation should be deferred pending the outcome of two controlled trials currently under way on amalgam safety. Dr. Martin is conducting one of these trials and expects results to be available within 5 years. Considering that the FDA forgot to address amalgam for the last 10 years, a further delay in regulation so that the results of these studies can be taken into account is not unreasonable. The proposed regulation is unreasonable in not taking into account scientific and medical information that became available over the last 10 years and in regulating free speech on the amalgam issue without regulating amalgam itself or requiring further study of its hazards.

Sincerely yours,

Andrew Hall Cutler, Ph. D.

Jon Murphy, MD

Subj: Fwd: Mercury in dental amalgams
Date: 5/17/2002 3:16:55 PM Pacific Standard Time
From: JBMURPH007

To: FDAockets@oc.fda.gov

Please be aware that among physicians in Florida and in West Va. there is real concern as to the amount of mercury which is absorbed from the mercury amalgams in the mouths of our patients. The report from the Agency for Toxic Substances and Dental Registry says much about the concerns of scientists and groups of researchers. I think the ADA would agree that research into mercury absorbed and the ability of all varieties of humans to eliminate the amount of mercury absorbed should now take place. The American Academy of Pediatrics along with the FDA has called for the elimination of mercury containing thimerisol from vaccines and other foods and drugs. Let us take time to study the issue of mercury in human mouths.

Sincerely,

Jon Murphy,MD,
1701 fifth ave., Charleston, WV 25312

RE:Mercury in dental amalgams
Date: 5/17/2002 2:59:21 PM Pacific Standard Time
From: JBMURPH007

To: FOXNEWSONLINE@FOXNEWS.COM
Dear Foxnews:

My name is Jon Murphy,MD, and I am an Internal Medicine Physician and Pediatrician, board certified in both fields and I have recently read info from junk science news reports. The issue was whether or not fillings and root canals in humans contains mercury and whether any mercury in these dental repairs holds any responsibility for illness in humans. Let me be clear first that the silver colored fillings do in fact contain 50+% elemental mercury and that measurable levels of mercury vapor is present in the mouths of those individuals with these fillings. Because of this fact I routinely advise children under 12 and pregnant female patients to request their dentist to use composite type fillings since the jury remains out on what degree the mercury placement may have on peoples health but these groups are among the more at risk for even low levels of mercury if absorbed and since there are effective choices in fillings(composite material).

It is rare but there are hypersensitivity(allergic) reactions to mercury as well as nickel which is only 5% of filling material but which is seen in jewelry more often.

Those who are at some risk for mercury toxicity from the small amounts of mercury released from dental amalgams during chewing(mastication) and the somewhat higher levels present during placement and removal of amalgam material are those who are unable to adequately eliminate the mercury from their systems such as those with reduced renal(kidney) function, those with reduced metabolic and sulfur conjugation function either because of reduced hepatic(liver) function or reduced sulfur containing amino acid intake and reserves. I'm talking about diabetics with reduced kidney function, fibromyalgia sufferers, and Alzheimers disease patients. I believe most healthy adults can conjugate and eliminate safely any mercury which they might absorb from fillings.

Just to make a point I ask that you remember that the EPA has long considered mercury as a poison and even considers the amalgam once removed from the dental patient as a hazardous waste material which is handled according to hazardous waste guidelines which I don't think 'Junk Science' has reviewed.

Sincerely,

Jon Murphy,MD
FamilyCare, Family Enrichment Center, Charleston WV

Felix Liao DDS

Subject: Against FDA rule: Docket Number 01N-0067
Date: 5/20/2002 4:47:08 PM Pacific Standard Time
From: FelixLiao@earthlink.net

To: fdadockets@oc.fda.gov

To: Docket Management Branch, Food & Drug Administration

RE: Against proposed FDA rule Docket number 01N-0067

From: Felix K. Liao, D.D.S.
600 Wampanoag Trail, East Providence, Rhode Island 02915

Dear FDA Rule Makers:

I am writing to protest in strongest terms AGAINST the proposed rule, docket number 01N-0067. I am doing so because your proposed rule will stifle the cure of many medical mysteries, prolong the suffering of countless Americans, including yourself, and increase the cost of medical care.

The basis of my protests are:

- A. Any high school student in Europe or Asia can tell you that mercury is poisonous to both the environment and wild life. Why is it any different for American people like you and I?
- B. If mercury is not very poisonous, why don't you try putting a micro-drop into your own eyes or paint it onto your skin?
- C. Your proposed warning ignores recent research world-wide that have concluded that mercury fillings are poisonous while in the mouth, from which it goes to the brain, the gut, the lymphatics, liver, kidneys, and throughout nervous system.
- D. If OSHA and EPA considers mercury as poisonous, how can FDA ignore their findings and the research behind them?
- E. If states are removing mercury thermometers from the market place, why is FDA continuing to sanction mercury fillings?
Are you protecting the patient public, or the American Dental Association and U.S. Government interests?
- F. How dare you try to rush this rule through without proper hearings and without advice from your Advisory Panel, which has not met for eight years. Imagine if I had not taken a continuing education course in that amount of time!
- G. Public health is far more important than ADA's own self-serving interests. Dentists can be re-trained to reverse a major medical travesty of the past 150 years.
- H. If you failed to classify mercury as a hazardous substance a decade ago, then this is the time to make up rather than cover up. Your proposed warning does not even tell consumers that mercury fillings are poisonous before going into the mouth and hazardous waste when removed.
- I. Whatever happens to the latest major federal report on mercury by the Agency for Toxic Substances and Disease Registry? What do you have an Advisory Panel for?
- J. As a U.S. Citizen, environmental concerns is reason enough to ban mercury in fillings. Do you know where discharges from dentists' offices go? It's no different than acid rain. Eventually it will get back into your biology, and those of your loved ones, and not just your average American tax payers.

Shame on you for trying to pull a fast one on the American public you are created to serve and protect. You have my address. I await your considered reply.

Felix K. Liao, D.D.S.

Rosemary Fecteau, Ph.D., Educational Administrator/Consultant

Subj: Fwd: Docket Number 01N-0067 - AGAINST FDA RULE
Date: 5/20/2002 7:52:29 AM Pacific Standard Time

To: fdadockets@oc.fda.gov

Subj: Docket Number 01N-0067 - AGAINST FDA RULE
Date: 5/20/2002 10:40:11 AM Eastern Daylight Time
From: Romyphd99
To: %20fdadockets@oc.fda.gov

Rosemary Fecteau, Ph.D., Educational Administrator/Consultant; 140 West Pownal Road; North Yarmouth, ME 04097-6819 - AGAINST the FDA Rule concerning the Subject Docket Number.

On December 28th, 1994 my husband, Jack R. Fecteau Sr., died of pulmonary fibrosis (His lungs hardened.). A cause of the pulmonary fibrosis, diagnosed by a Board-certified, highly qualified physician specialist and supported by an objective laboratory test, was an industrial level of mercury toxicity from 15 mercury/amalgam fillings implanted in his teeth. Because the American Dental Association, some healthcare providers and his insurance carrier denied the cause of his disease, he did not receive the medical treatment that he required early in the identification of the cause and the physician-prescribed treatment. Scientific evidence cannot, now, be disputed as to the significant deleterious effects of the use of mercury/amalgam to the health of the unborn, women, men, and children.

r A warning regarding the implanting of mercury/amalgam fillings must clearly advise consumers that mercury/amalgam fillings contain approximately 50% mercury, Mercury, one of the single most toxic metals, is a protoplasmic poison that penetrates all living cells of the human body. Research has demonstrated that mercury vapor is continuously released from mercury/amalgam fillings in measurable quantities from the moment fillings are inserted into teeth. In 1988, scrap dental mercury/amalgam was declared a hazardous waste material by the Environmental Protection Agency. Once a dentist removes a mercury/amalgam filling from a mouth, it once again becomes a hazardous waste material and, according to the Material Safety Data Sheet for mercury, which OSHA mandates be present in every dental office, the scrap mercury/amalgam must be handled in the following manner: 1. Store in unbreakable, tightly sealed containers, away from heat; 2. Use a no touch technique for handling the mercury/amalgam; 3. Store under liquid, preferably glycerin or photographic fixer solution.

Is the FDA ignoring the recent research available on thousands of international websites documenting the work of thousands of dedicated men and women throughout the world? If your Advisory Panel has not met for eight years, a lifetime in science, you are ignoring laws that numerous States have enacted regarding this issue. What weight have you given to the latest major federal report on mercury by the Agency for Toxic Substances and Disease Registry?

The decisions of the Federal Drug Administration represent the safety and well-being of all Americans, and because of our exemplary Democracy, the safety and well-being of the people of the world. We believe that as physicians follow the Hippocratic Oath, "FIRST DO NOT HARM," the primary mission of the Federal Drug Administration in all of its decisions is: "FIRST DO NO HARM".