ENVIRONMENTAL RISKS OF AND REGULATORY RESPONSE TO MERCURY DENTAL FILLINGS

HEARING

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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ENVIRONMENTAL RISKS OF AND REGULATORY RESPONSE TO MERCURY DENTAL FILLINGS

WEDNESDAY, NOVEMBER 14, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DOMESTIC POLICY,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:34 p.m., in room 2154, Rayburn House Office Building, Hon. Dennis J. Kucinich (chairman of the subcommittee) presiding.

Present: Representatives Kucinich, Burton, Cummings, and Watson.

Staff present: Jaron R. Bourke, staff director; Jean Gosa, clerk; Nidia Salazar, staff assistant; Leneal Scott, information systems manager; Benjamin Chance, minority clerk; and Jill Schmalz, minority professional staff member.

Mr. KUCINICH. The Subcommittee on Domestic Policy of the Committee on Oversight and Government Reform will now come to order.

Today's hearing will examine the environmental risks and regulatory response to dental mercury.

I ask unanimous consent that all opening statements, written statements, other materials be inserted into the record and, without objection, the Chair and the ranking minority member will have 5 minutes to make opening statements followed by opening statements not to exceed 3 minutes by any other Member who seeks recognition.

Without objection, Members and witnesses may have 5 legislative days to submit a written statement or extraneous materials for the record.

To my right is the Honorable Dan Burton of Indiana with whom I have had the honor of serving on this committee and the full committee for many years, and to my left is the Honorable Diane Watson, the gentlelady from California who I am pleased to serve with in this House and whose work together with Mr. Burton has brought us to this important discussion today.

Mercury is toxic to the environment. It is a naturally occurring toxin and a manmade pollutant. It bioaccumulates, meaning that even and ever higher concentrations buildup in organisms at higher levels of the food chain.

Mercury toxicity causes brain and liver damage, even death. The FDA advises women of childbearing age and children to avoid cer-

tain kinds of fish and limit their intake of others due to levels of methylmercury in those tissues.

Mercury, in the elemental form, is present in the teeth of many Americans. According to the EPA, dentists use between 34 to 54 tons of mercury per year to create or replace mercury dental fillings in Americans. Dentists are the third largest category of user of mercury in the economy, and existing dental fillings account for more mercury in use at the current time than any other application including thermometers, batteries, switches and paints, over 1,000 tons.

Methylmercury, which is the most toxic and mobile form of mercury, is created through the actions of microbes and by combustion of mercury-containing materials. Dental mercury becomes methylmercury when the mercury-containing byproduct of sewage treatment plants, known as sludge, is incinerated and when it is applied to agricultural land. Methylmercury is created when corpses containing mercury dental fillings are cremated.

How significant is dental mercury to the emission of mercury into the environment? Assessing the question is one of the purposes of this hearing.

According to the U.S. Environmental Protection Agency, it would seem that with all the mercury in use and annually used in dentistry, only a tiny fraction is emitted into the air. But there is reason to believe that the EPA's estimates significantly understate the reality.

For instance, EPA estimates airborne mercury attributable to sludge incineration to be 0.6 tons per year annually. However, EPA admits that its mercury emission data for sludge incineration is poor, a deficiency it attributes to both the small number of facilities tested and the fact that these facilities were not a random sample of the industry.

The Northeast States for Coordinated Air Use Management estimated that mercury emissions in the northeast alone amount to 0.5 tons per year.

EPA estimates of total mercury emitted as a byproduct of cremation of human remains is around 0.3 tons per year. However, EPA's estimate might significantly understate the magnitude of mercury emissions from this source as well.

A newly published article authored by the EPA environmental scientist estimates mercury emissions from cremation to be 10 times more than the EPA estimate, about 3 tons per year or 10 EPA's estimate.

Indeed, today, the Mercury Policy Project will testify that total actual mercury emissions could be as much as five to six times the EPA's estimates.

Why is this important? It is important because the EPA prioritizes its activities based in part on this number.

EPA's only dental-specific initiative is its so-called gray bag program. This is a voluntary program to encourage student dentists to collect mercury amalgam before it enters the wastewater stream. A voluntary educational outreach program might be justified for a de minimis pollution source, but it may not be appropriate for a source as significant as dental mercury.

EPA does not seem to be alone in tolerating the significant understatement of dental mercury's threat to the environment. Mercury dental devices are regulated by the Food and Drug Administration.

The FDA, with all Federal agencies, is legally required to consider the environmental requirements imposed by the National Environmental Policy Act of 1969. The NEPA requires an environmental assessment or environmental impact statement for all governmental actions that have a significant effect on the environment.

Dental fillings are subject to regulation under the Medical Device Amendments of 1976. Medical Device Amendments mandated that all devices in use prior to enactment be reviewed and classified pursuant to the act.

FDA did classify the component materials, liquid mercury and amalgam powder, separately in 1987, and it began the process for classifying dental mercury amalgam by promulgating a proposed rule in 2002. However, the FDA did not take steps to finalize the classification rule and, as of now, the dental mercury amalgam used in dental offices remains an unclassified medical device.

One of the concerns shared by advocates and the FDA is the appropriateness of the FDA's 1987 action classifying liquid mercury as safe for general use. Devices receiving this classification are not subject to much regulation, and other devices so classified include toothbrushes.

One of the questions this hearing will consider is whether or not the FDA's classification of dental mercury amalgam does in fact require environmental reporting because of possible significant effects on the environment. It has been the FDA's position that the classification does not have such an effect and thus no reporting is required, but they may be unique in holding this view as our witnesses will testify.

Mercury is a danger for the environment, and dentistry seems to be a significant contributor to that environmental threat. Today, we will examine the magnitude of the threat and the steps being taken to mitigate the environmental damage.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement
Dennis J. Kucinich, Chairman
Domestic Policy Subcommittee
Hearing on environmental impacts and response to Dental Mercury
Wednesday, November 14, 2007
2154 Rayburn HOB
2:00 P.M.

Mercury is toxic to the environment. It is a naturally occurring toxin and a man-made pollutant. It bioaccumulates, meaning that ever higher amounts build up in organisms at higher levels of the food chain. Mercury toxicity causes brain and liver damage, even death. The FDA advises women of child-bearing age and children to avoid certain kinds of fish and limit their intake of others, due to levels of methylmercury in those tissues.

Mercury, in the elemental form, is present in the teeth of many Americans. According to the EPA, dentists use 34 tons of mercury per year to create or replace mercury dental fillings in Americans. Dentists are the third largest category of user of mercury in the economy, and existing dental fillings account for more mercury in use at the current time than any other application, including thermometers, batteries, switches, and paints. Over 1000 tons.

Methylmercury, which is the most toxic and mobile form of mercury, is created through the actions of microbes and by combustion of mercury-containing materials. Dental mercury becomes methylmercury when the mercury-containing byproduct of sewage treatment plants, known as

"sludge," is incinerated and when it is applied to agricultural land. Methylmercury is created when corpses containing mercury dental-fillings are cremated.

How significant is dental mercury to the emission of mercury into the environment? Assessing that question is one of the purposes of this hearing. According to the U.S. Environmental Protection Agency, it would seem that with all the mercury in use and annually used in dentistry, only a tiny fraction is emitted into the air. But there is reason to believe that EPA's estimates significantly understate the reality.

For instance, EPA estimates airborne mercury attributable to sludge incineration to be 0.6 tons per year annually. However, EPA admits that its mercury emission data for sludge incineration is "poor," a deficiency it attributes to both the small number of facilities tested and the fact that these facilities were not a random sample of the industry. The Northeast States for Coordinated Air Use Management estimated that mercury emissions in the northeast alone amount to 0.5 ton per year.[1]

EPA estimates of total mercury emitted as a byproduct of cremation of human remains to be around 0.3 tons per year. However, EPA's estimate might significantly understate the magnitude of mercury emissions from this source as well. A newly published article authored by an EPA environmental scientist, estimates mercury emissions from cremation to be

[1] NESCAUM, Inventory of Anthropogenic Emissions of Mercury, (November 2005). (Online at http://www.nescaum.org/documents/inventory-of-anthropogenic-mercury-emissions-in-the-northeast/)

ten times more than the EPA estimate, about 3 tons per year, or 10 times EPA's estimate.[2]

Indeed, today the Mercury Policy Project will testify that total actual mercury emissions could be as much as 5 to 6 times EPA estimates.

Why is this important? It is important because EPA prioritizes its activity based in part on this number. EPA's only dental-specific initiative is its "gray bag" program. This is a voluntary program to encourage dentists to collect mercury amalgam before it enters the wastewater stream. A voluntary, educational outreach program might be justified for a *de minimis* pollution source, but it may not be appropriate for a source as significant as dental mercury.

EPA does not seem to be alone in tolerating the significant understatement of dental mercury's threat to the environment. Mercury dental devices are regulated by the Food and Drug Administration (FDA). FDA, as with all Federal agencies, is legally required to consider the environmental requirements imposed by the National Environmental Policy Act of 1969 (NEPA).[3] NEPA requires an Environmental Assessment or Environmental Impact Statement for all governmental actions that have a "significant" effect on the environment.[4]

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[2] Alexis Cain et al., "Substance Flow Analysis of Mercury Intentionally Used in Products in the United States," Journal of Industrial Ecology, Volume 11, Number 3 (2007)

[3] 42 U.S.C. §§ 4321-4345.

[4] 42 U.S.C. § 4332. NEPA requires that all agencies of the Federal Government report on the environmental effects of all proposed government actions "significantly affecting the quality of the human environment."

Dental fillings are subject to regulation under the Medical Device Amendments of 1976 (MDA).[5] MDA mandated that all devices in use prior to enactment be reviewed and classified pursuant to the Act. FDA did classify the component materials – liquid mercury and amalgam powder -- separately in 1987, and it began the process for classifying dental mercury amalgam by promulgating a proposed rule in 2002. However, FDA did not take steps to finalize the classification rule, and, as of now, the dental mercury amalgam used in dental offices remains an unclassified medical device.

One of the concerns—shared by advocates and FDA—is the appropriateness of FDA's 1987 action classifying liquid mercury as safe for general use. Devices receiving this classification are not subject to much regulation, and other devices so classified include toothbrushes. One of the questions this hearing will consider is whether or not FDA's classification of dental mercury amalgam does in fact require environmental reporting because of possible significant effects on the environment. It has been FDA's position that the classification does not have such an effect and thus no reporting is required.[6] But they may be unique in holding that view, as our witnesses will testify.

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[5] P.L. 94-295. The Act created a regulatory regime consisting of classifications of devices, where a "I" is considered safe for general use, a "II" is subject to special controls, and a "III" may be subject to evaluation and clinical studies and require approval before they may be introduced in the market.

[6] In its 2002 draft device classification, FDA proposed that dental mercury amalgam qualified for a Categorical Exclusion (CE), thereby exempting FDA from NEPA's environmental reporting requirements. *See* 21 C.F.R. § 25.34 (outlining CE's for device classifications).

Mercury is a danger for the environment, and dentistry seems to be a significant contributor to that environmental threat. Today we will examine the magnitude of the threat and the steps being taken to mitigate the environmental damage.

Mr. KUCINICH. There is a vote on and so, excuse me a minute, I am going to confer with my colleagues.

We are going to take a 15 minute recess. There is a vote on. We should be back perhaps even before then, but the Chair declares a recess for 15 minutes.

I want to thank our witnesses for their patience. This is a flow here that we don't have total control over. We will be right back.

[Recess.]

Mr. KUCINICH. Thank you for your patience. Now, this committee is back in session.

The members of the committee have agreed that they will submit their opening statements for the record, and I want to thank them for their cooperation, and we will move right to the opening statements of the witnesses.

[Witnesses sworn.]

Mr. KUCINICH. Let the record show that the witnesses answered in the affirmative.

We have the following witnesses:

Mr. Ephraim S. King has been Director of the Office of Science and Technology in the U.S. Environmental Protection Agency's Office of Water since May 2005. Prior to that office, he was a Division Director and Branch Chief in the Office of Ground Water and Drinking Water for 9 years. From 1987 to 1996, he was Chief of the National Pollutant Discharge Elimination System. Welcome.

Dr. Norris Alderson, Associate Commissioner for Science, Food and Drug Administration [FDA], the majority of his FDA career has been in the Center for Veterinary Medicine, holding a number of management positions culminating in the position of Director, Office of Research. In 2001, he became Acting Senior Advisor for Science and Acting Director, Office of Science Coordination and Communication. In 2002, he was appointed Senior Associate Commissioner for Science and Director, Office of Science and Health Coordination. That title was later changed to Associate Commissioner for Science.

Mr. King and Dr. Alderson, I would ask that each of you give a brief summary of your testimony, keeping the summary under 5 minutes in duration. Your complete written statement will be included in the hearing record.

So, Mr. King, you will be our first witness and you may proceed. Thank you.

STATEMENTS OF EPHRAIM KING, DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY, OFFICE OF WATER, U.S. ENVIRONMENTAL PROTECTION AGENCY; AND NORRIS ALDERSON, DIRECTOR, OFFICE OF SCIENCE AND HEALTH COORDINATION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF EPHRAIM KING

Mr. KING. Thank you, Mr. Chairman and members of the committee. I appreciate the opportunity to discuss mercury and dental amalgam and the steps that EPA is taking to address its release as well as other releases of mercury from other sources in the environment.

Your opening statement outlined the persistent and widespread nature of mercury releases. EPA fully recognizes this and, for EPA, mercury releases are a very, very high priority and a major focus.

Today, what I would like to do is talk a little bit about how EPA is using its legislative authorities to address mercury releases, both generally and in the context of dental amalgam. The two statutes I am going to focus on are the Clean Water Act and the Clean Air Act.

Under the Clean Water Act, I think the point that we would like to make is that in establishing water quality standards, those standards operate to drive publicly owned treatment works, municipal wastewater treatment systems around the country, to drive their efforts to control the introduction of mercury amalgam from dental offices down sewer systems.

A good example of that is some standards in the Great Lakes, 1.3, 1.8 nanograms per liter. Those standards are extremely challenging to meet and what they have operated to do is encourage municipalities in that region to really focus hard on the contribution of dental amalgams and what can be done to reduce their contribution.

The other point I would make is that we and the Clean Water Program also regulate biosolids. When a dental amalgam, if it is not captured in the dentist's office by a separator or by a trap, it goes down into the sewer system. It goes into the POTW, the treatment works. The treatment works generally get about a 99 percent removal efficiency which means that most of whatever waste is there then goes into the biosolids and those biosolids are regulated by EPA under Section 503 of the Clean Water Act.

A recent report by AMSA, 2002, concluded that in terms of mercury release into the environment, probably less than 1 percent of the releases into the environment for mercury come from municipal treatment works and dental amalgam.

If I turn to the Clean Air Act, this is an area where EPA has made very substantial progress over the last several years with the establishment of maximum achievable control technology standards for municipal waste combustion and for medical waste incineration. Mercury emissions from those two sources alone have been reduced by over 90 percent.

More recently, in 2005, with the promulgation of the Clean Air Mercury Rule, emissions from coal-fired utilities will be reduced by over 70 percent, and we regard that as very substantial progress.

Applying these authorities to mercury and dental waste, sort of to start this part of the conversation, we simply start in the dentist's office and observe that the wastes themselves come from the new fillings as well as replacing old fillings. The waster is then put into a screen or a chair-side drain.

There are tools available—amalgam separators, traps, screens—to reduce that solid waste. The waste then either goes to recycle, which we strongly encourage, or to solid waste disposal.

One of the examples that I am going to give in terms of the amalgam separator, the city of San Francisco has set a goal of all 900 of its dental offices putting in amalgam separators, and it also has a goal of providing incentives for the low income areas to support those dental offices. We think that is a terrific example of a

city using this new technology to reduce the generation of mercury amalgams going into the sewer system, highly effective.

The other point we would make is that when you go into the sewer systems themselves, if you look at sewage sludge, EPA 503 standards apply to land application. We have standards that limit the amount of mercury that can go into land-applied sludge, and we also have air emission standards that limit the amount of mercury that can be emitted from incineration.

One particular item that may be of interest to the committee is that in 2006, this past year, EPA has undertaken a study of certain portions of the health services industry. One part of that are dental offices and the discharge of amalgams with mercury from dental offices, and we will be completing that study probably in the fall of 2008. We expect that information will give us a lot of valuable data on the volumes and the kinds of BMPs and practices that are being engaged in there.

Under the Clean Air Act, one of the questions being asked by the committee is the significance of dental amalgam mercury emissions. One of the points that we would make in this hearing is that EPA regards these missions as important. As we compare them, however, to other national sources of mercury emissions, we conclude, based upon the information to us, that they are a relatively small proportion of national emissions of mercury.

One of the things we would point out is that our focus on the air program has been to focus on the largest contributors of air emissions and that is why, for example, we have focused on coal-fired utilities. That is why we have focused on medical waste incinerators and why we have focused on the municipal combustion.

One area we would like to emphasize is the whole area of waste minimization and prevention. I mentioned amalgam separators. That is a great example of taking the wastes and making sure they don't get into the sewer, so they don't get into the environment which is the goal that we all have.

Another area that we would point out, another example of a publicly owned treatment work that has done a great job responding to Clean Water Act standards for mercury is Duluth, Minnesota. That POTW took a look at its water standards. It then asked the question, where was the mercury from in the POTW? The answer is a single industry and a whole number of smaller sources.

That utility worked with its dental offices to develop a practice manual and reduce the discharges from dental offices by over two-thirds, a great example of a POTW affirmatively engaging and doing a terrific job.

The only other point I would make under our legislative authorities and how they relate to dental amalgam is that we established a fish tissue criteria for specifically methylmercury which, Mr. Chairman, you mentioned in your opening statement. That limit is 0.3 parts per million, and it has been adopted by 13 States and five tribes.

That standard, as a water quality standard, will in turn drive again municipal wastewater systems to go back up the pipe and ask the question, how can we effectively reduce the discharge or contribution from dental offices and mercury amalgam?

Finally, Mr. Chairman, I would just like to highlight the joint public health partnership between EPA and FDA. You referred briefly to a fish advisory, a health advisory that has been issued by our two organizations in 2004, and that health advisory is, in essence, advising women of childbearing age, women who are pregnant, nursing, or young children not to eat more than 12 ounces of fish a week.

There have been national reports recently indicating that women should eat unlimited amounts of fish, and we simply want to take this occasion to affirm that the FDA and EPA continue to strongly stand behind their advice which is don't eat more than 12 ounces of fish and the fish that you do eat should be low in mercury. This is something we think makes an awful lot of sense and protects public health.

In closing, Mr. Chairman, I want to thank the committee for the opportunity to share with you the work that EPA is doing both in the air program and in the water program. We are committed to understanding and reducing mercury releases into the environment.

One final note that I would make is an additional resource that would be available to the committee—you may already have it—is EPA's 2006 Roadmap to Mercury which lays out much more comprehensively the full range of activities that the Agency is doing.

Thank you very much. That concludes my testimony.

[The prepared statement of Mr. King follows:]

STATEMENT OF
EPHRAIM KING
DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON DOMESTIC POLICY
OF THE
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

November 14, 2007

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Ephraim King, Director of the Office of Science and Technology in the Office of Water, at the U.S. Environmental Protection Agency (EPA). I appreciate this opportunity to discuss mercury in dental amalgam and actions EPA is taking to address its releases and other releases of mercury.

INTRODUCTION

Mercury is a naturally occurring element. It enters the environment from natural sources (such as volcanoes) and human activity (such as industrial combustion and mining). Mercury is widespread in both the U.S. and the global environment. Human activities have increased the amount of mercury in the atmosphere; in soils and sediments; and in lakes, streams, and oceans. While there are significant efforts to reduce mercury use, it continues to be used in some industrial processes such as chlorine manufacturing and in some products such as batteries, light bulbs, and thermometers. Mercury persists in the environment, and, under certain conditions, can be transformed by microorganisms into methylmercury, the form of mercury of greatest concern in the U.S., where exposures occur primarily through fish consumption. This transformation enables mercury to bioaccumulate through the aquatic food chain. The higher concentrations are found at the top of the food chain in larger predatory fish, such as shark and swordfish.

EPA is effectively using its legislative mandates under the Clean Air Act (CAA), Clean Water Act (CWA) and other laws to reduce the U.S. contribution to the worldwide environmental mercury burden. We continue to pursue our goals of limiting toxic releases to ensure increased public health benefits and environmental welfare. For example, the National Pollutant Discharge Elimination System (NPDES) permits under the CWA specify effluent limitations where necessary to protect water quality. For municipal wastewater treatment plants (i.e., Publicly Owned Treatment Works [POTWs]) that are subject to these effluent limitations, the National Pretreatment Program requires control of commercial and industrial sources of pollutants before they reach the POTWs. Under the CAA, EPA has substantially limited U.S. emissions of mercury to the atmosphere through Maximum Achievable Control Technology (MACT) and solid waste combustion/incineration regulations. As a result, the U.S. has cut its emissions by over 90% from two of the three largest categories of sources -- municipal waste combustion and medical waste incineration – since 1990. For the other largest category, in 2005, EPA finalized the first-ever regulations to reduce mercury emissions from coal-fired electric utilities – the Clean Air Mercury Rule (CAMR) – which is expected to further reduce mercury emissions from power plants by about 70% from 1999 levels at full implementation.

MERCURY IN DENTAL WASTE

Dental amalgam contributes a small proportion of all mercury released to the environment from human activities. Mercury-containing amalgam wastes may find their way into the environment when new fillings are placed or old mercury-containing fillings are drilled out and waste amalgam materials that are flushed into chair-side drains enter the solid waste stream. Dental facilities may employ a variety of controls and management practices to reduce the discharge of mercury amalgam in wastewater. Management practices include the use of precapsulated alloys, proper disposal and recycle of captured amalgam, and avoiding the use of oxidizing cleaning agents and heat disinfection for amalgam containing materials.

Application of these practices in conjunction with traps and vacuum pump filters can reduce discharges of mercury-containing amalgam in wastewater by over 75 percent. Amalgam separators remove particulate mercury amalgam and in combination with traps and vacuum pump filters achieve better than 95 percent removal.

Some of the waste amalgam particles that reach the sewer system settle out in the sewers, and some are carried to POTWs. The physical processes used in POTWs remove about 95% of the mercury received in wastewater. The mercury removed from wastewater then resides in the biosolids or sewage sludge generated during primary and secondary treatment processes. The Association of Metropolitan Sewerage Agencies (AMSA, now known as the National Association of Clean Water Agencies) in a March 2002 study reported that mercury from domestic wastewater and municipal treatment plants accounts for less than one percent of U.S. mercury entering the environment.

Three of the more common use or disposal practices for sewage sludge are application to land, placement on a surface disposal site, and firing in a sewage sludge incinerator. Numeric standards for mercury, and other pollutants in EPA's biosolids regulations are based on conservative multi-pathway exposure and risk assessments. The ceiling concentration for mercury in land applied biosolids is 57 milligrams per kilogram on a dry weight basis.

Under the Part 503 Regulation, Publicly Owned Treatment Works (POTWs) are required to demonstrate that the total mercury emissions from all of the biosolids incinerators located at their site does not exceed the mercury National Emission Standards for Hazardous Air Pollutants (NESHAP) limit of 3,200 grams/24-hour. In almost all cases, compliance is demonstrated by reviewing available data concerning the mercury concentration in their biosolids and making a worst case assumption of zero percent mercury removal efficiency for their air pollution control devices (i.e., mercury in the biosolids equals mercury

emitted to the atmosphere). NACWA found that mercury emissions from biosolids incineration facilities are typically substantially below the NESHAP limit described above.

Dental amalgam is also a source of mercury air emissions, though it is a relatively small source when compared to a number of other source categories, such as coal-fired power plants, industrial boilers, and hazardous waste incinerators. EPA estimates that about 1.5 tons (or a little more than 1%) of total U.S. mercury air emissions are due to dental amalgams, of which only a small fraction comes from crematoria. EPA does not currently regulate air emissions associated with dental amalgams. Our priority has been to first control the bigger contributors of mercury air emissions including medical waste incinerators, municipal waste combustors and power plants which emitted about 70 percent of the total U.S. mercury emissions in 1990.

Actions to Reduce Mercury Emissions Associated with Dental Amalgams

Preventing dental amalgam from getting into the water in the first place reduces the amount of dental amalgam and, thus, mercury in wastewater. The American Dental Association (ADA) has identified many Best Management Practices (BMPs), including chair-side screens and traps. On October 2, 2007, the ADA updated its BMPs to include the use of amalgam separators. Amalgam separators are also available at relatively low cost to remove fine particles of waste amalgam. Several studies, including one conducted by EPA's Environmental Technology Verification Program, show separators are highly effective.

Another way to reduce the amount of amalgam entering the sewers is for dentists to use mercury-free fillings. Alternatives to mercury-containing dental amalgams exist. As fewer mercury-containing dental amalgams are used, they will become less of a source of mercury in the environment. We encourage dentists to consider non-mercury dental amalgams, however, the choice of dental treatment rests solely with dental professionals and their patients.

In 2006, EPA initiated a study to collect and compile information on mercury discharges from dental offices, BMPs, and control technologies (such as amalgam separators) and their costs. This study is being conducted under the effluent guidelines planning authority in section 304(m) of the Clean Water Act.

Through the NPDES permit and the National Pretreatment Programs, EPA encourages POTWs to implement pollution prevention strategies that reduce the amount of mercury they receive. Effective mercury source reduction relies on the POTW effectively communicating the fact that small scale individual efforts can collectively reduce mercury released to the environment. Forming partnerships and working with sector representatives to investigate mercury sources, explore alternatives, and assist in implementing selected options are integral parts of a successful reduction strategy. For example, the City of San Francisco has a goal of installing amalgam separators in all 900 dental offices in the city. They are offering assistance and incentives to those dental offices least able to afford the separators – specifically those serving low-income communities. Additionally, the Western Lake Superior Sanitary District determined that one industry and many small other sources, including dental facilities, contributed a major portion of the mercury in their wastewater. With respect to dental offices, the local POTW in Duluth, Minnesota, worked with the local dental offices to produce a manual containing BMPs on proper disposal of mercury in amalgam. Monitoring by the POTW shows that the amount of mercury discharges from those dental offices has been reduced by over two-thirds.

OTHER MERCURY RELATED WATER ACTIONS

Under the Clean Water Act, EPA develops recommended water quality criteria. States then adopt these criteria into water quality standards to protect public health and the environment. These levels can be used to set permit limits. In January 2001, EPA published a new water quality criterion for methylmercury that is expressed as a fish and shellfish tissue value (0.3 parts per million) rather than as a

water column value. Because different water conditions may affect conversion of mercury to methylmercury differently, a fish tissue value more accurately represents the levels of potential human concern. The States are starting to adopt the new criteria in their water quality standards. To date 13 states and five tribes have adopted these fish-tissue based criteria.

However, nearly all fish and shellfish contain traces of mercury, and would continue to contain traces of mercury, even if all new loadings of mercury to the environment were eliminated. Some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. The risks from mercury in fish and shellfish depend on the amount of fish and shellfish eaten and the levels of mercury in the fish and shellfish. Therefore, in 2004 the Food and Drug Administration (FDA) and EPA issued advice that women who may become pregnant, pregnant women, nursing mothers, and young children should avoid eating certain types of fish that are higher in mercury (such as shark and swordfish) but that they should eat **up to** 12 ounces a week of fish and shellfish that are lower in mercury (such as shrimp and salmon). EPA and FDA recently reaffirmed this advice despite recent national news reports on a recommendation encouraging women of child-bearing age to consume unlimited amounts of fish, including fish higher in mercury.

To implement the Great Lakes Water Quality Guidance, the states in EPA Region 5 established water quality standards in 1995 (1.3 ng/l for protection of wildlife and 1.8 ng/l for human health protection) for the Great Lakes and their tributaries. This was the first time water quality standards took into account the effects of mercury on birds and mammals that consume contaminated fish. These very stringent standards have proven challenging to comply with as there is presently no treatment technology for mercury capable of achieving this standard. However, EPA's Region 5 office, working with the states, developed Regional Mercury Pollutant Minimization Program (PMP) Guidance and the states are requiring permittees, including POTWs, to implement PMPs to move them towards compliance with the standard.

Control of dental amalgam is expected to play a significant role in reducing loadings of mercury to POTW systems in the Great Lakes states.

CONCLUSION

In closing, let me assure the Committee that EPA is committed to understanding and reducing mercury-related risks to citizens and the environment. We will continue to use our authorities to call for cost-effective reductions of environmental releases of mercury that present human health or environmental risks.

We will continue to use our authorities to reduce environmental releases of mercury. As an additional resource, I would direct the Committee to EPA's 2006 Roadmap for Mercury which describes the latest information on mercury sources, the Agency's progress in addressing mercury issues domestically and internationally, and outlines EPA's major ongoing and planned actions to manage such risks.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions you or your colleagues may have.

Mr. KUCINICH. I thank the gentleman.
Dr. Alderson, thank you.

STATEMENT OF NORRIS ALDERSON

Mr. ALDERSON. Mr. Chairman and members of the subcommittee, we appreciate your invitation and the opportunity to discuss the issue of dental amalgam and FDA's implementation of the National Environmental Policy Act of 1969 with respect to dental amalgam.

Dental amalgam is a restorative material that is used for the direct filling of carious legions or structural defects in teeth. It is made onsite in a dentist's office by mixing elemental mercury and powdered alloy composed of primarily of silver, tin and copper.

The Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act gave FDA specific authority to regulate the safety and effectiveness of medical devices. Dental amalgam as well as its components are medical devices.

Devices that were first introduced into commercial distribution after enactment of the Medical Device Amendments are known as post-amendments devices.

Devices that were in commercial distribution before the enactment of the Medical Device Amendments are commonly referred to as pre-amendments devices and were assigned to one of three classes: Class I, II or III. This classification is based on risk and controls necessary to provide reasonable assurance of safety and effectiveness.

The act also has a specific procedure for effecting a change to the classification of a pre-amendments device.

Accordingly, in a rule published on August 12, 1987 and based on the comments received, FDA placed dental mercury in Class I and amalgam alloy into Class II. FDA agreed with the comments urging that dental mercury be classified into Class I.

The encapsulated form, encapsulated amalgam, was not separately classified during the original classification process. However, FDA has regulated the encapsulated form as a Class II device in accordance with the requirements applicable to the component of the higher classification.

The Dental Products Panel of the Medical Devices Advisory Committee met in 1993 and 1994 to discuss the classification, reclassification and safety of dental amalgam devices. The panel unanimously recommended to classify dental mercury and amalgam alloy into Class II with special controls.

The panel stated that there were no major risks associated with encapsulated amalgam when used as directed but recognized there was a small population of patients who may experience allergic reactions to the materials in the device. The panel also noted that improper use of the device by practitioners presented risk associate with mercury toxicity.

In February 2002, FDA proposed a rule to bring all amalgam products into Class II and increase the Agency's regulatory oversight over these devices by requiring ingredient labeling and proposing conformance to international standards. FDA twice reopened the comment period and received more than 750 comments on this proposal.

The majority of the comments stated that the Agency was not proposing enough restrictions on the marketing and use of dental amalgam and that the proposed special controls do not adequately address the potential health risks of the device.

Numerous U.S. Public Health Service reviews of the safety and use of dental amalgam conducted in the 1990's concluded that the available studies did not support claims that individuals with dental amalgam restorations will experience problems including neurologic, renal or developmental effects, except for rare allergic or hypersensitivity reactions.

In 2006, FDA held a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee to address a series of questions FDA had posed. The committee asked FDA to expand its literature review to include additional data bases and searches.

They agreed that the most recent well controlled clinical studies showed no evidence of neurological harm from dental amalgam and generally agreed that there is no evidence that dental amalgam causes health problems in the vast majority of the population.

While the committee did not take consensus votes on these issues, non-consensus opinions included a panelist recommendation that FDA consider labeling requirements related to the use of dental amalgam in pregnant women and small children as well as patient information to ensure that consumers understand these devices contain mercury. The comments on that meeting drew 3,500 comments.

As for the National Environmental Policy Act, FDA's regulation implementing the National Environmental Policy Act are contained in 21 CFR 25: Environmental Impact Considerations. This regulation describes Agency actions that require preparation of an environmental assessment, actions that require preparation of an environmental impact statement and those Agency actions that are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement, absent extraordinary circumstances.

It should be clarified that the analysis is determined by the action taken by the Agency, not the product in question.

The 2002 proposed rule cited the categoric exclusion contained in 21 CFR 23, 24(b) which categorically excludes the classification or reclassification of a device from the requirement to prepare an environmental assessment. If it is not reasonably foreseeable that there would be any effect in the amount of mercury introduced into the environment that would constitute an extraordinary circumstance, the Agency would appropriately rely on its existing categorical exclusion for such an action.

Mr. Chairman, we continue to evaluate the available information to determine appropriate next steps to fulfill the Agency mission of protecting and promoting public health.

Thank you again for this opportunity, and I will be glad to answer any questions.

[The prepared statement of Mr. Alderson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

NORRIS ALDERSON, Ph.D.
DIRECTOR, OFFICE OF SCIENCE AND HEALTH COORDINATION

FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
SUBCOMMITTEE ON DOMESTIC POLICY
HOUSE OF REPRESENTATIVES

November 14, 2007

FOR RELEASE ONLY UPON DELIVERY

Introduction

Mr. Chairman and Members of the Subcommittee, I am Dr. Norris Alderson, Director, Office of Science and Health Coordination at the Food and Drug Administration (FDA or the Agency). I appreciate your invitation and the opportunity to discuss the issue of dental amalgams and FDA's implementation of the National Environmental Policy Act of 1969.

In my testimony today, I will first briefly describe dental amalgam and how FDA regulates these medical devices. Then, I will describe Federal government activities related to dental amalgam. I will also describe FDA's implementation of the National Environmental Policy Act of 1969 with respect to dental amalgam.

Background

Dental amalgam is a restorative material that is used for direct filling of carious lesions or structural defects in teeth. It is made onsite in a dentist's office by mixing elemental (liquid) mercury and a powdered (amalgam) alloy composed primarily of silver, tin, and copper (the mixture is also called "encapsulated amalgam alloy and dental mercury" or simply "encapsulated amalgam").

Let me begin with a brief overview of our regulatory authorities regarding medical devices and how we exercise them in the case of dental amalgam. As defined by Federal law, the term "medical device" encompasses several thousand health products, from simple articles

such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers and imaging technologies. Dental amalgam, as well as its components – dental mercury and the alloy with which the mercury is combined – are medical devices. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) gave FDA specific authority to regulate the safety and effectiveness of medical devices. The FD&C Act prescribes a variety of mechanisms to achieve this goal. These include classification of medical devices, establishment registration, Quality Systems Requirements for manufacturing, and controls over the market introduction of medical devices.

Classification and Reclassification of Medical Devices

Devices that were in commercial distribution before the enactment of the Medical Device Amendments of 1976 (May 28, 1976), are commonly referred to as "preamendments devices" and were assigned to one of three "classes" consistent with the procedures described in the statute. Under section 513 of the Act, FDA classifies preamendments devices according to the following steps: (1) FDA receives a recommendation from a device classification panel (an FDA advisory committee); (2) FDA publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA publishes a final regulation. The Act also has a specific procedure for effecting a change to the classification of a preamendments device, which includes issuing a regulation (section 513(e) of the Act) and, if the Agency believes appropriate, obtaining a recommendation from the panel that provided the original classification recommendation. Devices that were first introduced into

commercial distribution after enactment of the Medical Device Amendments Act of 1976, are known as "postamendments devices."

Let me describe the statutory criteria FDA used when classifying medical devices. Devices posing the lowest risk, such as elastic bandages, were placed in Class I. Class I devices are subject to the "general controls" applicable to all devices. Class II devices, which pose incrementally greater risk and for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, are subject to "special controls" in addition to general controls. Special controls may include labeling requirements, performance standards, post-market surveillance studies to conformance with mandatory performance standards, or other controls the Agency deems necessary to provide reasonable assurance of the safety and effectiveness of the device. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and may be marketed only after approval of a premarket approval application, which includes clinical studies and other information establishing the safety and effectiveness of the device. Preamendments devices classified into Class III are not subject to the requirement of premarket approval until the Agency issues a regulation requiring the submission of applications.

Dental mercury and amalgam alloy are preamendments devices that FDA classified in accordance with the procedure described above. In a Final Rule published on August 12, 1987, FDA placed dental mercury into Class I (Title 21, *Code of Federal Regulations*, section 872.3700) and amalgam alloy into Class II (Title 21, *Code of Federal Regulations*, section 872.3050). This action was taken because comments submitted to the Agency acknowledged

that the risks to health presented to dentists and other dental workers are inherent in the device and would not be reduced through establishment of performance standards for the device. The comments also stated that manufacturers have voluntarily accomplished actions to protect dentists and others from the inherent risks presented by the device such as packaging the device in leak proof containers and placing cautionary statements in the labeling of the device. FDA agreed with the comments urging that dental mercury be classified into Class I. The encapsulated form of amalgam, which consists of measured proportions of amalgam alloy and dental mercury that are separately sealed and sold as a single-use capsule, was not separately classified during the original classification process. However, like other products that are a combination of more than one device, FDA has regulated the encapsulated amalgam in accordance with the requirements applicable to the component with the higher classification. Accordingly, the encapsulated form of amalgam (which includes amalgam alloy and dental mercury) is regulated as a Class II device.

The Dental Products Panel of the Medical Devices Advisory Committee met in 1993 and 1994 to discuss the classification, reclassification and safety of dental amalgam devices. After considering testimony and other information, the Panel unanimously recommended to classify dental mercury and amalgam alloy intended for the restoration of teeth into Class II. The Panel also recommended that the device be subject to voluntary performance standards, voluntary testing guidelines, and requirements that the device be used only on the written or oral authorization of a licensed practitioner, and only by persons with training or expertise in its use. The Panel stated that there were no major risks associated with encapsulated amalgam when used as directed, but recognized there was a small population of patients who

may experience allergic reactions to the materials in the device. The Panel also noted that improper use of the device by practitioners presented risks associated with mercury toxicity.

As mentioned earlier, the FD&C Act authorizes the Agency to "reclassify" a medical device into a different regulatory class as more knowledge emerges regarding product risk gained from actual use. In most cases, devices are down-classified. Occasionally, however, devices are reclassified into a higher class.

2002 Proposed Rule Reclassifying Amalgam Products

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

FDA received significant adverse public comments on the 2002 proposed rule. The majority of the comments stated that the Agency was not proposing enough restrictions on the marketing and use of dental amalgam and that the proposed special controls did not adequately address the potential health risks of the device.

Dental Amalgam Literature Reviews

In January 1993, the United States Public Health Service (USPHS) published a broad scientific report about the safety and use of dental amalgam and other materials commonly used to fill dental cavities. USPHS reaffirmed these conclusions in 1995 and 1997. Since then, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and FDA have continued to study the issue. The National Institute of Dental & Craniofacial Research at NIH has also provided grants to study the safety of dental amalgam and to develop non-mercury alternatives. This effort included research and clinical studies of dental amalgam use in children. In addition, USPHS scientists analyzed approximately 175 peer-reviewed studies submitted in support of three citizen petitions received by FDA after the 1993 report. The USPHS concluded that data in these studies did not support claims that individuals with dental amalgam restorations will experience problems, including neurologic, renal or developmental effects, except for rare allergic or hypersensitivity reactions.

2006 Joint Meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee

In 2006, FDA held a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee. The joint committee deliberated on a series of questions FDA had posed on its most recent draft review of the dental amalgam literature, and provided recommendations to the Agency related to those questions. The Committee asked FDA to expand its literature review to include additional data bases and searches for information on special populations. The 2006 joint committee generally agreed,

however, that there is no evidence that dental amalgam cause health problems in the vast majority of the population. The 2006 joint committee also agreed that the most recent well-controlled clinical studies showed no evidence of neurological harm from dental amalgam. While the committee did not take consensus votes on these issues, non consensus opinions included a panelist recommendation that FDA consider labeling requirements related to the use of dental amalgam in pregnant women and small children, as well as patient information to ensure that consumers understand that these devices contain mercury.

The National Environmental Policy Act (NEPA)

The National Environmental Policy Act of 1969 (NEPA) requires that Federal agencies evaluate whether major actions they take will significantly affect the quality of the human environment. FDA's regulations implementing NEPA are contained in 21 CFR Part 25, "Environmental Impact Considerations." This regulation describes Agency actions that require preparation of an Environmental Assessment (EA), that require preparation of an Environmental Impact Statement (EIS), and those Agency actions that are categorically excluded, generally, from the requirement to prepare and EA or an EIS absent extraordinary circumstances. Actions are categorically excluded from the requirement to prepare an EA or an EIS where the Agency has made a finding that the category of action does not individually or cumulatively have a significant effect on the human environment. If the Agency finds that a particular action, that would otherwise be categorically excluded, may significantly affect the quality of the human environment (referred to as an "extraordinary circumstance"), the Agency would prepare either an EA or an EIS. It should be clarified that the analysis is

determined by the action taken by the Agency, and not the product in question. FDA has no reason to think that changing the classification of mercury, by itself, will affect its level of use, e.g., either increase or decrease, in a way that would have a significant effect on the environment.

In the case of a classification of dental amalgam, reclassifying dental mercury from Class I to Class II does not necessarily affect the amount of mercury introduced into the environment. If it is not reasonably foreseeable that there would be any increase in the amount of mercury introduced into the environment that would constitute an extraordinary circumstance, FDA would appropriately rely on its existing categorical exclusion for such an action. The 2002 Proposed Rule noted above cited the categorical exclusion contained in Title 21, *Code of Federal Regulations* section 25.34(b), which categorically excluded the classification or reclassification of a device from the requirement to prepare an EA.

Next Steps/Options

We will continue to evaluate the available information to determine appropriate next steps to fulfill FDA's mission to protect and promote public health.

Mr. Chairman, thank you again for the opportunity to address this important topic. I will be happy to answer any questions.

Mr. KUCINICH. Thank you, Dr. Alderson.

We are going to begin with questions of Mr. King. I will ask questions for 5 minutes, and then I will go to my colleague, Mr. Burton, who will ask questions and then to Ms. Watson who will continue.

Now, Mr. King, you have testified that dental amalgam contributes a small proportion of all mercury release into the environment, but there is reason to doubt EPA's assessment. I want to go over the data with you, just follow it along.

How much mercury do dental offices use each year? What is your EPA estimate?

Mr. KING. We estimate about 34 tons go into a dental office.

Mr. KUCINICH. That is the lowest. Does it go as low as 34 and as much as how much?

Mr. KING. I don't have the upper end, but 34 is what we sort of start with.

Mr. KUCINICH. How does that compare with the amount of mercury used to thermostats and thermometer?

Mr. KING. I don't have that information.

Mr. KUCINICH. Is it more or is it less?

Mr. KING. But I would be happy to get it for you, happy to provide it for the record.

Mr. KUCINICH. Well, I would like to see what you have.

The information that our staff put together is that it is actually more, that thermostats contribute 15 to 21 tons per year; thermometers, 9 to 17 tons per year; and that the high end that we have from other EPA documents with respect to dental amalgam mercury source, 34, the low end, as you pointed out, to 54 tons per year.

Do you have any knowledge or any estimates of how much mercury is estimated to be currently in teeth of the American people? Do you have any estimates of that?

Mr. KING. Forgive me. Could you repeat that question?

Mr. KUCINICH. Are you familiar with any general estimates of how much mercury is right now in the form of dental amalgams that people have in their mouths?

Mr. KING. No, sir, I don't have that information.

Mr. KUCINICH. OK. It is, according to staff information, this is an EPA number, by the way. It is 1,200 tons. Does that number sound familiar to you now?

Mr. KING. It does not, but I would be happy to confirm it if you would like.

Mr. KUCINICH. But what is your position with the EPA?

Mr. KING. Mr. Chairman, my position is I am Director of the Office of Science Technology in the Office of Water, and my expertise lies in the area of water quality standards and technology-based information.

Also, Mr. Chairman, our position and our view and what we are trying to communicate to this committee is that we, in fact, regard mercury as a very significant issue and that we think we have taken a number of steps under the Clean Water Act that will establish water quality standards to drive more effective control of mercury amalgam, and we believe under the Clean Air Act that we

have established regulations which have resulted in very significant reductions of mercury emissions.

Mr. KUCINICH. Well, since your knowledge isn't in the areas of quantification, then let's go to an area that might be closer to your area of expertise. What is the percentage of mercury ending up in municipal sewage treatment plants that comes from dental offices?

Mr. KING. The numbers range anywhere from 20 to 30 percent.

Mr. KUCINICH. Could it be as high as 36 percent?

Mr. KING. Yes.

Mr. KUCINICH. Now, as you know, the report of the 31st Conference of New England Governors and Eastern Canadian Premiers Mercury Taskforce Activities and Workplan puts the figure closer to 50 percent. Have you seen that report?

Mr. KING. I have not seen that report. I think one of the things we like to emphasize, we are entirely open and welcome to new information. Our position is not to challenge the new information but rather to sit down and understand it.

Under the Clean Water Program, we would continue to move forward trying to strengthen perturbment programs and trying to strengthen the relationship between municipal waste systems and their abilities to work with dental offices to reduce amalgam.

Mr. KUCINICH. Now a lot of sludge byproduct of sewage treatment plants is incinerated. What is EPA's estimate of airborne mercury attributable to sludge incineration?

Mr. KING. About 0.6 tons.

Mr. KUCINICH. Is EPA very confident in that number?

Mr. KING. Mr. Chairman, I am confident that is the current number that our air program has in Research Triangle Park. One thing that you learn after a while working with scientists, that there is always new science. There are new data, new methodologies, and I am aware there is recently an article out indicating that number could be higher.

Mr. KUCINICH. Thank you.

Isn't it true that the EPA has admitted its mercury emission data for sludge with respect to incineration is poor? Can you tell us why the EPA's confidence in this number as poor?

Mr. KING. That would go to simply the number of facilities that we have sampled at and the more facilities you sample, the broader the random sample, the more information available to you and the greater the strength of your confidence.

Mr. KUCINICH. I assume that you do know that the Northeast States for Coordinated Air Use Management estimated that mercury emissions in the northeast alone amount to 0.5 tons per year.

Mr. KING. I am aware of that number, yes.

Mr. KUCINICH. So is it impossible that the real national emissions number is considerably higher?

Mr. KING. It is possible, and that is something we are more than happy to take a look at.

Mr. KUCINICH. Could it be two tons? Could it be four? Could it be two tons?

Mr. KING. I would be very cautious about offering you a number on that, sir.

Mr. KUCINICH. I understand that you would be cautious. Could it be four tons?

Mr. KING. I would welcome the opportunity.

Mr. KUCINICH. You really don't know is what you are saying.

Mr. KING. The number that I have is the 0.6. We would be delighted to sit down with additional researchers and get more data on that.

Mr. KUCINICH. We are going to come back. I am going to recognize Mr. Burton of Indiana.

Thank you, Mr. Burton, for being here. You have the rostrum here. Go ahead.

Mr. BURTON. Thank you, Mr. Chairman.

We had a hearing in October 2003, and in it we had testimony that collectively Americans are walking around today with 800 metric tons of mercury in their mouths and tens of millions of mercury-containing fillings continuing to be put into Americans' teeth every single year.

What I can't figure out, and we have a list of facts about mercury that is almost two pages long and the reference material that goes with it, talking about how mercury amalgams affect not only the environment but the people that have these things in their mouths. Have you ever seen any of this? Have you ever seen these?

I mean there are references for every one of these facts. Have you seen this?

Mr. KING. Mr. Representative, I don't believe I have seen that particular document.

Mr. BURTON. I want to give both of you a copy of this. Would you make a copy and make sure both of them get it.

Mr. KING. Thank you.

Mr. BURTON. The thing that bothers me—I don't know that I am going to have a whole bunch of questions—is we have been holding hearings on this for years when I was chairman and up to now, and the FDA and the EPA continue to say, well, you know, don't eat over 12 ounces because of the mercury, and you have to be careful about burning things that have mercury in them because it gets into the atmosphere, and you have to be careful about the mercury getting into landfills because it leaches down into the water supply and causes contamination of the water.

Yet, we continue to say that the mercury in your mouth doesn't have an adverse impact on human beings. I just don't get it.

If when it goes into the dentist's office, when they are mixing it, it is dangerous. They put it into your mouth, and it is not hard yet. It is still dangerous. While it is in your mouth, it is not dangerous anymore. But when it comes out of your mouth, it is dangerous.

Everything in the environment that has mercury in it is dangerous but not when it is in your mouth. I just don't get it.

We had hearings, with Ms. Watson being one of the major contributors, on vaccinations. When I was a boy, we had no vaccinations and when you got measles, they put a sign on the front of your house, saying quarantined. But today a child gets as many as 28 to 30 vaccinations before they start the first grade.

We have gone from 1 in 10,000 children that are suffering from neurological disorders to 1 in about 140 now. It is an absolute epidemic, and yet our health agencies continue to say that the mercury in the vaccines has no impact on that and they say that the mercury in the amalgam doesn't have any impact on it.

There has to be some doubt. There has to be some doubt. Even if you don't agree with the scientific facts that I have before me, there has to be some doubt. If there is doubt, why do we continue doing it?

Why do we continue putting mercury in vaccinations when there is doubt about the amount of autism and other neurological disorders that are being caused because of it?

Why do we keep putting mercury in amalgams in people's mouths when there is doubt even among you folks about what kind of a neurological problem it creates?

We just keep going on, and it makes me wonder if maybe the medical institutions and the dental institutions have too much influence with our health agencies. It really bothers me, and I don't understand. I am sure you are not going to give me an answer to this because I am more or less filibustering on the issue, but it really bothers me.

Eventually, eventually, our health agencies are going to have to come to grips with the facts as they have about the mercury in fish, that mercury in any way into the human body is a threat. It is just a threat, and we are not doing a daggone thing about it.

You guys come up here, and we have been doing this since I was chairman back in the years 1998 to 2004, and you keep saying the same things over and over again, and nothing changes. More kids become neurologically damaged, more ancillary impacts from mercury.

Yet, our health agencies keep saying, well, it is not really any problem. It is not really a problem. Don't eat too much fish, but don't worry about the amalgams in your mouth. Don't worry about the shots that contain 50 percent methylmercury. Don't worry about any of that stuff. It isn't going to hurt you any.

But the facts are people are being damaged and even if mercury is a minor threat, it should be taken out of everything.

Let me just say, Mr. Chairman, here in Washington, DC, we had a little bit of mercury that was spilled in a classroom. They evacuated the school, burned everybody's clothes and just went through great efforts to make sure that there was no mercury in there.

In my district back in Indiana, they spilled a very small container of mercury in a city area. They evacuated the neighborhood, brought in firemen who looked like they were wearing spacesuits to clean that mess. Yet, we put mercury in our bodies, and you guys keep saying it is not any problem.

Eventually, eventually, the FDA and our health agencies are going to be really ashamed of themselves because it is going to be proven beyond a reasonable doubt that it is a major contributing factor to these neurological disorders, and everybody that comes up here and says that it isn't, history is going to show that you weren't doing the right kind of job for the American people that you should.

If there is any doubt whatsoever about mercury being put into a human being, being a damaging substance, then why don't we get it out of all of it?

We can give shots with no mercury, single shot vials. We can give dental fillings without any mercury in them. So why don't we do it?

I just don't understand it.

I have one question. Can I ask one question?

Mr. KUCINICH. You can ask any questions.

Mr. BURTON. OK, let's let Ms. Feinstein go. Thank you, Mr. Chairman.

Mr. KUCINICH. Senator.

Ms. WATSON. Ms. Feinstein here. [Laughter.]

I want to thank our chairman and I want to thank our ranking member for being sensitive to this issue. Now, everyone out there, you are looking at a person who had mercury poison, and just today I had to change my clothing. I had to send to my home to get a new set of clothing because I found out that the chemical in the knit that I had on was making me sick. I was violently ill earlier today.

So I appreciate this hearing being delayed because I was getting blurry. I was getting woozy and so on, and I had to go to Mexico to a dentist there.

I had my fillings put in when I was 9 years old. My father was a police officer in Los Angeles. You used to be able to go to the clinic, and pretty much they were free. I was wondering why I was having so much trouble with my blood and splotches and so on.

You know children break teeth all of the time. Teeth fall out all of the time. Teeth are pulled all of the time.

Every time you touch that amalgam, there is an emission. I was tested. I could look up at that screen, and I could see the fumes. They go right up to the T-zone, and they attack the meninges. That is that thin skin over the brain, Mr. King. They attack the meninges.

I can't, for the life of me, understand why we would risk putting it into amalgam, and you are saying it is well sealed. Well, tell that to the children who are riding their bikes, flip over, break their teeth, and they have an amalgam filling.

So I think the two of you have agreed that mercury in the environment, it is very toxic.

Mr. KING. Yes, ma'am.

Ms. WATSON. Both of you.

What is really hard for me to understand, and I have been at this for the last maybe 20 years now. I chaired the Health and Human Services Committee in the California State Senate for 17 years.

Before I left there, being termed out in 1998, I had a bill that would require the Dental Board to come up with a brochure so that a patient, a parent of a patient could know what was in that dental filling and make a choice. It took 17 years to get the Dental Board to do that.

Now, why? Why would they not want to alert you to what goes in your body?

It boggles my mind as a person who takes an oath to do no harm. I like to call it the Hypocritic Oath as in Hippocratic Oath.

It took us all those years. The administration had to change, dissolve the board, have a new board before we could get it done. We had a hearing. My colleague was with us at USC, if you remember, and we discussed that. The doctors who were all for it before were put off the board.

What is going on?

I would like to ask you this, and I am going to address this to Dr. Alderson. Are you a Ph.D. or are you an M.D. or a dentist, D.D.S.?

Mr. ALDERSON. Ph.D.

Ms. WATSON. OK. I am too, and I have to make the clarification when I am outside of this arena when they call me doctor.

Mr. ALDERSON. I understand.

Ms. WATSON. I am not an M.D., but I think I have had enough experience in the medical profession to feel like I have the accumulative knowledge to be an M.D.

What boggles my mind is that it just seems clear that the FDA cannot categorically state there is no significant impact of the use of mercury, and how do they know?

Mr. King, you weren't aware of the figures, and you said you don't work in that department. But do you know, Mr. King, that dentists are the third largest users of mercury?

Mr. KING. Yes, ma'am.

Ms. WATSON. You know that, OK. They account for 34 tons of mercury per year. You can followup on this fact. I am just throwing it out to you.

Can you tell me how—and I am going to address this to Dr. Alderson—how do you know that mercury cannot be classified as a very toxic and harmful ingredient to put into something that is in the mouth of a human for a while?

Mr. ALDERSON. I am not sure I understand the question, but I think you are asking.

Ms. WATSON. Well, you have not done, as I understand, a comprehensive environment assessment, true?

Mr. ALDERSON. That is correct.

Ms. WATSON. OK, that I am aware of. At a minimum, there is some scientific disagreement on the point and the amount and the harm that mercury can do, and I am wondering why the FDA has not done its own environmental assessment.

Mr. ALDERSON. Dental amalgams have been used for now over 100 years.

Ms. WATSON. We understand that.

Mr. ALDERSON. OK, and the classification in our regulations under the National Environmental Policy Act, our regs provide that unless there are extraordinary circumstances resulting from an action we have taken—in this case, we are talking about a reclassification and classification as it relates to the amalgam itself—that we do not have to go back and do an environmental assessment unless——

Ms. WATSON. Wait a minute. Wait a minute. It has been used for 100 years. We have other toxins in our environment. That is why I told you about my own experiences today.

FDA, the Food and Drug Administration, would not want to do its own assessment because it has been used for 100 years?

Here, a case is right in front of you, and I had to go out of this country to get the mercury amalgam removed. When I did, it changed my whole physical and emotional being when I got that mercury ingredient that is in the amalgam out of my mouth.

Do you say to me that you haven't had enough cases and therefore after 100 years of use that you don't feel the need to say to an adult, you know you have a choice?

You have a choice. You can take an amalgam that has mercury in it. You know silver amalgam is 50 percent mercury.

Yes, amalgam is 50 percent mercury. Maybe this is a new fact that you don't know. You can check it.

Mr. ALDERSON. I agree with the last statement.

Ms. WATSON. Yes, and so if there are 34 tons of mercury that come through the system in a dental office and they go out to the ocean.

Now I am from California, Los Angeles. There is a warning on the radio, on TV and in the newspaper, do not eat tuna off the coast of Southern California because the tuna fish has a high mercury level. Pregnant women do not eat tuna. Lactating mothers do not eat tuna.

So why would we not want to warn a parent when they take their child in that there is mercury in the filling, but there are options for you? I just can't understand how the Environmental Protection Agency and the Food and Drug Agency would not want to after 100 years.

I can get you people right now who have had a very negative reaction and didn't even understand until they were tested that mercury vapors were emanating from the fillings.

Mr. KUCINICH. The gentlelady's time is expired. I would like to come back to you, though. I am going to proceed with questions, then turn it over to Mr. Burton, and we are going to try to see if we can get through this round.

Mr. King, of the 1,200 tons of mercury in people's teeth, where would that mercury go when these individuals die?

Mr. KING. Where does the mercury go in terms of the diet?

Mr. KUCINICH. Yes, when someone dies, when someone passes away. We have all this mercury in people's teeth. So, mercury is in their teeth. They die. What happens?

Mr. KING. Mr. Chairman, I don't have specific information on that.

Mr. KUCINICH. Oh, you could figure this out now. I mean some people are buried, goes in the ground and others are cremated.

Mr. KING. I understand that, sir.

Mr. KUCINICH. Now if some people are cremated, where does the mercury go?

Mr. KING. If they are incinerated, the mercury is emitted into the air.

Mr. KUCINICH. OK. What is the EPA's estimate for the mercury emissions throughout the crematoria?

Mr. KING. I believe it is about 0.3 tons.

Mr. KUCINICH. That is correct.

How confident is EPA in that number?

Mr. KING. EPA, at the moment, believes that is an appropriate number. We are completely open to additional data and would be happy to sit down with folks who have that data and research.

Mr. KUCINICH. You are correct as far as the EPA's estimate, but I want to point out that an EPA environmental scientist recently published an article in the Journal of Industrial Ecology that esti-

mated that the actual mercury emission from crematoria are 10 times EPA's official estimate. In other words, they are saying not the EPA's estimate of 0.3 tons but 3 tons per year.

Are you familiar with that estimate?

Mr. KING. I am familiar with that. I am familiar with the fact that scientist used a different methodology, different assumptions, different factors, and I think our perspective would be to sit down, compare the two methodologies and to try to come up with the best information we can around that.

Mr. KUCINICH. Have you done that already?

Mr. KING. I have spoken with the gentleman over the phone.

Mr. KUCINICH. But I mean have you tried to recalculate your own numbers because he has one estimates and you have one estimate? They are both estimates.

Mr. KING. Our focus, Mr. Chairman, is to reduce mercury emissions to the environment. That is our mission, and that is why in the air program we focused on the largest emission, contributors of emissions in the country, and that is why under the water program we focused so heavily on water quality standards that in turn drive municipal waste treatment plants in terms of their relations with dental offices and drive reductions in mercury amalgam.

Mr. KUCINICH. Now, Mr. King, I have information here that says that the EPA's estimate derives from one test at one crematorium at Woodlawn Cemetery in Bronx, New York, in 1993. Is that correct?

Mr. KING. That is correct.

Mr. KUCINICH. But the EPA doesn't really know how much mercury is emitted from crematoria generally, does it?

Mr. KING. Its current estimate is 0.3 tons. I am fully aware and recognize and accept—in fact, I have spoken to the gentleman at some length—of the additional information that you just shared.

Mr. KUCINICH. OK, now when you add EPA's questionable—I will use that word—estimate of mercury emissions from sludge incinerators, mercury dental amalgam production and from crematoria, you get yearly emissions that can range upwards of 1.5 tons per year, but in our next panel we have witnesses that are prepared to say that the range could be as high as 7 to more than 9 tons per year. That is a pretty large discrepancy, isn't it, Mr. King?

Mr. KING. It is new science. It is new information. We would welcome the opportunity to sit down and take a look at what they are basing their estimates on and work with them directly.

Mr. KUCINICH. Now either dental mercury is relatively small amount of mercury contamination in the environment or it is a significant amount of mercury contamination of the environment. EPA is supposed to be able to make distinctions like this with a high degree of confidence.

What I am asking you is how can you be confident that the size of the problem is small when the estimates you use are shaky?

Mr. KING. Mr. Chairman, we regard mercury emissions from dental amalgam as important, and we regard them as important in terms of following up. Our focus under the air program is to again by focusing on the largest contributors of mercury emissions, and

in this case we respectfully do not believe that crematoria emissions are the largest contributors across the country.

Mr. KUCINICH. But we are really talking about overall the environmental pollution caused by dental use of mercury, and you have testified, if I am correct, that it is a small amount.

Mr. KING. I testified, Mr. Chairman, that we believe it is small in proportion to the total number of mercury emissions in the country. Again, the EPA strategy is to attempt to reduce the maximum amount of emissions that it possibly can, and we do that by focusing on the largest contributors of mercury emissions.

Mr. KUCINICH. You are trying to help us, I know, but you really don't know is what you are telling us. When you say small, I am looking back at the estimate that you have used where you estimate 34 tons of mercury from dental offices.

Mr. Burton.

Mr. BURTON. Mr. Chairman, we have another panel, so I am just going to ask two real quick questions. I am sure that will be a relief to you gentlemen.

Dr. Alderson, you are a veterinarian?

Mr. ALDERSON. No, sir.

Mr. BURTON. You are not?

Mr. ALDERSON. No, sir. Ph.D.

Mr. BURTON. Oh, Ph.D., OK. Well, then I was misinformed. I thought you worked in veterinary medicine.

Mr. ALDERSON. I did work in the Center for Vet Medicine most of my career at FDA.

Mr. BURTON. You worked where?

Mr. ALDERSON. At the Center for Vet Medicine.

Mr. BURTON. Oh, I see. Well, did you know that they used to put mercury into a substance that was put on horses' legs to make them feel better and make them work better?

Mr. ALDERSON. I am aware of that.

Mr. BURTON. Why do you think they took it out of that liniment?

Mr. ALDERSON. The fact of that case is that product was removed from the market because it was not an approved new animal drug application not because it was a product containing mercury.

Mr. BURTON. Oh, OK. Well, that is good to know.

My second question is for both of you. Do you think it would be better if we took mercury out of all vaccines and all substances that go in the human body? Do you think it would be better?

Mr. ALDERSON. I think from an overall perspective, looking at what we know about mercury, yes. In the overall concept of mercury, yes. But in terms of making that decision, we still should be relying on the best science to make that decision. [Laughter.]

Mr. BURTON. Oh, my gosh. I don't have any more questions.

Mr. KUCINICH. The Chair and the gavel will pass briefly to the distinguished gentlewoman from California. We are going to go vote. We will be back. Thank you.

Ms. WATSON [presiding]. This is such an important hearing because I have dedicated decades of my life on this.

I am just being made aware that we have three votes on the floor, and no one wants to miss three votes. But let me just state my concern and you can think about it. We will run and vote and be back.

I want to know why the FDA did not do an environmental impact statement when you proposed to classify mercury dental amalgam in the year 2007, Dr. Alderson and Mr. King, if you might know.

Mr. ALDERSON. I think you mean in 2002.

Ms. WATSON. Excuse me. I am still reeling from that bout I had with the fumes. 2002, yes.

Mr. ALDERSON. Under our NEPA regulations, those regulations provide for declassification actions that we do not have to do either an environmental assessment or an environmental impact statement based on that action. Keep in mind that the regs cover the action, in this case, the reclassification, not the product in question.

Ms. WATSON. OK.

Mr. ALDERSON. Unless there are actions as a result of that declassification, unless there is something that brings on a finding of extraordinary circumstances that the environment is going to be affected, then those regulations provide for a categorical exemption.

Ms. WATSON. Dr. Alderson, I think your legal counsel has misinformed you about the Agency's NEPA obligations.

In written testimony from the former NEPA Director of the White House Council on Environmental Quality, we learned that: "It seems clear that the FDA cannot categorically state there is no significant impact of the rulemaking at hand."

"How do they know? They have not completed a comprehensive"—a comprehensive—"environmental assessment of which I am aware and the literature and experience would not bear out that there is inherently no significant effect.

"At a minimum, there is some scientific disagreement on this point and that alone would be enough to preclude a categorical exclusion."

Has the FDA ever done an environmental assessment of the use of dental mercury amalgam?

Mr. ALDERSON. No.

Ms. WATSON. Dr. Alderson.

Mr. ALDERSON. No.

Ms. WATSON. OK, all right.

Mr. Clark goes on to testify, and it says, "It seems to me that such an assessment could help clear up some of the potential impacts or the scientific uncertainty.

"Although FDA and the agencies have reviewed the potential risk of the use of dental amalgam in humans, it is not clear that they have taken a look at the risk associated with the use of dental amalgam and its fate as it moves through the human and natural environment in water, in air and in soil."

That is precisely the type of policy that the authors of NEPA thought should be subjected to the rigors of analysis.

I would think that there is enough concern that the FDA of all agencies, would probably want to do and have their own scientific base, Mr. King. So I am also troubled by your use of the standard, reasonably foreseeable, because I think your legal counsel has made a grave error.

You know that mercury is a persistent bioaccumulative toxin. Would you agree to that? Bioaccumulative, it means it accumulates.

Mr. ALDERSON. I understand. I think, conceptually, I agree with you.

Ms. WATSON. OK. Now the language of the FDA regulation reads "Thus, classes of actions that individually or accumulatively do not significantly effect the quality of the human environment ordinarily are excluded from the requirement to prepare an EA or EIS."

Now you have testified that an environmental impact wasn't reasonably foreseeable, and that reasonably foreseeable standard is language appearing in the CEQ regulation at 1508.7, defining a cumulative impact. I will just read it to you.

"Cumulative impact is the impact on the environment which results from the incremental impact of the action when added to other past, present and reasonably foreseeable future actions regardless of what agency or person undertakes other actions."

Now, in light of mercury's inherent characteristics, it is bioaccumulative. In the language of the CEQ regulation on cumulative impact, how could FDA not reasonably foresee that mercury would accumulate in the environment from dental offices and their continued use of mercury and not have a cumulative impact?

So, Dr. Alderson, you need to do an analysis to conclude that there is no significant effect, and FDA hasn't done one yet. I would think with our concern that maybe you can get a hint that you should do it. Do you feel that way?

Mr. ALDERSON. Ms. Watson, to the 2002 proposed rule, we received over 750 comments. The comments to the 2006 meeting which you testified at, we received over 3,500 comments. FDA is currently reviewing all those comments and input we received from those two actions.

If we determine under the regulations that the actions we propose to take as a result of that work results in extraordinary circumstances, per our regulations on categorical exemptions, we be looking at doing an environmental assessment. But at this point in time, we have not reached a point to determine what action we will be taking on dental amalgams.

Ms. WATSON. If we are adding 34 to 54 tons of mercury into the environment, into the water per year, wouldn't you want to know what the effect would be, what the environmental impact would be?

Because of this hearing, would you want to take a closer look and a have a scientific base on which to come in front of the committee again and say there is really no significant impact?

Mr. ALDERSON. I agree with you, Ms. Watson. I think as we move forward in determining the actions we will be taking, this will be a consideration that we will be making.

Ms. WATSON. I am told that an environmental impact statement is intended to influence an agency's decisionmaking process, and already Section 1505.1 of the regulations states this: "Agencies shall adopt procedures."

I am talking real slowly because I am trying to get my point across.

"Agencies shall adopt procedures to ensure that decisions are made in accordance with the policies and purposes of the National Environmental Policy Act. Such procedures shall include but not be limited to requiring that the alternatives considered by the decisionmaker."

Now, Dr. Anderson, by alternatives, the regulation means in part alternatives to using mercury dental fillings. The whole idea behind NEPA is to force agencies to consider alternatives even if they don't want to do so.

Let me just ask you, are there alternatives to mercury dental fillings, Dr. Alderson?

Mr. ALDERSON. There are.

Ms. WATSON. Do they work safely and effectively in your opinion?

Mr. ALDERSON. The ones that we have approved at FDA, yes, I would agree with that.

Ms. WATSON. Do they contain mercury?

Mr. ALDERSON. No.

Ms. WATSON. Viewed strictly from an environmental impact lens, Dr. Alderson, which is likely to have a greater environmental impact, 34 to 54 tons of mercury per year or the alternative fillings?

Mr. ALDERSON. If you automatically assume that all of that gets into the environment.

Ms. WATSON. Wait a minute. Wait a minute. We have this statistic, and you need to go and look it up, that there are between 34 and 54 tons of mercury per year in mercury dental amalgam used by dentists, and then we are finding that it has affected the sea life in the ocean to the point that we are announcing to human beings, don't eat tuna because of its high mercury content.

It would seem to me a man with a scientific background would want to look into this and be able to say to us, scientifically, with an empirical base that we find that tonnage of mercury has not affected seafood or humans. I would think that this is something that FDA ought to do to minimize environmental harm. Would you agree?

Mr. ALDERSON. I think it is a purpose of everything we do.

Ms. WATSON. Would you agree that an assessment really is needed to reduce any kind of environmental harm?

Mr. ALDERSON. FDA is looking at the actions that——

Ms. WATSON. Would you agree, yes or no?

Mr. ALDERSON. I think, conceptually, yes, that is always the basis.

Ms. WATSON. All right, all right. Can I then get the two of you to agree an assessment is needed ASAP?

Mr. ALDERSON. I can't agree to that at this point in time. We have not completed our assessment of what action we will take and based on the NEPA regulations. Only in the finding of extraordinary circumstances——

Ms. WATSON. Why is there so much resistance to it? Can you, Mr. King? Can you, Dr. Alderson?

If you know mercury is toxic, if they are taking it out of thermometers, if we closed two schools because there was a mercury spill, why are you resisting taking a look at mercury that is used in the human body and doing an assessment?

Can you explain that to me?

Mr. ALDERSON. I don't think I am going to give you an answer you will like, but.

Ms. WATSON. No. You give me yours.

Listen, you don't have to give me an answer I like. I wouldn't be up here asking if I had liked anything you have done thus far. So

it is time for you to give me an answer and remember, we seek the truth in this committee.

Mr. ALDERSON. Ms. Watson.

Ms. WATSON. Wait a minute. You need to understand where I am coming from. I intend to clean our environment so that we can have healthy lives out there. We know there is a toxic substance in this casing called amalgam, and I would like the agency responsible for checking out drugs and food to at least be willing to do an assessment.

Now, respond.

Mr. ALDERSON. The Agency and other public health organizations——

Ms. WATSON. No. I want to talk about FDA. Talk about FDA. Isn't that where you are?

Mr. ALDERSON. That is correct.

Ms. WATSON. OK, let's talk about FDA.

Mr. ALDERSON. FDA has had numerous advisory committee meetings on this issue for a number of years, and the last one you attended in 2006. In none of those meetings, none of them, have those advisory panels of the best scientists we can bring to bear on this issue ever advised us that we need to be doing the action and taking action in terms of either environmental assessment or changing the way we regulate it.

The last meeting, we did receive some comments about some changes they recommended, and those are under review at the Agency.

Ms. WATSON. Dr. Alderson, I want to draw your attention to what appears to be a logical inconsistency in the 2002 proposed regulations concerning mercury dental amalgam. As I have already noted, FDA asserted that classifying the device called dental mercury amalgam would have no environmental impact. However, elsewhere in the proposed regulation, FDA acknowledged that the presence of mercury in the environment would add to the mercury burden on individuals and might make some individuals more sensitive to adverse health effects from mercury fillings put in their mouth.

FDA states: "Mercury is absorbed from many sources including food and air. Because of the variability of exposures to mercury from all sources in the population, the margin of safety for some persons may be lowered when mercury from amalgam fillings is added."

How could FDA acknowledge mercury pollution on one hand and suggest the possibility that they might have a human health effect for certain individuals while, on the other hand, FDA denied any environmental impact when it applied the categorical exclusion?

I am wondering what the effect might be if you did an environmental impact statement on the effect of that 34 to 54 tons of mercury per year into the water table, into the ocean. So maybe you can explain to me why there is so much resistance from FDA to do an environmental assessment.

Mr. ALDERSON. I don't detect there is resistance to it, Ms. Watson.

Ms. WATSON. Would you do it?

Mr. ALDERSON. I can't answer that today.

Ms. WATSON. You cannot?

Mr. ALDERSON. If we follow our regulations.

Ms. WATSON. Wait a minute. You cannot?

You cannot answer that today because I can go back to the law with you and I can tell you that you probably ought to look at it. Section 102 of the National Environmental Policy Act of NEPA says, all agencies, that is all agencies of the Federal Government, shall—not you may, it says shall—include in any every recommendation or report on proposals for legislation and other major Federal actions significantly effecting the quality of the human environment a detailed statement by the responsive official on, one, the environmental impact, the environmental impact of the proposed action and, two, any adverse environmental effects which cannot be avoided should the proposal be implemented and, three, alternatives to the proposed action.

I have a bill that I have had for several years now that would restrict the use of mercury in mercury amalgam in lactating women, pregnant women and children under the age 18.

I would think that, from what I just read to you and all of that combined, means that prior issuing of a device classification for a mercury-containing device, you shall, you shall consider the consequences to the environment of the use of mercury. So I would think you could make your decision.

If you don't know what the impact is, then I think you ought to do an assessment. Do you want to respond?

Mr. ALDERSON. As only then to say that as we are considering any action that we will take as a result of the comments we received in the last 2 years, 3 years.

Ms. WATSON. Why don't you do your own assessment?

Mr. ALDERSON. In our view, Ms. Watson, under our regulations, there is not a requirement at this point to do one.

Ms. WATSON. I am told that you cannot be in violation of this regulation. It says you shall. You shall. That means you are mandated. Are you going to say to me there is no mandate there?

Mr. ALDERSON. No, ma'am, I am not, obviously.

Ms. WATSON. Well, I am repeating from the regulation. You shall consider the consequences to the environment.

Mr. ALDERSON. I will assure you we will go back to our legal staff and define this discrepancy you have identified to us in the law versus what is in our regulation. Our regulation provides for——

Ms. WATSON. OK. Why are you resisting doing an assessment, FDA?

Mr. ALDERSON. I don't know that anyone is resisting.

Ms. WATSON. You are.

Mr. ALDERSON. No. No, I am not, Ms. Watson.

Ms. WATSON. Will you do an assessment?

Mr. ALDERSON. I can't give you. I am not going to give you an answer on that. I don't know the answer.

Ms. WATSON. Will you follow the law?

Mr. ALDERSON. We will follow the law.

Ms. WATSON. Will you reread that section?

Mr. ALDERSON. Absolutely.

Ms. WATSON. And interpret it.

You know what? Do we have the section on hand? I wish we had it up on the monitor because I would like you to look at it now and say to me that you are not going to do an assessment because there is no requirement.

Can someone get him that information?

Yes, we need to put that on the record. We really do.

Were they sworn in?

STAFF. Yes.

Ms. WATSON. OK. You are under oath now.

Mr. ALDERSON. I understand.

Ms. WATSON. OK. Can the Agency give me the interpretation? Do you have an attorney with you that can give us an interpretation?

Mr. ALDERSON. I do not have an attorney here today.

Ms. WATSON. OK.

Mr. ALDERSON. We will be glad. As I said, we will be glad to go back and give you our interpretation of our regs versus the law you are reading.

Ms. WATSON. Now I am going to read again to you, and I am being as clear as I can. Section 102, Section 102, somebody needs to take a note for you, of the National Environmental Policy Act.

NEPA says: All agencies of the Federal Government shall—that is a mandate—shall include in every recommendation or report on proposals for legislation—that is what is in front of us—and other major Federal actions significantly affecting the quality, significantly affecting the quality of the human environment a detailed statement by the responsible official.

I guess you would be the one. Are you the responsible official?

Mr. ALDERSON. In this case, no. That assessment would be done at our Center for Devices and Radiological Health.

Ms. WATSON. Well, it would include in every recommendation, OK, the environmental impact of the proposed action, any adverse environmental effect which cannot be avoided should the proposal be implemented and alternatives to the proposed action.

If the World Health Organization concluded that mercury should be taken out of thermometers, and I think you are aware of that, why would you want to put it into an amalgam that goes into someone's mouth? Do you want to answer that or try?

Mr. ALDERSON. The only answer I have to you, Ms. Watson, is that again in numerous advisory panel meetings of the best scientists we can bring on this issue, no one has told us to remove it, no one.

Ms. WATSON. I probably should be on that floor now, but this is too important.

Mr. King, all that the EPA has done about dental amalgam is a voluntary education outreach program for young dentists, what you call the gray bag program. Can you describe the gray bag program, Mr. King?

Mr. KING. Ms. Watson, I can briefly describe it. I would also like to add, however, we respectfully disagree that all we have done is voluntary, and I would be pleased to explain why we think we have done substantially more than that to reduce.

Ms. WATSON. What have you done? You want to tell us what you have done?

Mr. KING. I would be delighted to. In the Clean Air Program, the Agency has reduced emissions by 90 percent for medical waste incineration from municipal combustion. We are on track to reduce emissions by 70 percent, mercury emissions from coal-fired utility plants.

In the water arena, we have put into place, working directly with States, water quality standards both in the Great Lakes.

Ms. WATSON. OK, let me stop you there.

Mr. KING. Yes, ma'am.

Ms. WATSON. Can you address mercury amalgam?

Mr. KING. Yes, ma'am. When we establish a water quality standard under the Clean Water Act, States put it into their State standards and then those affect the discharge that a municipal wastewater treatment plant can make to waters of the United States.

Because our standards are so stringent for mercury, what those standards operate to do is, in essence, force or drive or encourage a municipal wastewater treatment plant to go back up the sewer to a number of the mercury dischargers including dental offices and to work with dental offices to reduce their dental mercury amalgam discharges to the sewer system.

Duluth, Minnesota was one example that has worked out very impressively, reducing them by two-thirds.

The city of San Francisco has adopted a goal of putting into place amalgam separators in 900, all of their dental offices. Those separators have a removal efficiency of mercury amalgam of over 95 percent.

The States in the Great Lakes have established extremely stringent mercury wildlife numbers. Those mercury wildlife numbers have operated to take six States in the Great Lakes, have them join together with EPA's Region 5 office and develop a pollution prevention reduction plan that goes directly to the reduction in part of dental mercury amalgam.

Ms. WATSON. Now this is what other States have done, right, and they have done it on their own, like San Francisco. They have done it on their one. What has EPA done?

You have a gray bag program, but it is voluntary. You get information out there. What have you done?

Mr. KING. The gray bag program goes the mercury amalgam that is removed in the dentist's office and to send it to a recycle.

Ms. WATSON. But it is voluntary, is it not?

Mr. KING. It is voluntary, yes, ma'am.

Ms. WATSON. OK. Now how many dental students have actually gone through your seminar up at Marquette University?

Mr. KING. Forgive me. Would you please repeat that? I apologize.

Ms. WATSON. Sure.

Mr. KING. How many dental students have gone through my seminar?

Ms. WATSON. Yes.

Mr. KING. I have not actually provided a seminar to dental students, but we have a great deal of outreach.

Ms. WATSON. It is an initiative that you are trying to develop?

Mr. KING. If you are referring to gray bags.

Ms. WATSON. I am talking about mercury amalgam.

Mr. KING. OK. I thought you were talking about water quality standards. I don't have the number on how many dental students have participated in that program.

Ms. WATSON. In the gray bag program?

Mr. KING. Yes, ma'am. I do not have that number with me right now. I am sorry. I will be happy to provide it for the record if that would be useful, OK.

Ms. WATSON. We would like that.

Mr. KING. Yes, ma'am.

Ms. WATSON. If actual air emissions of mercury caused by dental mercury use is closer to 10 tons per year, do you think that EPA's educational gray bag program is sufficient to address a problem of this magnitude?

Is it enough to give a seminar to dentistry students—it is a seminar—and not have some requirement that maybe we ought to mandate this?

Mr. KING. We think the gray bag program is a very valuable, albeit voluntary, program.

Ms. WATSON. Sure.

Mr. KING. That is only one of a number of things the EPA is doing to reduce mercury releases to the environment.

Ms. WATSON. What else are you doing? I would like to stick on mercury amalgam for a minute.

Mr. KING. You bet. We are focusing on working with municipal wastewater treatment systems to encourage them and provide them with guidance so that they, in turn——

Ms. WATSON. Let me ask you this directly.

Mr. KING. Yes, ma'am.

Ms. WATSON. Would you want to encourage the industry not to use mercury in amalgams?

Mr. KING. The use of mercury in amalgams is an area that falls within the purview of the FDA. Our focus at EPA is to address the release of mercury emissions into the environment, and we believe we have a number of substantial and effective regulations and programs in place to substantially reduce the release of those emissions.

We regard——

Ms. WATSON. Would you encourage dentists not to use mercury in the amalgams? Would you suggest that to your students?

Mr. KING. EPA does encourage.

Ms. WATSON. No. I am talking about you. You hold this seminar, am I correct?

Mr. KING. Yes, ma'am. Yes, ma'am.

Ms. WATSON. Is it you or EPA that holds that seminar?

Mr. KING. EPA conducts the seminar. It is a program that is not the program that I run, but I have spoken to that program and I know that they encourage the use of non-mercury amalgam. However, EPA is very clear in the importance of ultimately deferring to dental professionals and their patients on the most appropriate amalgam to suit their situation.

Ms. WATSON. I am being told that we have a major bill now up for a vote. I have missed all the votes leading up to it, but this is on the actual bill. So I am going to have to recess this panel, and

I want to thank you two gentlemen for being patient, for testifying and for hearing.

I am strongly suggesting that if we have a problem with a toxic, and I am passionately committed to this, the removal, if we could remove that toxic, it would be one less impact on the human body.

We are dealing with lead in children's toys, toys that were manufactured over in China with different standards. We are dealing with the runoff from the dental offices into the ocean where we are warning people not to eat tuna. We know asbestos was out there in building materials.

We have all these impacts. We are trying to clean up our environment. If I trust FDA, I would think this hearing would be very valuable to you if you are committed to keeping people safe.

With that, I want to thank you so much for your patience. We will dismiss the first panel. We will take a short recess, and we will bring up panel two. Thank you, gentlemen.

Mr. KING. Thank you.

[Recess.]

Mr. KUCINICH [presiding]. The committee will come to order.

I want to thank the witnesses for their patience. I think what I will do is I am going to introduce the witnesses and then we will swear or affirm their presence and their testimony.

Unfortunately, one of the witnesses that we had hoped to have here, Mr. Bruce Terris, had a last minute conflict. He will be submitting his testimony for the record.

Mr. Ray Clark, welcome. Mr. Clark is a senior partner in The Clark Group, LLC and was the National Environmental Policy Act Director at the White House Council on Environmental Quality from 1993 to 1995. He served as Associate Director of CEQ from 1995 to May 1999. He has also served as Principal Deputy Assistant to the Secretary of the Army with responsibility over environmental program management in millions of acres of DOD-owned land.

Second, we will hear from Michael Bender who is the Founder and Director of the Mercury Policy Project. The project works to promote policies to reduce and eliminate uses, releases and exposures to mercury at the local, national and international levels.

Mr. Bender has participated on a steering committee for the International Conference on Mercury as a Global Pollutant, as a member of the U.S. Federal Stakeholder Group on Surplus Mercury and is Co-Chair of the State of Vermont Advisory Committee on Mercury Pollution.

Dr. C. Mark Smith is the Deputy Director of the Office of Research and Standards of the Massachusetts Department of Environmental Protection and directs the agency's multimedia mercury program. His areas of expertise include toxicology, risk assessment and environmental policy particularly related to toxic chemicals such as mercury. He holds a Ph.D. in the fields of molecular and cellular toxicology and a Master's degree in environmental management from Harvard University.

Dr. Smith currently co-chairs the New England Governors and Eastern Canadian Premiers Regional Mercury Taskforce among other roles.

Finally, Dr. J. Rodway Mackert, he is a dentist and professor at the Medical College of Georgia and is representing the American Dental Association today. He has advanced degrees in dentistry and in materials science.

Gentlemen, it is the policy of the Committee on Oversight and Government Reform to swear in all witnesses before they testify. Whenever a witness says that they do not take such oaths, we ask them to proceed with an affirmation that this is their testimony. So whether you swear or you affirm, I would ask you to rise right now and answer this question.

[Witnesses sworn.]

Mr. KUCINICH. Thank you. Let the record reflect that our witnesses answered in the affirmative.

As with the first panel, I ask that the witnesses give an oral summary of your testimony and to keep this summary under 5 minutes in duration, although if you go a little bit more—you have been very patient, waiting for us—we will hear you out, but try to keep it under 5 minutes.

Bear in mind your complete written statement will be included in the hearing record.

Now in the interest of expediting Mr. Clark's schedule, you may proceed, and then we will go right down the row. Mr. Clark.

STATEMENTS OF RAY CLARK, SENIOR PARTNER, THE CLARK GROUP, LLC; MICHAEL T. BENDER, EXECUTIVE DIRECTOR, MERCURY POLICY PROJECT; DR. C. MARK SMITH, CO-CHAIR, MERCURY TASKFORCE, NEW ENGLAND GOVERNORS' CONFERENCE; AND DR. J. RODWAY MACKERT, DENTIST AND FACULTY MEMBER, MEDICAL COLLEGE OF GEORGIA

STATEMENT OF RAY CLARK

Mr. CLARK. Good afternoon, Mr. Chairman and members of the subcommittee. It is a real pleasure to be before the Domestic Policy Subcommittee on an important and very timely issue of classification of dental amalgam, dental mercury amalgam and the Food and Drug Administration's responsibility under the provisions of the National Environmental Policy Act.

Allow me a brief moment to provide you my background. I am a senior partner with The Clark Group, a Washington, DC-based environmental and energy consulting firm. I left public service in 2001 as the Principal Deputy Assistant Secretary of the Army, and from 1992 to 1999 I served in the Council of Environmental Quality in the Executive Office of the President.

I have been teaching NEPA implementation at Duke University since 1989, and I am the editor of a book on the history and the passage of NEPA, the current principals and practice and the future of the statute and its practice.

When Congress passed NEPA in 1969, they recognized the complexity of environmental issues and the role of the Federal Government in the perturbations and improvement in the human environment. Congress also recognized it was not only the direct effects agencies may have but the many polices, regulatory actions and the effects on markets.

NEPA provides the Nation with an environmental policy, a tool to reach that policy and an agency within the Executive Office of the President to ensure that the agencies understand the policy in Section 101 of the statute and develop and oversee the development of procedures to comply with the law.

With the passage of NEPA, Congress established the Council on Environmental Quality and directed the Federal agencies to work with governments at all levels to begin the arduous task of understanding the effects of manifold actions taken in the absence of full information.

No statute has offered a more structured and disciplined approach to Federal decisionmaking, and no statute has offered the public as transparent a window into Federal decisionmaking as NEPA. No statute has given the agencies more flexibility to establish the ways and means of meeting that mandate.

Since the passage of NEPA, Congress, CEQ and the courts have responded to the uncertainties of human experimentation on the natural landscape through statutes, regulations and court decisions. All have given great deference to the agencies, but they have all asked the agencies to take a hard look at proposed actions to try to ascertain the direct, indirect and cumulative effect of such actions.

Over the course of time and with the help of NEPA and the agencies' hard look, we now know more about the effects of many Federal actions, whether they be policies, projects or programs. We also know more about how complex environmental interactions are. We also understand that our collective environmental knowledge gap is wide.

Through the work of the FDA, the Environmental Protection Agency and other public and private science, we now know that mercury is a highly toxic, persistent and bioaccumulative neurotoxin.

We now know that it is released in the air through the burning of coal at power plants and the burning of mercury-containing wastes. It is released into water either directly or indirectly by deposition or to wastewater treatment plants or in the sludge treated at those plants.

In my opinion, it seems clear that at least one of the two following conditions exists: one, there is a clear environmental effect of the manner in which mercury amalgam is being treated and disposed; or, two, there are scientific uncertainties about the extent of the environmental effects.

Any statement that there is no environmental effect would be met with argument and likely scientific controversy as we see today. In either situation, however, there is a responsibility of the Food and Drug Administration to understand these effects or the differing scientific views before making a decision. NEPA requires such an understanding before FDA can make a decision on risk classification.

In order to categorically exclude such an action as was suggested today, as a rulemaking on classifying dental mercury amalgam, the FDA would have to reach one of two possible conclusions: either the mercury amalgam inherently has no significant impact or cumulative environmental effect, or through the experience of numer-

ous environmental impact analyses, they have consistently found that there is no significant impact.

It seems clear that FDA cannot categorically state that there is no significant impact of the rulemaking at hand. How do they know? They have not completed a comprehensive environmental assessment of which I am aware, and the literature and experience would not bear out that there inherently is no significant effect.

At a minimum, there is some scientific disagreement on this point, and that alone would be enough to preclude a categorical exclusion. There are uncertainties associated with the use of dental amalgam such as the amount discharged from dental offices, the fate of mercury in amalgam and the percentage of elemental mercury that is released from amalgam.

There are also others in State and local government taking precautions to assure safety, and that should clearly indicate to the FDA that the effects of the rule are not "inherently insignificant."

The second way FDA could categorically conclude there are no significant effects is by preparing one or more environmental assessments, each of which reaching a finding of no significant impact.

In fact, in 1997, FDA responded to a question about whether secondary or tertiary manufacturing processes involving food additives that may result in uncontrolled end products should be categorically excluded. The Agency responded appropriately, in my opinion, because they reviewed hundreds of environmental assessments that contained information regarding manufacturing sites and found no significant impact, that they decided to categorically exclude the process from further analysis, and I believe that is the appropriate way you come to the conclusion of a categorical exclusion.

To my knowledge, no comprehensive environmental assessment has been prepared on the issue of dental mercury amalgam. It seems to me that such an assessment could clear up some of the potential impacts of scientific uncertainty. Although FDA and the agencies have reviewed the potential risks of the use of dental amalgam in humans, it is not clear that they have a taken a hard look at the risks associated with the use of dental amalgam and its fate as it moves through the human and natural environment in water, air and soil.

The mercury discharged by dental offices may fall within the purview of many agencies, each approaching the problem through its particular regulatory lens. Each agency can move the mercury to a different media and different set of regulations without removing it from the environment, as we saw today with our two witnesses moving the mercury amalgam from one agency to another.

No one agency addresses the cumulative long term effects of mercury discharges, and there is no assurance that the mercury is ever effectively sequestered.

FDA may be right, that the environmental effects associated with the level of use is not significant. However, I cannot see how they have come to the conclusion. They have not produced any environmental assessment or impact statement, and the literature and practice is rife with questions about the use and disposal.

It is precisely the type of policy that the authors of NEPA thought should be subjected to the rigors of analysis. The rulemaking action clearly is a significant action anticipated by NEPA.

CEQ regulations define a major Federal action as "actions with effects that may be major and which are potentially subject to Federal control and responsibility."

Actions also include the "circumstance where the responsible officials fail to act and that failure to act is reviewable by courts or administrative tribunals under the Administrative Procedures Act."

Further quoting from the CEQ regulations defining a major Federal action: "Actions include new and continuing activities, including projects and programs entirely or partly financed, assisted, conducted, regulated or approved by Federal agencies; new or revised agency rules, regulations, plans, policies or procedures; and legislative proposals."

Mr. Chairman, there are ways such an assessment could be done efficiently and effectively. FDA could prepare a programmatic environmental assessment. If indeed the Agency could answer the questions being posed by sewage plants, by cities and counties and by health officials, perhaps many resources could be saved by those authorities.

Perhaps, FDA could identify mitigation techniques that would render the impacts insignificant. Perhaps a collaboration between FDA and other Federal, State and tribal governments would emerge and programmatic approaches could be developed.

A forward-looking FDA in 1978, Mr. Chairman, filed a programmatic environmental impact statement regarding the use of fluorocarbons in products subject to FDA regulation. The EIS was used as a basis for prohibiting chlorofluorocarbons as a propellant in self-pressurized containers if the use of the CFC was not deemed to be essential. This action seems all the more responsible in hindsight.

In conclusion, Mr. Chairman, there is much to commend in the FDA NEPA regulations. There is sound environmental policy. There is transparency and there is admonition to prepare readable analyses for the public and solid streamlining efforts which we should all support.

FDA has, in the past, used EISes for sound decisionmaking. However, on the question of whether there is sound footing to declare a categorical exclusion for rulemaking for classification of risks, I do not see a basis.

I would recommend to FDA to prepare a programmatic environmental assessment on the rule and allow the scientific community and the public to offer their advice and counsel before asking the decisionmaker to decide in the absence of any environmental impact analysis.

Thank you and I would be pleased to answer questions.

[The prepared statement of Mr. Clark follows:]

TESTIMONY

BEFORE

THE DOMESTIC POLICY SUBCOMMITTEE

OF THE

HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

RAY CLARK

SENIOR PARTNER

THE CLARK GROUP, LLC

WASHINGTON, DC

14 NOVEMBER 2007

Good Afternoon Mr. Chairman and Members of the Subcommittee. It is a pleasure to appear before the Domestic Policy Subcommittee on the important and timely issue of the classification of dental mercury amalgam and the Food and Drug Administration's obligations under the National Environmental Policy Act (NEPA).

Allow me a brief moment to provide you my background. I am the Senior Partner with the Clark Group, a Washington-based environmental and energy consulting firm. I left public service in 2001 as the Principal Deputy Assistant Secretary of the Army for Installations and Environment. From 1992 until 1999, I served in the Council on Environmental Quality in the Executive Office of the President. I have been teaching NEPA implementation at Duke University since 1989 and I am the editor of a book on the history of the passage of NEPA, the current principles and practice and the future of the statute and practice.

When Congress passed NEPA in 1969, they recognized the complexity of environmental issues and the role of the federal government in the perturbations and improvement in the human environment. Congress also recognized it was not only the direct effects agencies may have, but the many policies, regulatory actions, and the effect on markets. NEPA provides the nation with an environmental policy, a tool to reach that policy, and an agency within the Executive Office of the President to ensure that agencies understand the policy in Section 101 of the Act and to develop and oversee the development of procedures to comply with the law.

With the passage of NEPA, Congress established the Council on Environmental Quality (CEQ) and directed the federal agencies to work with governments at all levels to begin the arduous task of understanding the effects of manifold actions taken in the absence of full information. No statute has offered a more structured and disciplined approach to federal decision-making and no statute has offered the public as transparent a window into federal decision-making as NEPA. No statute has given the agencies more flexibility to establish the ways and means of meeting their mandate.

Since the passage of NEPA, Congress, CEQ and the courts have responded to the uncertainties of human experimentations on the natural landscape through statutes, regulation and court decisions. All have given great deference to the agencies, but they have all asked the agencies to take a "hard look" at proposed actions to try to ascertain the direct, indirect and cumulative effects of such actions. Over the course of time and with the help of NEPA and the agencies' hard look, we know more today about the effects of many federal actions, whether they be policies, projects, or programs. We also know more about how complex the environmental interactions are. We also understand that our collective environmental knowledge gap is wide.

Through the work of the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and other public and private science, we now know that Mercury is a highly toxic, persistent and bioaccumulative neurotoxin. We know that it is released into the air through burning of coal at power plants and burning of mercury-containing wastes. It is released into water either indirectly by deposition or directly to wastewater treatment plants or in sludge generated by the treatment plant. Typically, this sludge is composted or incinerated. Once mercury reaches a water body through rain or snow, bacteria convert it to a more toxic form, methylmercury, which accumulates in the tissues of plants, insects, fish, and animals.

A major source of mercury amalgam comes from the dental devices used by dentists. According to an EPA cradle-to-grave study on the use and release of mercury, the amalgam in wastewater from dental offices is the largest direct contributor of mercury to water in the United States at 7.4 tons/year.[1] As is often the case with environmental knowledge, the receptors often feel the impacts much sooner than the source understands the effects of the action. In this regard, wastewater treatment agencies were the first to detect and try to address mercury discharges by dentists. However, these waste water treatment agencies have limited jurisdiction, and their regulatory mechanisms vary. Some have adopted new bylaws specifically addressing the issue, while others relied on enforcing limits already in place, and still others negotiated special limits for dental offices. The resulting patchwork system means that dentists living in one county or city may be required to act differently than those in the adjoining jurisdiction.[2]

Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Oregon, and Vermont have all implemented some form of law requiring dental offices to use amalgam separators. Amalgam separators capture mercury amalgam from wastewater effluent for recycling or other disposal. In addition, several countries including, including Canada,

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[1] U.S. Environmental Protection Agency. 2002. *Use and Release of Mercury in the United States.*
[2] Savina, G. 2003. *Mercury in Waste Dental Amalgam: Why Is It Still a Problem?* Local Hazardous Waste Management Program in King County. Retrieved online from http://www.govlink.org/hazwaste/publications/WasteAmalgamProblems_03.pdf.

Sweden, Norway, Germany and Austria have now taken or initiated steps to reduce or eliminate the use of amalgam as a dental restorative material. These steps were taken by governments to control what was perceived as a potential threat to the human environment. A number of organizations, such as FDA, and scientific experts have studied the potential impacts of dental amalgam as used on humans. However, there are limited scientific studies on the fate of dental amalgam in the environment, and the wide range of results in these studies stop short of a comprehensive "hard look" at the potential impacts.

In my opinion, it seems clear that at least one of the two following conditions exist: (1) there is a clear environmental effect of the manner in which mercury amalgam is being treated and disposed or (2) there are scientific uncertainties about the extent of environmental effects. Any statement that there is no environmental effect would be met with argument and likely scientific controversy, as we see today. In either situation, however, there is a responsibility of the Food and Drug Administration to understand these effects or the differing scientific views before making a decision. NEPA requires such understanding before FDA can make a decision on risk classification.

There are three ways the FDA could meet the requirements of NEPA and CEQ regulations and document the agency has taken a "hard look". One is through development and deployment of a categorical exclusion. In order to categorically exclude such an action as a rulemaking on classifying dental mercury amalgam, the FDA would have to reach one of two possible conclusions; either that mercury amalgam inherently has no significant individual or cumulative environmental effect or through the experience of numerous environmental assessments which consistently found no significant impact.

It seems clear that FDA cannot categorically state there is no significant impact of the rulemaking at hand. How do they know? They have not completed a comprehensive environmental assessment of which I am aware and the literature and experience would not bear out that there is inherently no significant effect. At a minimum, there is some scientific disagreement on this point and that alone would be enough to preclude a categorical exclusion. There are uncertainties associated with the use of dental amalgam, such as the amount discharged from dental offices; the fate of the mercury in amalgam; and the percentage of elemental mercury that is released from amalgam.[3] There are also others in state and local government taking precautions to assure safety and that should clearly indicate to FDA that the effects of the rule are not "inherently insignificant".

The second way FDA could categorically conclude there are no significant effects is by preparing one or more environmental assessments, each of which reaching a finding of no significant impact. In fact, in 1997 FDA responded to a question about whether secondary and tertiary manufacturing processes involving food additives that may result in uncontrolled end products should be categorically excluded. The agency responded appropriately, in my opinion, because they reviewed hundreds of environmental assessments that contained information regarding manufacturing sites and found no significant impact, and so they decided to categorically exclude the process from further analysis.

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[1] U.S. E.P.A. and Environment Canada. 2004. *Options for Dental Mercury Reduction Programs: Information for State/Provincial and Local Governments.* Retrieved online from http://www.epa.gov/region5/air/mercury/dentaloptions3.pdf.

To my knowledge, no comprehensive environmental assessments have been prepared on the issue of dental mercury amalgam. It seems to me that such an assessment could help clear up some of the potential impacts or the scientific uncertainty. Although FDA and the agencies have reviewed the potential risks of the use of dental amalgam in humans, it is not clear that they have taken a look at the risks associated with use of dental amalgam and its fate as it moves through the human and natural environment in water, air and soil. At the same time, there exists disagreement concerning the amount of mercury currently captured in dental offices and 'captured' mercury is not necessarily sequestered from the environment depending on the method of disposal. The mercury discharged by dental offices may fall within the purview of many agencies, each approaching the problem through its particular regulatory lens. Each agency can move the mercury to a different media and a different set of regulations without removing it from the environment. No one agency addresses the cumulative long term effects of mercury discharges, and there is no assurance that the mercury is ever effectively sequestered.[4]

FDA may be right that the environmental effects associated with the level of use of dental amalgam are not significant. However, I cannot see how they have come to the conclusion. They have not produced any environmental assessments or impact statements, and the literature and practice is rife with questions about the use and disposal. It is precisely the type of policy that the authors of NEPA thought should be subjected to the rigors of analysis. The rulemaking action clearly is a significant action anticipated by NEPA. CEQ regulations define a major federal action as "actions with effects that may be major and which are potentially subject to Federal control and responsibility." Actions also include the "circumstance where the responsible officials fail to act and that failure to act is reviewable by courts or administrative tribunals under the Administrative Procedure Act or other applicable law as agency action." Further quoting from the CEQ regulations defining a major federal action: "(a) Actions include new and continuing activities, including projects and programs entirely or partly financed, assisted, conducted, regulated, or approved by federal agencies; new or revised agency rules, regulations, plans, policies, or procedures; and legislative proposals (Secs. 1506.8, 1508.17).

Federal actions, according to the CEQ regulations include the "adoption of official policy, such as rules, regulations, and interpretations adopted pursuant to the Administrative Procedure Act, 5 U.S.C. 551 et. seq." Further quoting CEQ regulations, "Adoption of formal plans, such as official documents prepared or approved by federal agencies which guide or prescribe alternative uses of Federal resources, upon which future agency actions will be based," would be considered a major federal action.

Once the action is deemed to be a "major federal action", the FDA must determine the appropriate level of analysis, that is, whether to conduct an Environmental Assessment or an Environmental Impact Statement. This can be accomplished using a number of factors to determine the potential significant environmental effects of the action. The CEQ regulations define significance as "context and intensity" (§ 1508.27). For context, some of the factors to consider include the affected region, society (human, national), and locality. It also includes the short-term and long-term potential to effect the environment. Intensity refers to the severity of

[4] Savina, G. 2003. *Mercury in Waste Dental Amalgam: Why Is It Still a Problem?* Local Hazardous Waste Management Program in King County. Retrieved online from http://www.govlink.org/hazwaste/publications/WasteAmalgamProblems_03.pdf.

the potential impact, including degree of impact, degree of controversy, and the cumulative effects of the action. The way these factors are identified and evaluated under NEPA is through a scoping process.

Mr. Chairman, there are ways such an assessment could be done efficiently and effectively. FDA could prepare a Programmatic Environmental Assessment. If indeed the agency could answer the questions being posed by sewage plants, by cities and counties, and by health officials, perhaps many resources could be saved by these authorities; perhaps FDA could identify mitigation techniques that would render the impacts insignificant; perhaps a collaboration between FDA and other federal, state and tribal governments would emerge and programmatic approaches could be developed. A forward looking FDA in 1978 filed a programmatic EIS regarding use of fluorocarbons in products subject to FDA regulation. The EIS was used as a basis for prohibiting CFCs as a propellant in self pressurized containers if the use of the CFC was not deemed to be essential. This action seems all the more responsible in hindsight.

In conclusion, Mr. Chairman, there is much to commend in the FDA NEPA regulations. There is sound environmental policy, transparency, an admonition to prepare readable environmental analyses for the public, and solid streamlining efforts which we should all support. FDA has in the past used EISs for sound decision-making. However, on the question of whether there is sound footing to declare a categorical exclusion for rulemaking for classification of risks, I do not see the basis. I would recommend to FDA to prepare a Programmatic EA on the rule and allow the scientific community and the public to offer their advice and counsel before asking the decision-maker to decide in the absence of any environmental impact analysis.

Thank you and I would be pleased to answer any questions.

Mr. KUCINICH. Thank you very much, Mr. Clark.
Mr. Bender, you may proceed.

STATEMENT OF MICHAEL T. BENDER

Mr. BENDER. Thank you, Mr. Chair and members of the subcommittee.

I am here today to testify on the environmental risk of mercury dental fillings. My name is Michael Bender, and I am the Director of the Mercury Policy Project. The project was formed in 1998 to reduce mercury uses and releases and exposure to mercury.

Next slide, please.

My presentation today will highlight the following. One, in 1997, EPA reported to Congress to establish a "plausible link between human-polluting activities and mercury levels in the environment. Dental mercury releases increased the load of mercury to the environment and also human exposures to methylmercury through the fish that people eat."

Two, while most other sectors have eliminated or drastically reduced their use of mercury, dental mercury use and release continues relatively unabated.

Three, the transformation of dental mercury to methylmercury in wastewater, surface water and soils is supported by a substantial body of research.

Four, while the ADA and its members appear to favor a voluntary approach, the record clearly shows that control requirements are necessary to reduce mercury pollution and are most cost-effective in doing so.

Finally, my presentation will clearly show that mercury air releases from dental uses may be more than five times recent EPA estimates.

Next slide, please.

As show in the EPA diagram from 2004, dental offices are the third largest user of mercury.

Next slide.

Over half of all mercury—and we have heard this repeatedly today—currently in use amounting to over 1,000 tons is in Americans' mouths according to the second EPA diagram from 2004.

Next slide.

Dental amalgam is by far the largest source of mercury to municipal wastewater treat plants in the United States, and numerous studies have demonstrated this. Dental mercury contributes more than three times the mercury than the next largest source. According to even the American Dental Association, dental mercury contributes 50 percent of the load to municipal wastewater streams.

Next slide, please.

Mercury emissions from cremations have nearly doubled in the past decade and are now over three tons per year and growing. In the next 15 years, emissions from crematoria are expected to rise still further.

There are two simultaneous trends contributing to this. First, the rise in the average number of fillings per person cremated, and this is because more recent dental healthcare has resulted in the retention of more teeth and more fillings as people age. Second, there

is a dramatic rise in the number of cremations due to the rising cost of burials.

Next slide.

Nationwide, about 20 percent of sewage sludge is incinerated in the United States according to a recent journal article by the EPA Region 5 official. Based on the extrapolation of the NSCAUM or Northeast States for Coordinated Air Use Management and States estimates, dental mercury emissions from sludge incineration are estimated about two tons per year nationwide.

Next slide.

It is estimated that municipal sewage sludge may release 15 to 18 pounds of mercury per day into the atmosphere, and nearly 1 ton of mercury is estimated to be released each year from land application of sludge.

Next slide, please.

A recent study of mercury discharges from dental offices indicate that they release about one ton of mercury per year to the air.

Next slide.

In King County, Washington, the resistance of the dental community to installing pollution control equipment contributed to the length of time and the changing strategies employed by the county. As you can see from this slide, starting around 2000, there were a number of educational outreach, so-called voluntary, initiatives that resulted in a very minimum requirement until 2003, when a law or a regulation went in place, mandating best management practices and installation of amalgam separators. This resulted in 97 percent compliance.

I might add that we are not talking about thousands and thousands of dollars. We are talking about maybe an average of $100 a month to prevent a dramatic amount of mercury releases to the environment.

Next slide, please.

Correspondingly, these regulations resulted in significant reductions in mercury concentrations in the sludge, and we have seen this in Toronto. We have seen this, and Mark Smith will be talking about the Massachusetts Water Resources Authority. Wherever amalgam separators and best management practices are put in place, there are dramatic reductions in pollution.

Next slide, please.

Based on the recognized need for mandating pollution control requirements at dental clinics, these nine States have either passed laws or regulations requiring these amalgam separators and pollution control equipment. I might add that there are approximately another 10 States that have proposed similar legislation.

Mr. Chair and members of the committee, that is how we have been able to effectively promote de facto national legislation over the last 5 or 6 years.

We have reduced and eliminated mercury uses in the large product categories ranging from mercury switches, relays and measuring devices to the point where 30 to 40 percent of the population lives in States now that no longer allow sales of mercury-containing products. We are now altering our focus a bit and expanding it to this collection arena because of the great quantities involved.

Finally, next slide, please.

This slide is hard to read, but it is really this table, in our extensive written testimony, summarizes and challenges these estimates by EPA that dental mercury uses only result in 1.5 tons of mercury air releases each year.

As discussed during this presentation, crematoria are estimated to release over three tons of mercury emissions in the air each year. Mercury emissions from sludge incineration are estimated to add another two tons per year, and another ton per year is added through direct releases from dental offices and those are air releases.

Combined with other smaller, yet significant releases, we estimate that the dental mercury releases to the air are more than 5 times as much as the EPA estimate of 1.5 tons per year. Our estimates range from a low of 7 to a high of 9.4 tons of mercury released to the air each year from dental uses.

Finally, last slide.

I don't know if you can read the cartoon, but the woman is saying, with all this mercury in my mouth, I must be an environmental problem.

I think it really goes to the heart of this issue, that we really, even with all this pollution control equipment, we really can't stop this pollution source until we stop using mercury dental fillings.

Thank you and I would be willing to answer any questions.

[The prepared statement of Mr. Bender follows:]

Testimony
By
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"Environmental Risks of Mercury Dental Fillings"

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Domestic Policy Subcommittee
Oversight and Government Reform Committee
2154 Rayburn HOB
2:00 P.M.
Wednesday, November 14, 2007

1 Background

1.1 Domestic Policy Subcommittee request

This paper has been prepared at the request of the Domestic Policy Subcommittee, Oversight and Government Reform Committee, in support of the testimony of Mr. Michael Bender, Director of the Mercury Policy Project, at a hearing on November 14, 2007, 2:00 PM in Room 2154 Rayburn House Office Building.

The hearing concerned the environmental risks due to the release of mercury from dental uses.

Mr. Bender was asked to testify on the significance of dental mercury amalgam as a precursor to methylmercury releases into the environment across the United States. Specifically, he was asked to discuss exposure via the following pathways:

1) incineration of municipal sewage sludge,
2) cremation,
3) all emissions from dental offices (including air releases, accidental spills, contaminated plumbing fixtures and buildings, wastewater discharges and disposal into municipal solid waste and hazardous waste facilities), and
4) direct emissions from sludge application to land and as a soil amendment.

Finally, Mr. Bender was also asked to discuss how dental mercury amalgam may be a factor in the US Environmental Protection Agency's (EPA's) finding that "most [publicly owned treatment works] POTWs will not meet [the mercury] criterion [adopted by Great Lakes states]" and what the consequences may be for mercury contamination of the Great Lakes and the development of total maximum daily loads (TMDL) for the Great Lakes and other bodies of water throughout the United States.

1.2 Mercury in the environment

Mercury is a naturally occurring metal and a persistent, bioaccumulative toxin. It enters the environment via natural events, such as volcano eruptions, as well as through human activities. Methylmercury is more mobile and even more toxic than elemental mercury, and it easily finds its way into the food chain, contaminating fish. Methylmercury is synthesized by microbial action on mercury-polluted sediments and soils, and among other sources, is generated as a by-product of the combustion of mercury-containing materials. The release of mercury by combustion occurs in a variety of settings, including coal-fired power plants, municipal incinerators, sludge incinerators, hazardous waste incinerators, industrial boilers, and other industrial processes.

1.3 Mercury in dental amalgam

As shown in the EPA figure below, dental offices are the third largest user of mercury, after wiring device/switch makers and manufacturers of measuring and control instruments.[1]

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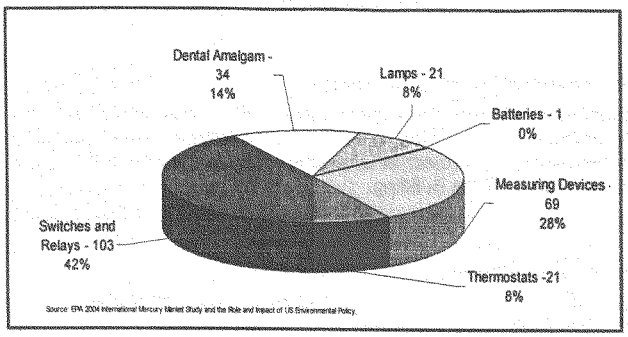
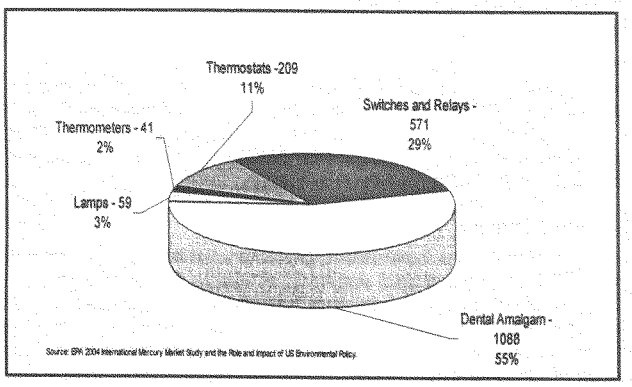
[1] EPA (2006) – Roadmap for Mercury p. 36 (online at http://www.epa.gov/mercury/roadmap/htm).

Figure 1 – Mercury consumption in the USA



Furthermore, as seen in the following EPA figure, mercury contained in the existing dental fillings of Americans comprises over half of all mercury "circulating in the economy" today, amounting to over 1000 tons.[2]

Figure 2 - Mercury circulating in the U.S. economy



Dental amalgam is a large source of mercury waste in the environment. According EPA, "Mercury discharges [in wastewater] from dental offices far exceeded all other commercial and residential sources."[3] EPA cited an estimate that 36 percent of mercury reaching

[2] EPA 2004 International Mercury Market Study, as cited in Mercury Policy Project, "Current Status of US Dental Mercury Reduction Initiatives" (Oct. 12, 2007)
[3] Roadmap *op. cit.*, p. 8

municipal sewage treatment plants is released by dental offices. Other investigations have put the figure closer to 50 percent (NEG-ECP 2007).

Mercury from dental amalgams is a significant source of airborne emissions, although data concerning precise quantities emitted are unavailable. EPA has estimated airborne mercury attributable to wastewater sludge incineration to be 0.6 ton per year, but the following discussion demonstrates that this figure is seriously underestimated. EPA emissions estimates do not include total mercury emitted during the cremation of human remains. However, cremation is also a significant source of emissions, due to the large amount of mercury in existing dental fillings. The largest source of airborne mercury is coal-burning power plants, which emit an estimated 48 tons of mercury per year.

1.4 Key issues re health risk via fish consumption

The effects of mercury exposure on human health and wildlife are driving a number of efforts to significantly reduce the level of this toxic, persistent, and bioaccumulative metal in the environment. Exposure to mercury, a neurotoxin, affects the brain and nervous system. The consumption of fish from waters contaminated with mercury offers the greatest risk of exposure to this pollutant (NACWA 2002).

Due in part to the EPA's human health criterion for methylmercury in fish tissue and the increasing number of fish advisories based on mercury, new mercury effluent limits are being imposed throughout the United States (Special Initiatives - NACWA Mercury Initiatives, http://www.nacwa.org/index.php?option=com_content&task=view&id=64&Itemid=72). In addition, increased monitoring of mercury in the water column and fish tissue, and the application of more stringent standards[4] has led to increasingly stringent mercury effluent limits in National Pollutant Discharge Elimination System (NPDES) permits, as authorized by the Clean Water Act.

As of 2001, approximately 6% of the major publicly owned treatment works (POTWs) in the United States had NPDES permits with mercury effluent limits and approximately 10% of the major POTWs had monitoring requirements (Morris, 2001). Of the agencies with limits, several (particularly in the Great Lakes region) have limits based on the Great Lakes Initiative (GLI) Wildlife Criteria (i.e., 1.3 ng/L), and have had difficulty meeting these limits (EPA 2001).

As more monitoring for mercury is conducted, the number of agencies with effluent limits imposed is likely to significantly increase. The National Association of Clean Water Agencies (NACWA) attributes this development, in part, to new analytical methods and sampling techniques that enable clean water facilities to measure levels of mercury that were previously undetectable (Special Initiatives - NACWA Mercury Initiatives, http://www.nacwa.org/index.php?option=com_content&task=view&id=64&Itemid=72).

Among other issues, the following analysis describes the links between environmental releases of dental mercury and methylmercury in fish.

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[4] Ranging from the California Toxics Rule (CTR) Saltwater Criterion (25 ng/L) to the proposed Maine Criteria (0.2 ng/L)

2 Mercury use in dental applications

Recent estimates of mercury use by the dental profession, entirely for amalgam fillings, range from 30 to 44 tons.[5] Within that range, the EPA figure of 34 tons is believed to be a reliable estimate.

The American Dental Association (ADA) has estimated that US dentists place some 100 million fillings per year. While less than 50% of these are now amalgam fillings (approx. 580mg Hg per filling), the majority of old fillings removed are amalgam, leading to the release of large amounts of amalgam waste.

Following the methodology used by Cain et al. (2007), of the 34 tons of "new" mercury consumed in a typical year by dental clinics, some amalgam is carved away or otherwise lost during a typical clinical procedure – averaging some 20-25% of the total amalgam. However, most of the mercury lost to discharge is not the amount of new amalgam lost due to "carving" but the amount of old amalgam that is removed to make room for the new filling. Considering that about 70% of fillings are replacements, that not all fillings are amalgams, etc., some 31 tons of mercury are calculated to go to emissions and waste.

The quantities of mercury consumed and mercury wastes generated by the dental profession are directly related to the average life of a filling. In a US Geological Survey report published in 2000, it was noted that the average life of a mercury amalgam filling is reported to be from 5 to 8 years, while a 1995 article in a Swiss dental medical journal reported the average life to be 10 years. Other estimates have ranged as high as 10-20 years (Reindl 2007).

3 Mercury wastes from dental applications

It should be noted that this section of the report discusses the types of mercury wastes and releases from dental practices, while Section 4 deals more specifically with the quantities of mercury involved.

3.1 Pathways to the environment

The primary sources of mercury waste that originate in the dental clinic include amalgam waste generated prior to the placement of a filling; the excess material carved from new amalgam fillings; the removal of old amalgam fillings; the removal of teeth containing amalgam; other mercury going to solid waste or wastewater; mercury emissions directly to the air; the traps, filters and other devices in dental clinics to remove mercury from the wastewater – and the "downstream" flows of mercury from there.

Most dental mercury waste results from the removal of previous fillings from patients' teeth. Together with waste from new fillings, removed teeth, etc., these dental wastes typically follow several main paths. They may be captured for subsequent recycling or disposal, they may be washed down drains that lead to the general municipal wastewater system, they may be placed in special containers as medical waste, or they may be simply discarded as municipal waste.

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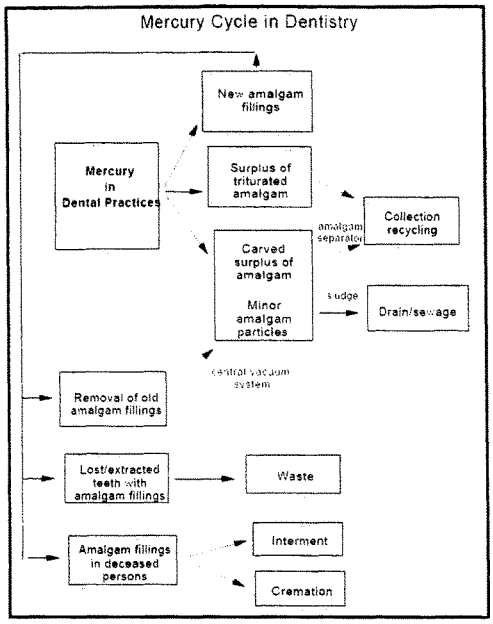
[5] Environ estimated 32 tons for 2004; B. Lawrence, a recycler, estimated 44 tons for 2001; the US EPA estimated 34 tons for 2004; 30.4 tons were reported by manufacturers to the IMERC database for 2004;etc.

Figure 3 is a simplified illustration of the general flow of mercury through the dental clinic and "downstream." Among other details, it does not show, for example, that mercury may be released to the air both within the clinic and from the clinic wastewater system, nor does it make clear that mercury may be released by certain dental techniques (e.g. cleaning or polishing mercury amalgams) even when fillings are not placed or removed. These releases are, however, taken into account in the subsequent analysis.

Figure 3 - General flow of mercury through the dental clinic



Source: Horsted-Bindslev *et al.* 1991 (as cited by Wisconsin Mercury Sourcebook 1999)

Next to each dental chair most dental facilities have a basic chairside filter (or trap) in the wastewater system to capture the larger amalgam particles, and some have secondary vacuum filters just upstream of the vacuum pump. In addition, separator technologies are available that can remove over 95% of the mercury from wastewater.

Dental mercury may enter the environment from a number of paths. For example, if a mercury-containing item is discarded as municipal waste, some mercury may eventually be released into the atmosphere from landfill emissions, or the mercury may vaporize if the waste is incinerated. If mercury passes any filtering devices and enters the wastewater system, most mercury will typically adhere to the wastewater sludge, where it has the potential to volatilize when the sludge is disposed of. Mercury is able to evaporate easily, especially as the temperature increases, after which some is deposited locally and the rest travels through the atmosphere in a vaporized state (Wisconsin Mercury Sourcebook 1999).

Once mercury is deposited into lakes and streams, in the open ocean, or even on land, bacteria convert some of the mercury into an organic form called *methylmercury*. This is the form of mercury that humans and other mammals ingest primarily through eating fish, although some communities suffer exposure through the consumption of marine mammals as well. Methylmercury is particularly dangerous because it *bioaccumulates* in the food chain. Bioaccumulation occurs when the methylmercury in fish tissue concentrates as larger fish eat smaller fish (Wisconsin Mercury Sourcebook 1999).

3.2 Wastewater releases

3.3 Municipal wastewater system

It is commonly accepted that most municipal wastewater systems encounter significant levels of mercury, and it has been determined that typically close to 50% of that mercury originates from dental practices (AMSA 2002a). Some observations are summarized in the table below.

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

The quantity of mercury going to wastewater systems from dental clinics is difficult to quantify, but it should be noted that most municipal wastewater treatment systems are not designed to treat or remove mercury from the wastewater stream. In fact, it is economically far preferable to keep mercury from reaching the wastewater plant.

Most of the mercury entering the wastewater stream will concentrate in the sewage sludge or "biosolids," and the rest will be discharged to downstream surface waters along with the treated effluent. If a wastewater treatment plant incinerates its sludge, and operates with a wet scrubber system, mercury from amalgam may be carried back to the headworks of the treatment plant. Therefore, mercury that came into the plant as an amalgam waste may later be discharged to a receiving water as another form of mercury (no longer amalgam).

It should be underlined that various conditions during the wastewater treatment process may be favorable to the methylation of mercury. Furthermore, since the majority of sludge waste is disposed of by spreading it on agricultural or other land, or by incineration, there is the further likelihood for the mercury to follow these pathways especially to methylation, surface water runoff and to the atmosphere (and later deposition, additional methylation and uptake in the food chain).

3.3.1 Dental clinic and piping system

Over many years the piping systems in dental clinics have accumulated mercury that settles to low parts of the system, sumps, etc., or attaches itself to the inside of metallic pipes. The slow dissolution and re-release of this mercury is often sufficient, even after dental clinic emissions have been greatly reduced, to exceed wastewater discharge standards, and then serves as a long-term source of mercury to a wastewater treatment facility. For example, large amounts of mercury were recovered (average 1.2 kg per clinic) during the remediation of 37 abandoned dental clinics in Stockholm in 1993–2003 (Engman, 2004). Similar accumulations were observed during more recent work in a Swedish dental clinic (Hylander *et al.* 2006a). These studies indicate that serious maintenance work on a dental clinic wastewater system should ensure that all pipes and plumbing fixtures are cleaned and/or replaced since they can constitute an ongoing source of mercury releases.

3.3.2 Septic tanks

In areas lacking a public wastewater system, dental practices are often connected to septic systems. As in parts of wastewater treatment systems, certain conditions may exist in a septic system that promote the methylation of mercury, which may contaminate local soils and groundwater. Likewise, sewage sludges may be periodically removed and dispersed over agricultural and other soils, or contribute to the mercury loading at wastewater treatment facilities.

3.4 Solid waste generated

Mercury-containing solids and sludges removed from traps and filters are increasingly being recycled or disposed of as hazardous wastes.

3.4.1 Municipal landfill and incineration

Despite regulations regarding the characterization and disposal of mercury bearing wastes, many solid dental wastes still follow the low-cost route of disposal as municipal solid waste and are subsequently disposed of in landfills or by municipal incineration. Depending on the characteristics of the landfill, dental amalgam may decompose over time and the mercury may enter the leachate (which may itself be disposed of in a manner that permits the mercury to be released), groundwater, soils, or volatilize into the atmosphere. Studies have documented methylmercury in gases emitted from landfills (Lindberg *et al.* 2001). Municipal incinerator operators will not accept mercury waste if they are able to identify it in advance, but it often enters the solid waste stream unmarked and undetectable.

3.4.2 Hazardous waste landfill and incineration

The regulations for hazardous waste treatment are normally stricter and more closely monitored than those for municipal waste. Therefore, both hazardous waste landfills and incinerators are better equipped to deal with mercury wastes, and to minimize releases. On the other hand, because this disposal path is typically more expensive than recycling, dental professionals may be reticent to send dental wastes to hazardous waste disposal.

3.5 Air emissions at the dental clinic

Mercury emissions to the air from dental clinics may occur during handling and placing and removal of mercury amalgams, or they may occur as releases from the wastewater system at the clinic.

3.5.1 Air emissions during dental work

Dental personnel may be exposed to the following sources of mercury vapors: "accidental mercury spills; malfunctioning amalgamators, leaky amalgam capsules or malfunctioning bulk mercury dispensers...; trituration, placement and condensation of amalgam; polishing or removal of amalgam; vaporization of mercury from contaminated instruments; and open storage of amalgam scrap or used capsules" (JADA 2003).

3.5.2 Air emissions from the dental clinic wastewater system

As already mentioned, dental clinical procedures generate mercury wastes, slurry and fine particulate and dissolved matter from mercury amalgam filling materials. Some of these wastes are discharged into the municipal wastewater system via the clinic vacuum pump or a similar system. This system may also discharge large volumes of air, including mercury vapor, either into the atmosphere outside the dental clinic or into the wastewater system, depending on the type of equipment used (Rubin and Yu 1996).

3.6 Infectious waste treatment

A survey in 2000 found that 25-30% of dentists disposed of some of their dental amalgam waste as infectious waste due to the potential presence of pathogens (KCDNR 2000). Typically infectious waste is disposed of by "autoclaving" and landfill, which may as well result in some mercury vapor releases, discharge of effluents to the wastewater system, etc. (HCWH 2002).

3.7 Recycling

Recycling of dental amalgam wastes is increasing, although less than 5% of the nation's dentists use amalgam separators today. This is a logical way to deal with large amounts of amalgam waste with a high mercury content, and the high-temperature retorting process employed by recyclers is also able to address concerns about pathogens in the amalgam wastes.

The recycling process also generates some air emissions of mercury, but these are generally low. Some stakeholders are concerned about the fate of the mercury after recycling, noting that it may end up being sold for use by artisanal gold miners, or the manufacture of products or other applications that are associated with significant and/or diffuse mercury releases.

3.8 Mercury storage and final disposal

Until fairly recently, most dentists had stocks of mercury in their clinics which they used, in the past, to make dental amalgams by hand. Given the relatively few state clean-out programs conducted nationwide, it may be assumed that there remain some quantities of mercury in storage in dental clinics. These stocks of mercury are at risk of accidents, improper disposal or other releases due to neglect.

3.9 Burial

Amalgam fillings may continue to release mercury after death, and most often end up in a cemetery, from where the mercury will eventually enter the soil and/or groundwater. Furthermore, as burial space is increasingly scarce and expensive, cremation is becoming more common.

3.10 Cremation

As mentioned above, cremation is a more and more common practice in the US, as the cost of burials increases over time. Cremation is typically carried out at a high temperature that vaporizes virtually all of the mercury in any dental amalgams, although it has proven quite difficult to balance the amount of mercury present in dental amalgams with measurements of mercury emissions in the crematorium flue gases. Depending on the crematorium design, it appears that some mercury may adhere for a time to internal parts of the flue gas system. Often crematoria are located within cities and close to residential areas, and stacks tend to be relatively low (UNEP 2003).

4 Air emissions related to the use of dental mercury

It should be noted that this section of the report focuses largely on the quantities of mercury wastes and releases from dental practices, while Section 3 above deals more specifically with the types of mercury wastes and releases generated.

4.1 Estimating waste mercury quantities and pathways

It is frequently assumed by those developing estimates of mercury flows that all processes operate in a similar manner to certain ones that may have been studied or measured. However, it is especially evident in dealing with mercury flows, which traverse virtually the gamut of water, land, waste, and air emission and disposal issues, that this is not the case. For example, some mercury waste is still incinerated in burn barrels or discarded in unauthorized landfills, septic systems operate where wastewater systems are unavailable, wastewater "exceptions" and overflows are common, and dental clinics face a range of challenges in the proper installation and maintenance of separators. In these and related instances, substantial dental mercury wastes continue to be discarded to the municipal waste system, etc.

As in the chlor-alkali industry, another large mercury user, even if only 10-20% of the facilities operate in a substandard manner, it is enough to greatly influence the quantities of mercury otherwise assumed to be following various pathways. This must be kept firmly in mind when modeling mercury flows.

4.2 Municipal wastewater and sewage sludge

4.2.1 Quantities generated, and dental contribution to POTW Hg burden

US EPA has estimated the total quantity of mercury in sewage sludge at about 15 tons per year,[6] and the Association of Metropolitan Sewerage Associations (AMSA) has estimated the dental contribution to that at just under 7 tons of mercury (AMSA 2002b). Scarmoutzos and Boyd (2004) have estimated the dental mercury contribution to sewage sludge at 6-12 tons. According to a Jan 2006 white paper by the National Assoc. of Clean Water Agencies (formerly AMSA), "the ADA [American Dental Association] estimates that 50% of the mercury entering POTWs is from dental offices."[7] NESCAUM (2005) concurs with this observation.

Miniscule but constant releases from mercury amalgams are ingested and then excreted by the human body, entering the wastewater system and the environment, partially methylating and accumulating up the food chain to fish, and potentially returning to humans in the form of methylmercury in the diet. Research has shown that the 74% (or approximately 6.3 million persons at the time of the study) of the population in Sweden with amalgam fillings continuously released over 200 lbs Hg/year to the wastewater system simply by chewing, swallowing and excreting (Skare and Engqvist, 1994; Kemi, 2004). Based on this research, the US population could well emit 1.5-2 tons Hg/year to wastewater from this source, which would be included in the sewage sludge calculation above.

For the purpose of establishing a rough mass balance for dental mercury, it is estimated that 40-50% of the mercury passing through chairside traps/filters is captured, although Christensen *et al.* (2004) have suggested the percentage is lower. It is further assumed that separators capture perhaps 70-80% of the mercury passing through. Based on four US studies cited by Bender (2002), it is estimated that some 40-50% of the mercury not captured by separators or disposed of as solid waste goes into the municipal wastewater system. Based on the above, and referring to the methodology of Cain et al., the quantity of dental mercury entering the municipal wastewater system, including 1-1.5 tons from human wastes, is estimated at over 9 tons, of which just over 90% may be retained in wastewater treatment sewage sludge under normal operating conditions.

The total dental mercury going to wastewater treatment plants may therefore be estimated at about 8.5 tons.

4.2.2 Sewage sludge disposal

According to Cain et al. (2007), about 20% of sewage sludge is incinerated, some 60% is spread on agricultural and other land, about 15% is landfilled, and the rest is disposed of in other ways.[8] Each of these disposal pathways leads to some air emissions, the most important of which are sludge incineration and volatilization of mercury from land applications.

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[6] Statement of Geoffrey Grubbs, Director, Office of Science and Technology, U.S. Environmental Protection Agency, before the Subcommittee on Wellness and Human Rights of the Committee on Government Reform, United States House of Representatives, October 8, 2003.

[7] See http://www.nacwa.org/images/stories/public/2006-01dmercwp.pdf.

[8] The mercury content in sewage sludge, while quite variable, is typically considered tobe in the range of 1-3 mgHg/kg dry weight (AMSA 2002b).

With regard to the quantities of sewage sludge that are incinerated, Cain et al. (2007) estimate that some 60% of the mercury goes to the atmosphere, which would imply close to 1.5 tons of emissions related to dental mercury. However, the figure could be somewhat higher. While the performance of different facilities may be expected to vary widely, data from testing of coal-fired utility emission controls suggests that the scrubber controls typically found on SSIs may capture no more than 20-30% of the mercury. The rest of the mercury ends up in incinerator residues and is mostly spread on the land.

Therefore, there is no doubt that the EPA estimate of 0.6 ton mercury emissions from SSI significantly undercounts sludge-related mercury pollution.[9] A report from the Northeast States for Coordinated Air Use Management (NESCAUM 2005) has calculated, based on measurements, that sewage sludge incinerators (SSIs) in the Northeast US release 543kg, or about 1200 pounds, of mercury per year, and they estimate that half of that quantity is from dental mercury. The NESCAUM region has only 8% of the US population, but a higher per capita concentration of SSIs than the rest of the US, implying that a higher percentage of sewage sludge is incinerated in that region than the US average. After accounting for these differences, if the NESCAUM observations are extrapolated to the rest of the US, they imply SSI air emissions of "dental" mercury of about 2 tons nationwide.

Furthermore, since nationwide about 20% of sewage sludge is incinerated on average, and 60% of the mercury content is assumed to be emitted to the atmosphere (Cain et al. 2007), this implies total mercury in sewage sludge of some 17-18 tons, with a dental mercury content in the order of 8.5 tons.

Carpi et al. (1997) have calculated that the 800,000 acres of land amended with municipal sewage sludge may release 15-18 pounds of mercury per day into the atmosphere, especially during the warm summer months. These releases, as well as smaller releases from sludge disposed to landfills, etc., amount to some 0.8 tons per year released to the atmosphere just from the application of sewage sludge to land, assuming about 50% of the contribution is due to dental mercury.

4.2.3 Amalgam separators

Through the use of amalgam removal systems such as chairside traps/meshes, vacuum filters and separators in the wastewater stream, dental clinics may theoretically remove 95-99% of the mercury. In practice, however, waste mercury removal devices may be missing or improperly maintained. Moreover, an industry source has reported that at present probably less than 5% of dental clinics are equipped with amalgam separators. Therefore, the average level of amalgam removal from the dental clinic wastewater system is much lower than the theoretical level cited.

Figure 4 below shows the two main types of wastewater flow systems installed in dental clinics. Without any added separator, the "dry" vacuum pump system removes an estimated 30-40% of the mercury in the waste stream, whereas the "wet" vacuum pump system, incorporating an additional vacuum filter, may remove up to 50%. If a "separator"

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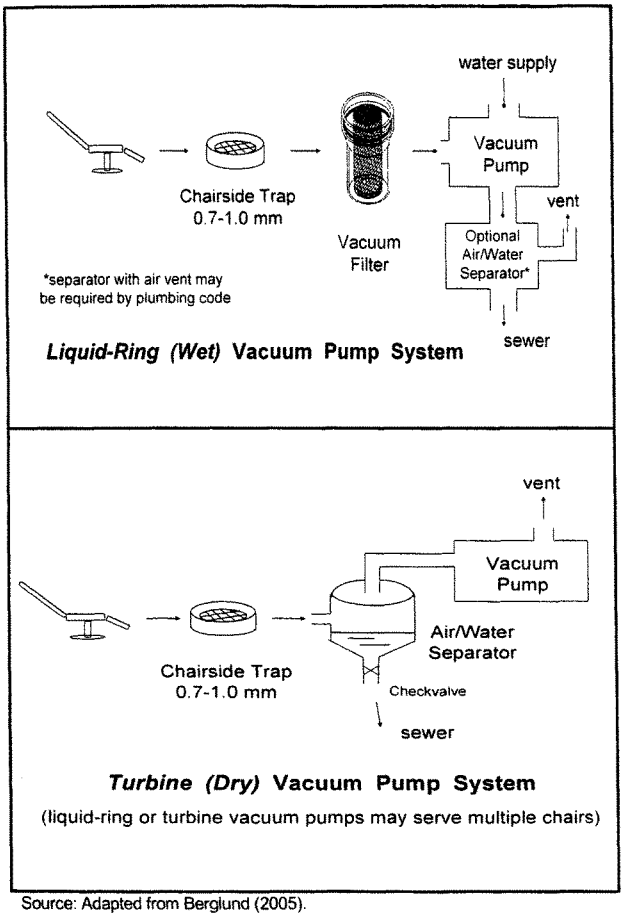
[9] EPA has admitted that its mercury emission data for sludge incineration is poor, a deficiency it attributed to both the small number of facilities tested and the fact that these facilities were not a random sample of the industry. Emission Factor Documentation for AP-42 Section 2.2, Sewage Sludge Incineration, Office of Air Quality Planning and Standards, EPA, pp. 3-5 and 4-98 (July 1993) (online at http://www.epa.gov/ttn/chief/ap42/ch02/bgdocs/b02s02.pdf).

is installed, efficiencies of 80-90% total mercury removal may realistically be achieved if the system is properly maintained. However, a 1998 Swedish study found that one in four separators installed in dental clinics in Stockholm did not operate correctly (due to incorrect installation, blockages or inadequate maintenance), leading to excessive discharges, and more recent investigations have discovered that problems persist (Hylander *et al.* 2006a, 2006b and personal communication).

Figure 4 - Typical dental clinic waste flow systems (without amalgam separator)



Source: Adapted from Berglund (2005).

It should also be noted that both of these systems must be vented to the air. Research carried out in the US (Rubin and Yu 1996) measured mercury releases to the air from the wastewater system at about 60 mg/day per dentist. The number of dentists range from 133-175 thousand (AMSA 2002b; Scarmoutzos and Boyd 2007), suggesting over 2 tons air emissions. The methodology used by Cain et al (2007) suggests total air releases directly from dental clinics at just under one ton.

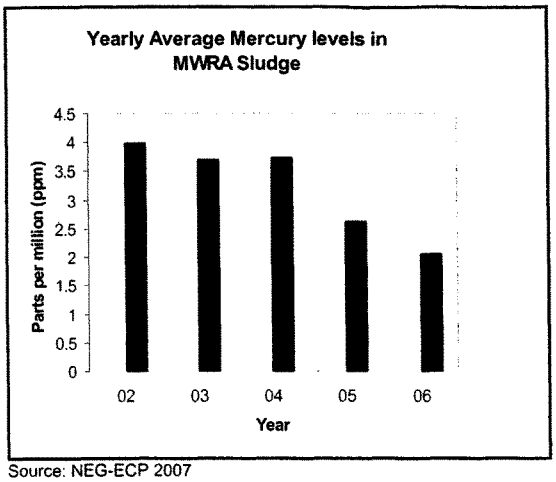
In the EU overall, legislation requiring "environmentally sound management of dental amalgam waste" is considered to imply that at least 95% of the mercury content of amalgam waste has to be removed from the waste stream (and managed as hazardous waste), effectively obliging dental clinics to install amalgam separators in order to comply with EU legislation. However, as already discussed above, there is evidence that the number of dental clinics in the EU with properly functioning separators remains well below 50% (Maxson 2007). Even in Denmark, a country where efforts to deal with the dental waste problem are quite advanced, and instructions were widely distributed to dental associations and clinics, a recent study estimated that 20% of dental clinics still lacked separators (Christensen et al. 2004).

Problems that have been mentioned with regard to amalgam separators include difficulty in getting information about the number of clinics that have actually installed separators; confusion among definitions of traps, filters, separators, etc., in assessing compliance; limited inspection of dental clinics to ascertain the level of compliance; the lack of procedures or penalties to deal with non-compliance; the theoretical efficiency of amalgam separation equipment vs. actual practice; the difference between installing separation equipment and operating it properly; the need for routine and competent maintenance in order for separation equipment to achieve a high level of efficiency, etc., not to mention the difference between rated mercury removal efficiency and actual efficiency; and last but not least, what to do with the amalgam wastes once they have been collected/separated.

Despite difficulties mentioned above, the use of amalgam separators is highly cost effective in preventing releases of mercury to the environment, particularly when compared to the cost to remove mercury at a wastewater treatment plant of approximately $21 million per pound, or $46,000 per gram (AMSA 2002b).

In Norway amalgam separators have been mandatory for dental clinics since 1995, greatly contributing to an enormous reduction in mercury discharged into municipal sewers – from 350 kg in 1995 to 60 kg in 2003.

Recent data from the Boston area Metropolitan Water Resources Authority (MWRA) (see figure below) showed a 48% reduction in mercury concentration in sludge as amalgam separator use increased from less than 20% to over 80%. Additional data is being collected and assessed to evaluate whether these reductions are typical across the region, and to estimate the overall regional reduction in mercury releases attributable to these programs (NEG-ECP 2007).



Source: NEG-ECP 2007

4.2.4 Voluntary vs. mandatory separators

The American Dental Association (ADA) now recommends that amalgam separators be installed in all dental offices, but they maintain that adequate levels of compliance can be achieved through a voluntary program. While there are multiple and complex factors that may influence the success, or lack thereof, of a voluntary program, there is a growing body of evidence that a mandatory approach, while administratively more demanding, is necessary to achieve a faster and more comprehensive result, and even more importantly, to create a level playing field that does not discriminate against the vast majority of dentists who wish to comply with the ADA recommendation to install separators.

King County in Seattle may be taken as an example. King County employed three distinct strategies to limit or control the amount of mercury discharged from dental offices over the 13-year time frame of this case study. The initial resistance of the ADA and dental community to installing separators contributed to the length of time and the changing strategies that had to be employed by the county. The King County Program 1995-2000 focused on an intensive outreach program for dentists including an annual poster, monthly ads in a local journal, a Voucher Incentive Program, EnviroStars, information dissemination, and trade shows/mercury roundups.

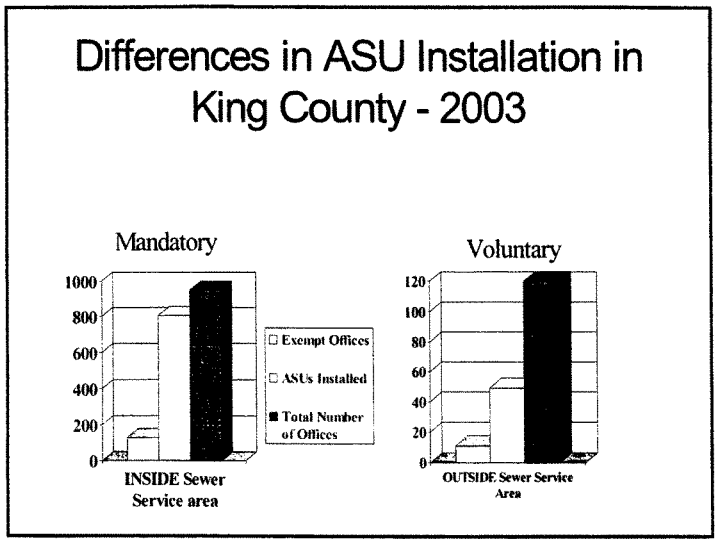
Even after these efforts a 2000 study in King County found that more than three-quarters of dental offices did not recycle or sequester mercury-bearing waste captured in chairside traps and vacuum pump filters. Rather, they put it in the waste bin, included it with medical waste, stored it onsite for eventual disposal or flushed it down the drain (Savina 2003).

As a result, the following practices were made mandatory by July 1, 2003:

- Use best management practices (BMPs) for amalgam waste;

- Demonstrate compliance with K.C. Local Limits (0.2 mg/l) for mercury discharge to sewer (0.1 mg/l for > 5000 gpd, and 0.2 mg/l for < 5000 gpd). These limits are achievable for dental offices with adequate amalgam separators.

The following figure demonstrates the difference in compliance by 2003 in King County between an area with mandatory requirements and an area without, despite the fact that the county's outreach program was targeted at the entire county. By 2005 there was a 97% compliance rate in the King County sewer service area – where separators are mandatory.



For these reasons, a growing number of states have opted for a mandatory requirement for amalgam separators in dental offices, either through law or regulation, as presented below.

- **Connecticut (2003)**
- **Maine (2005)**
- **Massachusetts (2006)**
- **New Hampshire (2006)**
- **New Jersey (2009)**
- **New York (2008)**
- **Rhode Island (2007)**
- **Oregon (2011)**
- **Vermont (2008)**

4.2.5 Dental mercury in municipal solid waste

Whether in dental offices or water treatment plants, captured mercury is often not sequestered from the environment. A 2000 study in King County, Washington (USA), found that more than three-quarters of dental offices did not recycle or sequester mercury-bearing waste captured in chairside traps and vacuum pump filters. Rather, they put it in the waste bin, included it with medical waste, stored it onsite for eventual disposal or flushed it down the drain (Savina 2003).

Based on the Cain et al. (2007) methodology, 9.5-10 tons of dental mercury likely end up in the municipal waste stream each year, of which about 20% is assumed to be incinerated, with most of the remainder going to landfill.

4.3 Cremation

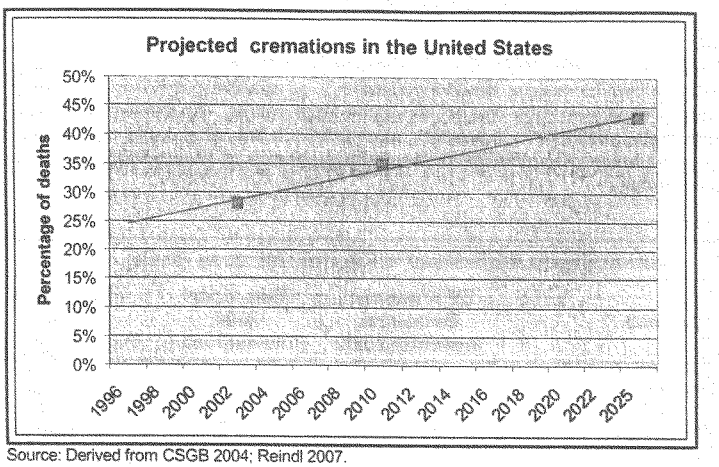
According to the Cremation Association of America, there are about 1,900 crematoria in the US. Nationally, over 30% of Americans are now cremated, a figure that is anticipated to rise to 43% by 2025. The 1998 Northeastern States Mercury Study estimated that each person cremated had an average of 2.9 grams of mercury in fillings, and this figure is still widely considered to be in the right range. (Reindl 2007)

Cain et al. (2007) have estimated that about 3.3 tons of mercury were emitted by crematoria in 2005. In the model used, 25% of these emissions were assumed attached to particulates, which would settle to the ground locally and be classified as land deposition, and 75% assumed to be elemental mercury emissions to the atmosphere. Based on a literature review including ground deposition studies in New Zealand and Norway (Reindl 2007), it appears justifiable to allocate up to 90% of the mercury entering crematoria as emissions to the atmosphere, with some of the balance retained, at least temporarily, in combustion equipment and the stack.

In the next 15 years, emissions from crematoria are expected to rise considerably. There are two simultaneous trends contributing to this: a rise in the average number of fillings per person cremated (better dental health care has resulted in the retention of more teeth, and more fillings, as people age), and a rise in the number of cremations. This will only eventually be counter-balanced by the gradually increasing replacement of amalgam fillings with mercury-free alternatives.

Figure 5 provides an indication of US cremation trends and projections to 2025.

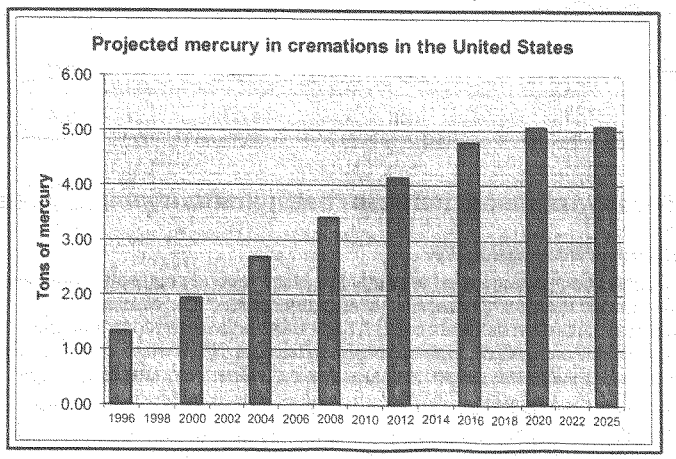
Figure 5 – Projected cremations in the USA (1996-2025)



Source: Derived from CSGB 2004; Reindl 2007.

Figure 6 demonstrates how the increasing number of cremations combines with the increased retention of teeth per person cremated to magnify the quantities of mercury potentially released during cremations.

Figure 6 – Rapidly increasing quantities of dental mercury to be dealt with by crematoria



Source: P. Maxson projections based on data in Reindl (2007)

4.4 Summary of dental mercury atmospheric emissions

The 2002 EPA National Emissions Inventory (version 3) gave atmospheric emissions related to dental mercury as in the first column of the table below. The EPA numbers are compared with those presented in this report, summarized in the second and third columns, which are given as ranges of emissions for the main categories of emission related to dental uses of mercury.

Atmospheric emissions of dental mercury (tons)			
Pathway	**EPA National Emissions Inventory 2002**	**This report 2005 (low estimate)**	**This report 2005 (high estimate)**
Human cremation	0.3	3.0	3.5
Dental clinics	0.6	0.9	1.3
Dental mercury sewage sludge incineration	0.6	1.5	2.0
Dental mercury sludge spread on land and landfilled	n.a.	0.8	1.2
Dental mercury MSW incineration and landfill	n.a.	0.2	0.5
Dental mercury infectious and hazardous waste	n.a.	0.5	0.7
Human respiration	n.a.	0.2	0.2
Total	**1.5**	**7.1**	**9.4**

5 Dental mercury releases increase methylmercury exposures

5.1 Mechanisms of bioavailability

There has been some debate concerning the extent to which mercury released from dental uses may be transformed into methylmercury – thereby becoming "bioavailable" and susceptible to eventual uptake in the food chain. It has been shown above that dental mercury contributes significantly both to the atmospheric burden, from where it eventually deposits on the soil and in waterways, and it is also released directly to waterways.

The main environmental and health impacts of dental mercury releases are due to the bacteriological transformation of inorganic mercury to the highly toxic compound methylmercury, as described in the box below. It has been well established that as dental

mercury releases increase the load of mercury to both the local and global environment, they also increase human exposures to methylmercury through the fish that people eat (US EPA, 1997).

Environmental conversion of dental amalgam to methylmercury in water

Dental amalgam (or silver filling) is a metallic alloy comprised primarily of mercury (42-58%) and silver (20-40%) with minor components of tin (4-17%) and copper (1-16%). Depending upon the particular brand of dental amalgam, it may also contain small concentrations (<2%) of zinc, indium, palladium and platinum.

The formation of methylmercury from dental amalgam requires two steps:

Step 1: Conversion of metallic mercury (the form of mercury in dental amalgam) to inorganic mercury.

Step 2: Conversion of inorganic mercury to methylmercury. Once mercury is in the methyl form, it bioaccumulates up the food chain.

Step 1

The conversion of metallic mercury to inorganic mercury is not a spontaneous chemical reaction and it requires oxidizing agents, in particularly oxidizing agents of sufficient strength to bring about the chemical reaction. Oxidizing agents of sufficient strength include bleach, chlorine, hydrogen peroxide, brominating and chlorinating agents (the type of chemicals used in swimming pools and spas), dissolved oxygen in combination with certain types of dissolved metal ions (e.g., iron or ferric ions, or "Fenton" type oxidants).

It is expected that all these oxidizing agents are readily present in wastewater discharge lines, sewer lines and in sewer waters. Unlike the metallic mercury in dental amalgam, inorganic mercury is water-soluble and, once formed, becomes readily transportable in the environment.

In addition, dental amalgam in contact with dissimilar metals may generate galvanic corrosion (the so-called "battery effect"). Galvanic corrosion would release mercury from the amalgam thereby making it available for conversion into methylmercury.

Outside the sewer lines, the action of ozone and the combination of oxygen and sunlight can convert metallic mercury into inorganic mercury.

Step 2

The conversion of inorganic mercury to methylmercury is brought about by microorganisms. The most widely studied microorganisms for methylmercury formation are the sulfate-reducing bacteria (SRBs), anaerobes that are important mediators of mercury methylation in many ecosystems. Methylating bacteria can generate methylmercury in both freshwater and marine sediments.

Many other microorganisms can produce methylmercury from inorganic mercury. For example, the gastrointestinal (GI) microorganisms in humans as well as in other mammals can form methylmercury from inorganic mercury.

Source: Scarmoutzos and Boyd (2004), cited with permission.

5.2 Empirical evidence of bioavailability

The transformation of dental mercury to methylmercury is further supported by findings over 30 years of research, including the following:

5.2.1 Environmental and Animal Studies

Aquarium tests with 1- and 2-summer old salmon (*Salmo salar*) at the Swedish National Environmental Protection Board (SNV) test lab revealed that granulated tooth amalgam releases mercury into the surrounding water in a form that can accumulate in fish. Test results gave a very uniform picture on this point. With 0.5 g of amalgam added for each liter of water, the content of mercury in the livers of test fish increased up to 60 times the original content after an exposure period of 28 days. The results also showed that the mercury was transferred from the livers of the fish into their musculature (Ekroth 1978).

The bioavailability and accumulation of mercury from external environmental exposure to mixed, cured, milled, sieved and proportioned dental amalgam was examined in the common goldfish, *Carassius auratus*. The fish were exposed to dental amalgam (particle size range from <0.10 to 3.15 mm) representative of the particle size and distribution of that found in the typical dental office wastewater discharge stream. Mercury was found in several tissues, and generally increased with exposure to higher amounts of dental amalgam. Compared to controls, concentrations in the whole body, muscle and liver of fish exposed for 28 days to the highest concentration of amalgam were 200-, 233-, and 40-fold higher, respectively. This study shows that mercury from an environmental exposure to representative samples of dental amalgam typically found within the dental wastewater discharge stream is bioavailable to fish and may accumulate in internal tissues (Kennedy 2003).

Research was carried out to establish whether monomethyl mercury (MMHg) is present in dental-unit wastewater, and if present, to determine the concentration relative to total mercury. In fact, environmentally important levels of MMHg were found to be present in dental-unit wastewater at concentrations that are orders of magnitude higher than seen in natural settings (Stone *et al.* 2005).

It has been demonstrated that the routine application of municipal sewage sludge to cropland significantly increases both total and methyl mercury in the surface soil (Carpi et al. 1997).

5.2.2 Human studies

The capacity of the oral bacteria *Streptococcus mitior*, *S. mutans* and *S. sanguis* to methylate mercury was investigated *in vitro*. Mercuric chloride and pulverized dental amalgam, respectively, in distilled water were used as sources of mercury. Methylmercury was found in the bacterial cells of all three tested strains. The results indicate that organic mercury compounds may be formed in the oral cavity (Heintze *et al.* 1983).

Leistevuo *et al.* (2001) found a correlation between the total amalgam surfaces and organic mercury – presumably as methylmercury (CH_3Hg^+) derived from oral bacteria biomethylation of inorganic mercury – in saliva. These results are compatible with the hypothesis that amalgam fillings may be a continuous source of organic mercury, which is more toxic than inorganic mercury, and almost completely absorbed by the human intestine.

The concentration of total mercury in stimulated saliva was studied in humans with dental amalgam fillings and in 2 non-amalgam groups. The probability of exceeding the limits of mercury permitted in wastewater increased proportionally as the number of amalgam-filled surfaces increased. The mercury limit for sewage is 0.05 mg/l (= 250 nmol/l) effluent according to the Council of European Communities directive 84/156/EEC. In neither of the non-amalgam groups was this limit exceeded, but 20.5% in the amalgam group exceeded the limit ($p < .001$). The risk of exceeding the limit increased 2-fold for every 10 additional amalgam-filled surfaces (odds ratio = 2.0; 95% confidence interval = 1.3, 3.3). These results demonstrated that humans, especially in populated areas, can be a significant source of mercury pollutants. As a consequence of mercury release, bacteria may acquire mercury resistance, as well as resistance to other antimicrobial agents, thus resulting in failure of antibiotic treatment (Leistevuo *et al.* 2002).

6 Dental contribution to mercury contamination of the Great Lakes and other water bodies

Under the US Clean Water Act, states are required to develop a total maximum daily load (TMDL) estimate for mercury pollution for impaired water bodies. A TMDL can be defined as the sum of the individual waste load allocations (WLAs) for point sources of pollution, plus the load allocations (LAs) for non-point sources of pollution, plus the contribution from background sources of pollution. It can be expressed in terms of either mass per time, toxicity, concentration, a specific chemical, or other appropriate measure. In essence, A TMDL is a calculation of the maximum amount of a pollutant from all sources that a water body or group of water bodies can receive and still meet applicable water quality standards, in this case fish that are considered safe to eat. To comply with this requirement the New England states and New York completed a draft regional TMDL for mercury that was released on April 11, 2007. This TMDL concluded that anthropogenic mercury inputs to the region's freshwater water bodies will need to be reduced between 86 and 98 percent to restore the contaminated fisheries and lift the consumption advisories now in place (NEG-ECP 2007).

If one considers dental mercury releases compared to all other mercury releases to wastewater treatment plants, as discussed previously, the contribution is somewhere very close to 50%. This should raise a warning, especially as an uncertain but very real rate of methylation takes place under a variety of circumstances. Likewise, it has been shown that dental mercury also contributes some 50% of the mercury load to land areas where it is applied, with further opportunities for methylation and releases.

If one looks only at dental mercury atmospheric emissions compared to total US atmospheric emissions, the present contribution may be in the range of 10%. However, if we keep in mind that coal-fired power plant emissions are slated to be reduced by 70-90% in the relatively near future, we can see that dental mercury emissions will soon comprise a far greater percentage of the total. Therefore, with or without reductions from coal-fired power plants, dental mercury discharges will have to be significantly reduced in order to meet stringent TMDL requirements under the Clean Water Act.

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Mr. KUCINICH. Mr. Smith.

STATEMENT OF C. MARK SMITH

Mr. SMITH. Thank you, Chairman Kucinich and members of the committee, for inviting me to testify today on the environmental impacts of dental mercury.

I would like to start by saying that as a scientist, as a father and as a fisherman, I have been very concerned about mercury pollution and its effects on the environment and our children's health.

I think it is a real sad state of affairs when we have to tell our kids that the first keeper fish that they catch they can't eat because it is too toxic due to mercury contamination, which is something I have had to do with both my daughter and my son over the past few years. I anticipate that I may end up having to do that with my grandchildren at the pace we are going with dealing with some of our mercury issues.

To help address this problem, I have been engaged in mercury policy and research for the past 15 years. As Chairman Kucinich mentioned, I currently direct my agency's mercury reduction strategy.

I have been the Massachusetts representative on the Quicksilver Caucus, a national multi-State group addressing mercury issues across the country, and I co-chair the New England Governors and East Canadian Premiers Mercury Taskforce, and I have done that for the past 10 years now.

I am speaking on behalf of the New England Governors' Conference which is a multi-State organization established by the Governors of the New England States to address policy issues of a regional nature including environmental issues like mercury. I am also representing my agency, the Massachusetts Department of Environmental Protection.

To address the serious impacts of mercury pollution in the northeast region of our country and also in Canada, the New England Governors and Eastern Canadian Premiers unanimously adopted a binational regional mercury action plan in 1998.

I think it is notable just to point out that this plan was endorsed by both U.S. political parties and by, I believe, three different political parties in Canada. I get those a little confused, but I think it was three different parties north of the border as well. So we had real multi-partisan support for this particular effort.

This plan called for the virtual elimination of mercury, anthropogenic mercury releases in our region and established interim goals of a 50 percent reduction by 2003 and a 75 percent reduction by 2010. That is compared to a 1998 baseline.

I am pleased to report that we beat our 2003 goal, achieving over a 54 percent reduction in regional mercury emissions by that date, and we are well on our way to hitting the 75 percent reduction target by 2010.

This has been accomplished through the implementation and adoption of very strict regulations that far exceed Federal U.S. EPA requirements in pretty much every instance which have resulted in dramatic reductions in mercury emissions from trash incinerators where our regional limits are three times more strict than EPA requires.

Coal-fired power plants where cameras targeting a 70 percent reduction which probably will not be achieved until after 2020 because of banking of credits. In Massachusetts, we have a 95 percent control requirement by 2012.

Mercury products, as Michael mentioned, many States including all of the New England States have laws in place now that are phasing out many unnecessary uses of mercury, requiring products to be labeled and remaining products to be recycled, and we are also addressing the dental sector.

As we have heard, many estimates have concluded that the dental sector, in the absence of the use of amalgam separator pollution controls, accounts for 50 percent or more of the mercury entering municipal wastewater where it concentrates into sewage sludge. In areas where amalgam separators have been required including in my State, Massachusetts, mercury levels in sludge have decreased by a lot, typically by around 50 percent.

This is important because mercury discharge from dental offices is ultimately released to the environment when sewage sludge is incinerated or when it is land-applied and reused as a fertilizer.

Dental mercury can also be released to the environment in wastewater treatment plan wastewater discharges, in overflows of combined sewers where storm events exceed treatment plant capacities, in solid waste if the material is inadvertently or inappropriately disposed of to solid waste streams, and upon the cremation of individuals with amalgam fillings.

In my area, in the Northeast, sewage sludge incinerators were estimated to be the third largest source of mercury emissions prior to amalgam separator requirements in our States, accounting for about 1,100 pounds of emissions. That is 12 percent of our total regional emissions of mercury in 2003.

It is important to note that this estimate did not include releases attributable to the reuse of sewage sludge treated biosolids which would significantly increase the total.

In 1997, land-applied sewage sludge was estimated to release over 10,000 pounds of mercury per year in the United States and Europe.

The large surface area of the small amalgam particles typically released into dental wastewater enhances the mobilization of the mercury contained in the amalgam in comparison to an intact filling, resulting in its bioavailability for methylation. This conclusion was supported by numerous experiments including one where mercury levels in fish increased by 200fold after exposure to amalgam particulates for 28 days.

Amalgam separators are inexpensive technologies that can reduce mercury dental pollution by greater than 95 percent. The northeast region adopted in 2005 a goal that 75 percent of our region's dentists that generate amalgam wastes should install amalgam separators by 2007 and 95 percent by 2010.

The national Canada-wide standards also established a 95 percent goal for all of Canada. The northeast region is well on its way to meeting these goals. Montreal, the first northeast city to mandate separators has reported that mercury levels in their sludge have been decreased by greater than 50 percent since they required the separators.

Overall, in Eastern Canada, more than 50 percent of their dentists and, in New England, more than 78 percent of our dentists are now using amalgam separators.

In Massachusetts, we have worked collaboratively with our State and the Massachusetts Dental Society and adopted an MOU in 2001 to encourage amalgam separator use and the use of best management practices. A followup program was initiated a couple of years later in 2004 when my agency announced that we would be developing regulations to require separators with an anticipated adoption date of 2006.

To achieve faster mercury reductions, the agency also initiated a voluntary early compliance program. We provided some incentives to the dentists including waiving permit fees that would be required and also grandfathering systems that were installed under the program that met a 95 percent amalgam removal efficiency.

By the end of the first year, 75 percent of Massachusetts' dentists certified that they had installed amalgam separators preventing the discharge of many hundreds of pounds of mercury into our wastewater. Regulations requiring the use of amalgam separators were ultimately adopted in the spring of 2006.

Data from our largest wastewater treatment plant, the Massachusetts Water Resources Authority which treats sewage for 2.5 million people in the greater Boston area, indicate that our program has been very successful. Over the 2004 to 2006 time period, when our amalgam separator use increased to over 80 percent in Massachusetts, mercury levels in MWRA sludge from that treatment plant have decreased by over 48 percent.

In conclusion, the dental sector can be a significant source of mercury pollution to the environment. Amalgam separators can significantly reduce such releases. Collaborative initiatives to expand the use of these control technologies, which include quantifiable goals and objectives and meaningful compliance deadlines, are very effective based on our State experiences and should be pursued nationally.

I would also like to point out that the Northeast States recently determined that anthropogenic mercury releases will need to be reduced by greater than 86 percent to restore our contaminated water bodies and make their fish safe to eat. To achieve such reductions, all preventable sources of mercury releases to the environment will need to be addressed.

Thank you again and I am willing to answer any questions that you may have.

[The prepared statement of Mr. Smith follows:]

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Before the

Domestic Policy Subcommittee

Oversight and Government Reform Committee

Wednesday, November 14, 2007

2154 Rayburn HOB

2:00 P.M.

Thank you Chairman Kucinich, Ranking Member Issa and members of the Committee, for inviting me to testify today on the environmental impacts of dental mercury. As a scientist, a father and a fisherman I am very concerned about the effects of mercury pollution on our environment and our children's health. To help address this problem, I have been engaged in mercury policy and research for the past 15 years. I currently direct my agency's mercury program; represent MA on the Quicksilver Caucus and co-chair the New England Governors and Eastern Canadian Premiers (NEG-ECP) Mercury Task Force.

Today I am speaking on behalf of the New England Governors Conference, which was established by the Governors of New England to coordinate regional policy programs in several areas including the environment, and the Massachusetts Department of Environmental Protection.

To address the serious impacts of mercury pollution in the northeast, the New England Governors and Eastern Canadian Premiers unanimously adopted a bi-national Mercury Action Plan in 1998. This plan called for the virtual elimination of anthropogenic mercury pollution in the region and established interim goals of a 50% reduction by 2003 and 75% by 2010. The region has exceeded this plan's first goal and is well on its way to the 2010 target. This has been accomplished through strict regulations that exceed federal requirements, addressing mercury pollution from trash incinerators, coal-fired power plants, mercury products and the dental sector.

Several assessments have estimated that the dental sector, in the absence of amalgam separator pollution controls, accounts for 50% or more of the mercury entering municipal wastewater systems, where it concentrates into sewage sludge. In areas where amalgam separators are required, mercury levels in sludge have declined significantly, often by more than 50%.

Mercury discharged from dental offices is released to the environment when sewage sludge is incinerated or reused. Dental mercury can also be released in treatment plant effluent; combined sewer overflows; solid waste and upon the cremation of individuals with amalgam fillings.

Sewage sludge incinerators were estimated to be the third largest point source of mercury emissions in the northeast prior to regional requirements that dentists use amalgam separators, and accounted for over 1,100 pounds or 12% of total emissions. This estimate did not include releases from wastewater or land applied sewage sludge, which would significantly increase the total.

In 1997, land applied sewage sludge was estimated to release over 10,000 pounds of mercury per year in the US and Europe. Although mercury in amalgam is less volatile and soluble than other forms, the large surface area of small amalgam particles released into dental wastewater enhances mercury mobilization compared to intact fillings, resulting in its bioavailability. This conclusion is supported by experiments in which mercury levels in fish increased over 200-fold after exposure to amalgam particulates.

Amalgam separators are inexpensive technologies that can reduce dental mercury pollution by greater than 95%. To reduce mercury releases attributable to the dental sector our region adopted a 75% amalgam separator use goal for 2007, and 95% for 2010. The national Canada-wide standards also call for 95% of Canadian dentists to use these controls.

The region is well on its way to meeting these goals. Montreal, the first municipality in the northeast to mandate amalgam separators, reports that mercury levels in their sludge have decreased by greater than 50%. Overall, in the Eastern Canadian provinces more than 53%, and in the New England states, more than 78% of dentists who generate amalgam waste are now using amalgam separators.

In MA we have worked collaboratively with the Massachusetts Dental Society and an MOU was adopted in 2001 to encourage amalgam separator use. A follow-up program was initiated in 2004 when MassDEP indicated that it was developing regulations requiring amalgam separators. To achieve faster mercury reductions, the agency also initiated a voluntary early compliance program. As an incentive, permit fees were waived and acceptable separators were grandfathered until 2010. This incentivized early compliance program was very successful - about 75% of MA dentists installed amalgam separators by the end of the first year preventing several hundred pounds of mercury discharges. Regulations requiring the use of amalgam separators were ultimately adopted in 2006.

Data from the Massachusetts Water Resources Authority (MWRA), which treats sewage for 2.5 million people in the Greater Boston Area, indicates that this program has been effective. Over 2004 – 2006, when amalgam separator use increased to over 75% in MA, mercury levels in MWRA sludge decreased by 48%.

In conclusion, the dental sector can be a significant source of mercury pollution. Amalgam separators can significantly reduce such releases. Collaborative initiatives to expand the use of these control technologies, which include quantifiable goals and objectives and meaningful compliance deadlines are effective and should be pursued nationally.

I would like to again thank you, Mr. Chairman, Ranking Member, and other members of this Subcommittee, for your interest in this issue and for allowing me to share my state's and region's views. I would be happy to answer any questions you have at this time.

Mr. KUCINICH. Thank you, Mr. Smith.
Dr. Mackert, please proceed. Thank you.

STATEMENT OF J. RODWAY MACKERT

Dr. MACKERT. Thank you, Mr. Chairman and members of the subcommittee.

My name is Dr. Rod Mackert. I am a dentist and a professor at the Medical College of Georgia. I am pleased to offer testimony today on behalf of the American Dental Association.

The ADA is the world's largest and oldest dental association representing more than 155,000 dentists nationwide. It is our understanding that the focus of this hearing is on amalgam's impact on the environment. We are grateful for the opportunity to comment on this topic.

I don't want to overlook the obvious, so I will first define what we are here to discuss. Dental amalgam is an alloy made by combining silver, copper, tin and zinc with mercury. It has been studied and reviewed extensively and, based on the best available science, dentists continue to rely on it as a safe and effective option for treating dental decay.

Now, allow me to share our thoughts on amalgam and environmental issues. We are very proud of our efforts to protect the environment. We have developed and implemented best management practices or BMPs on amalgam waste and are pleased to note that we recently added the use of amalgam separators to that list.

The ADA actively promotes its BMPs which have had a very positive impact. As one example, we have virtually eliminated the use of bulk mercury in dentistry. Dentists now used encapsulated amalgam, capsules containing a small amount of elemental mercury and the powdered metals with which it is mixed. Because amalgam is now encapsulated, mercury spills are virtually eliminated in the dental office.

The ADA's BMPs have also greatly promoted the recycling of waste amalgam by calling on all dentists who either replace or remove amalgams to use chair-side traps and vacuum pump filters. These standard control methods remove approximately 77 percent of the scrap amalgam before it enters the wastewater. The amalgam captured by these devices can then be recycled.

None of this would have been possible without the ADA vigorously promoting its best management practices with dentists throughout the Nation. We have distributed posters and brochures explaining the BMPs to every dentist in the Nation, not just to ADA members. The ADA promotes BMPs on its Web site and offers, in partnership with State dental societies, training programs for dentists.

In addition, the ADA sponsored the most thorough peer-reviewed study, which I have here, on the issue of dental office wastewater.

As I mentioned, the ADA this year amended its list of BMPs to include the use of amalgam separators. We took this action because we have gained a lot of experience with separator technology and even assisted the ISO, an international standard-setting organization, in developing standards for the devices.

We have learned that the systems work well, and we now feel comfortable including them in our best management practice rec-

ommendations. We are just beginning to promote our revised BMPs and will make every effort to ensure that every dentist in America has that information at hand.

Another point to consider is the declining use of dental amalgam. In 1990, dental amalgams constituted 68 percent of all dental restorations. By 1999, that figure had dropped to 45 percent. Our most recent estimate is about 30 percent. We expect this trend to continue. In other words, this is a problem shrinking on its own.

I am proud that the ADA and the Nation's dentists are taking these steps voluntarily. We are working to protect the environment by educating our members, encouraging recycling and promoting highly effective best management practices. If there are additional things we can do to improve our BMPs, I am confident that we will take the necessary steps to do just that.

Dentistry is proud of its efforts to protect the environment just as we have always protected the health and well being of our patients. We pledge to continue our efforts. We appreciate the opportunity to share this information with you.

Thank you.

[The prepared statement of Dr. Mackert follows:]

J. Rodway Mackert, Jr., DMD, PhD
Oral Statement of the American Dental Association
before the
Domestic Policy Subcommittee
Oversight and Government Reform Committee
"Environmental Risks of and Regulatory Response to Dental Mercury Amalgam"
Wednesday, November 14, 2007
2154 Rayburn HOB

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Mr. KUCINICH. Thank you. Thank you very much, Dr. Mackert, for being here.

To Mr. Clark, in the FDA's written testimony, they have also stated that the analysis is determined by the action taken by the Agency and not the product in question. FDA has no reason to think that changing the classification of mercury by itself will affect its level of use in a way that would have a significant effect on the environment.

In other words, FDA is saying that all they are doing is ratifying what is already the status quo, so no EIS is needed.

Would you comment on the FDA's interpretation of the National Environmental Policy Act?

Mr. CLARK. I would be happy to, Mr. Chairman.

FDA is quite right, that the focus of NEPA is the action or, in other words, the decisions that are at hand. It is still unclear, though, how they know, what kind of action or what kind of behaviors are going to be generated as a result of their action or their decision.

It is quite clear that they have some concern about the risk associated with mercury amalgams. They are, in fact, taking some of the action based on safety concerns, and so it seems to me that the question remains at hand how do they know.

In fact, it is a status quo. It is status quo because they have been doing the same thing, but you can't keep doing the same wrong thing and saying that we ought to continue doing that.

Mr. KUCINICH. But would it be fair to say that when you take that view, that the analysis is determined by the action taken by the Agency and not the product in question, that in a sense can have a way of rewarding an Agency that doesn't do an thorough analysis by being able to say, well, it wasn't that much of a problem to begin with, so we didn't have to take that much action?

Mr. CLARK. Well, I listened to the last speaker, and he said two different things over and over, it seemed to me. One of the things he said was that yes, he thought some kind of analysis might be justified, and then he would say but our regulations say that we don't have to do it.

And so, I think there is much, much, too much of a reliance on some kind of legal interpretation that they have made without the benefit of any analysis ever as far as anyone is concerned.

The major point, I think, is that the cumulative effects analysis over these years of the status quo, as you say. The status quo keeps building and mercury keeps accumulating in the environment. The problem doesn't really get better. The problem gets worse, and so there ought to be some kind of assessment.

Mr. KUCINICH. I appreciate your involving yourself in this discussion because when I look at this statement, the analysis is determined by the action taken by the Agency and not the product in question, it seems that they have the cart before the horse here.

If you have a product, you analyze the product. You don't base your analysis of the efficacy or the challenge to that product by asserting that if you take action, then there must be something wrong with the product. There might be some inherent situation with that, an inherent problem with the product.

Mr. CLARK. That is right. Their action is changing or establishing behavior, and those behaviors are subject to the National Environmental Policy Act.

Mr. KUCINICH. I am going to just go to one more question and then take it to Mr. Burton. But I just want to say, Mr. Burton, that we heard the gentleman here testifying, representing various agencies, and if they don't see the extent of the problem and they don't quantify it, then what they are basically saying is that, well, we didn't have to take any action because we didn't really see that the product in question was that ubiquitous in the environment.

I just want to have one more question. They also use a standard, that is the FDA, that they call reasonably foreseeable as in if it is not reasonably foreseeable that there would be an increase in the amount of mercury introduced in the environment that would constitute an extraordinary circumstances, FDA would appropriately rely on its existing categorical exclusion.

Would you please comment on reasonably foreseeable, that standard, in complying with the National Environmental Policy Act?

Mr. CLARK. I, again, think they are quite right to say that CEQ reg mandates them to look at what is reasonably foreseeable, and the interesting point is that if they would read the definition of cumulative effect, then they would see that they have to look at what is reasonably foreseeable, not only what they are doing but what everybody else is doing in the environment as well.

The CEQ regulation definition of cumulative effect says all past, present and reasonably foreseeable. That is the context in which they use reasonably foreseeable, that you have to consider all the things that have gone before you, all the things that are before you now, and not only what FDA is putting in the environment with regard to mercury but what all other entities, and not only Federal, not only FDA, but all the other Federal agencies and not only all the Federal agencies but all the other users.

And so, essentially, they need to be looking at the environment-up instead of their action-down.

Mr. KUCINICH. Thank you, sir.

Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman.

I am only going to ask a couple of questions. It is late, and I know you are tired of waiting on us running back and forth to the floor to vote.

So the first question is, do you think that people who are having mercury put into their bodies in any form should know about it?

All of you, I want to ask each of you. Do you think if a person is getting an amalgam filling, they ought to know that it is 50 percent mercury?

How about you, Doctor? Shouldn't we inform them what they are getting?

Dr. MACKERT. Well, certainly, the ADA has supported and we have a brochure that will be ready by the end of the year that talks about all. We have currently brochures that talk about all the different filling materials, what they contain, their advantages and disadvantages.

I think that should be discussed by the patient and the dentist together in making any decision about restorations.

Mr. BURTON. So you think it is the obligation of the dentist to say to the patient before they put any kind of substance in their mouth, what it is. If you are putting a silver filling in someone's mouth, just say, here is what we are putting in your teeth, copper, zinc, mercury.

Dr. MACKERT. Well, I mean we could say the same things about the white fillings that have bisphenol A and diglycidyl dimethacrylate and all sorts of chemicals, that you could bewilder a patient for sure with a list of materials that are in the white filling material, silanes.

Mr. BURTON. Mercury is known to be one of the most toxic substances on the earth. Don't you believe?

Dr. MACKERT. It is really not.

Mr. BURTON. What is that?

Dr. MACKERT. It is really not. The OSHA maintains a list of 340 some odd toxins.

Mr. BURTON. Where is mercury? Where is mercury on that list?

Dr. MACKERT. It is not No. 1. It is not even a number.

Mr. BURTON. Well, where is it?

Dr. MACKERT. I have that information. I can provide that for you.

Mr. BURTON. Well, I would like to have it. But you will admit it is toxic, mercury.

Dr. MACKERT. Yes, but so is vitamin A.

Mr. BURTON. No, no, no.

Dr. MACKERT. I mean we need to know that it doesn't completely define something to say that it is toxic. Vitamin A is a toxin. Chromium is a toxin.

Mr. BURTON. You know what really gets me, Doctor, is the Dental Association and the FDA and the HHS, all the agencies, don't want to just flat-out tell people they are putting mercury in their mouths. You don't want to do it.

Dr. MACKERT. We have done it.

Mr. BURTON. You can use every argument you want about other vitamins, minerals and everything else that may be toxic, but mercury is 50 percent of what goes into a filling and you don't want to tell people that.

I don't know how many I have talked to who have fillings in their mouths, and they say I just have silver fillings. You say, do you know what is in the silver filling, and they don't know. Most people don't know. They don't know it is 50 percent mercury.

Dr. MACKERT. Most people don't know the ingredients in the dental, the white filling materials.

Mr. BURTON. You guys amaze me.

Anyhow, let me ask the rest of you gentlemen. Don't you think that people have a right to know when mercury is being put into their mouths?

Mr. CLARK. Sir, I am a major believer in truth in advertising.

Mr. BURTON. OK, how about you, Mr. Bender?

Mr. BENDER. We actually commissioned a Zogby poll in 2006 on this issue, and it was a statistically significant finding to the question of what is in an amalgam filling. Seventy-five percent of Americans didn't know the main ingredient was mercury. When told

that the main ingredient was mercury, 75 percent will be willing to pay more to choose something else. Seven to one were in favor of requiring dentists to tell patients that mercury was in amalgam.

There are a few other important statistics, and I will submit them for the record in the next 5 days.

Personally speaking, I absolutely believe that it is a right to know issue. We have informed consent from many other product categories, and we know that mercury in the mouth is not helping anyone's health condition. Thank you.

Mr. BURTON. How about you, Mr. Smith.

Mr. SMITH. Yes.

Mr. BURTON. Thank you. That is very succinct and very to the point.

The other thing I would just like to ask a question about is mercury in all forms getting into the environment is a real problem for civilization. So I would just like to ask you, individually, don't you think mercury should be taken out of product that is possible so it doesn't get into the environment?

Mr. CLARK. I am afraid I couldn't answer that as succinctly because I would like to know what kinds of things are tradeoffs. I would want to know some of the risk assessments. I would want to know some of the mitigations.

I think that there s a major role for mercury and certainly in my background, from the national security background, I know that is an element that is absolutely essential, but I also know that there are plenty of safe ways to deal with it and keep it out of the environment.

Mr. BENDER. The State of Maine asked the Lowell Center for Toxics Use Reduction to do an analysis of what the alternatives were to mercury and products and processes in the United States, and they did an extensive, actually two or three extensive reports and found that for almost every single use, except for mercury in fluorescent lights, there is a viable cost-effective alternative.

In the case of dental amalgam, I have been over to the Scandinavian countries and interviewed the dental authorities in those countries. In the case of Norway and the case of Sweden, the use of mercury amalgam is a non-issue because over 95 percent of the placements today are not mercury fillings.

I would submit that those societies are not having problems chewing or digesting their food or anything else, that societies are surviving without mercury amalgam, and I would again challenge the mainstream dental establishment to demonstrate why these alternatives that are being put in every day are not sufficient.

Finally, I would also submit that there is an association of mercury-free dentists, the IAOMT, whose members pledge not to use any mercury and, including myself, I can attest that there is not a need for mercury in fillings.

Mr. BURTON. Mr. Smith.

Mr. SMITH. Yes, I would just like to point out that quite a number of States, including my State and all of the New England States, have adopted fairly comprehensive mercury products legislation that is phasing out many unnecessary uses of mercury, and there are literally hundreds of those.

The legislation that we also, that we have also requires that remaining uses of mercury to be labeled by the manufacturers so that consumers know that there is mercury present in the product and to provide appropriate information about how that material, how those products at the end of their useful lives can be recycled. Our legislation in Massachusetts also prohibits the disposal of those mercury-containing items into regular trash and requires manufacturers to support recycling programs in our State.

Mr. BURTON. Mr. Chairman, I would just like to request of the panel.

Mr. Bender, if you have statistical data like you have, I would like to have a copy of it because we are going to be talking about this in the future, and the facts that you have stated and the polling data and all that stuff is very important. I would like to have that.

Mr. Chairman, thank you very much.

Mr. KUCINICH. The Chair would appreciate your cooperating with that request for Mr. Burton.

Mr. Smith, the New England States have been leaders in changing the behavior of dentists with regard to how they handle the mercury they use and create in their work.

Can you tell us about the relative merits of the voluntary and mandatory rule on the use of mercury separators and, in general, do you believe you have been able to make significant reductions in mercury emissions? What lessons do you have for the Nation?

Mr. SMITH. Sure. We started initially working with the Massachusetts Dental Association in a very collaborative way, and they were really confident at the start of our efforts in 2001 that they could encourage their membership to voluntarily adopt the use of amalgam separators. We entered into a memorandum of understanding in 2001 with the MDS, basically focused on outreach to dentists to encourage the installation of separators and the use of best management practices.

Frankly, we did not track the installation very closely, but the MDS reported that somewhere between 10 and 15 percent of dentists, after 2 years of that voluntary program, were using amalgam separators, and that estimate was fairly consistent with reports from manufacturers of amalgam separators. So we did have some success in increasing their use, but it wasn't as fast as we really wanted to see.

In 2004, we, as I mentioned in my testimony, initiated a program to develop mandatory regulations that would require the use of the separators with a voluntary early compliance program. That has been very successful, and we had 75 percent of the dentists sign up in the first year of that program.

We now have the rule in place. It was adopted in the Spring of 2006, and essentially all of our dentists are using amalgam separators.

Mr. KUCINICH. As far as the Massachusetts Dental Society, was the Society in favor of your mandatory requirement on dentists to use mercury separators?

Mr. SMITH. I wouldn't go so far as to say that they were in favor of it, but they did participate actively in a stakeholder work group

that we convened to develop our regulations, and they did not actively oppose it.

Mr. KUCINICH. So do you feel you can do the job of reducing mercury emissions to levels low enough to yield fish that are safe to eat?

Mr. SMITH. Well, we are working in that direction, and we are seeing some positive results. I didn't speak to this today, but we have some extensive fish monitoring that we have been doing in Massachusetts and we have documented 20 to 30 percent reductions in mercury levels in our freshwater fish consistent with the timeframe where we have been implementing our regional action plan.

That is encouraging. Those fish are still not safe to eat, so we have a long ways to go.

Mr. KUCINICH. Thank you, Mr. Smith.

Dr. Mackert, ADA has obviously recognized and reacted to the environmental threat posed by mercury emissions coming from dentists' offices, but one of the conditions that ADA seems to have placed on its participation in the effort is that State laws and regulations requiring that dentists use mercury separators be voluntary rather than mandatory on dentists.

Will you explain why the ADA believes dentists should be given the discretion to continue to pollute the environment with mercury?

Dr. MACKERT. Well, let me first address the end of your question which is the contribution of dentists to the environment where I have the EPA 2002 report here, and they are listed both by total releases and by consumption. Dentists are No. 7 on this list. Gold mining is No. 1. Utility coal combustion is No. 2. Switches and relays are No. 3.

We are less than 1 percent of the total amount of mercury entering the environment according to the EPA's report. Gold mining accounts for over 90 percent of it by itself. So we can eliminate dental mercury tomorrow, and essentially all of the mercury that is in the environment today will be still be entering the environment if amalgam were not.

Mr. KUCINICH. I look forward to having a hearing on gold mining, but I am looking at dental amalgams here. What I would like to know is mandatory or voluntary, which is it? You are speaking on behalf of the ADA.

Dr. MACKERT. That is correct.

Mr. KUCINICH. Can you agree that it would be better for the environment, since dentists are environmentalists, to participate in a mandatory program?

Dr. MACKERT. I don't agree that it would because we are currently able to take time to develop and promulgate mandatory standards, and the ADA is already working now. Even though this was passed by our House of Delegates only at the beginning of last month, and yet we are already working on publishing this information, encouraging through the things that we have learned.

I mean there have been incidents in the past like have been mentioned here about efforts that have not been successful, but we have learned from these and we will marshal all of the available resources of the ADA to effect compliance.

Mr. KUCINICH. So, Doctor, is it the position of the ADA that you do not support mandatory separation? Do you support it or not?

Dr. MACKERT. We believe that we can accomplish it more rapidly, more effectively by voluntary compliance.

Mr. KUCINICH. But why should dentists be able to choose whether or not to use the best available mercury-reduction technology? Why should you be able to choose that?

Dr. MACKERT. Well, because it is going. I mean we have 100,000 dental offices in the United States. Are we going to have to develop a government program to monitor 100,000 dental offices to see? Why not see if we can accomplish this by voluntary means as has been done, for example, in Minnesota?

Mr. KUCINICH. Let me ask you this, if I may, because we are running out of time here. What percentage of dental fillings are in fact replacements of existing fillings?

Dr. MACKERT. I don't have that information, but I can get that for you.

Mr. KUCINICH. We understand it is about 70 percent according to staff. Would you say that most of replaced fillings are probably mercury amalgams? Is that from your experience?

Dr. MACKERT. Well, it probably would not be at this point because only 30 percent of the fillings placed are amalgam fillings.

Mr. KUCINICH. Where do the replaced fillings go?

Dr. MACKERT. They are collected. I mean they are removed from the patient's tooth and then collected in the traps or if the dentist has amalgam separators.

Mr. KUCINICH. So how many tons of mercury in existing fillings could be potentially replaced?

Dr. MACKERT. I got about 1,200 tons.

Mr. KUCINICH. Right, that is what the EPA says, 1,200 tons. So that is a potential of over 1,000 tons of mercury that has to be safely sequestered.

Dr. MACKERT. The total amount is less than the gold mining that is released in 1 year.

Mr. KUCINICH. I know. I mean you keep talking about gold mining, and I want to have a hearing on that.

Dr. MACKERT. Well, if we have a budget problem, for example, in our personal finances.

Mr. KUCINICH. Doctor, really, please, let's try to stay on the page here. It is a potential of over 1,000 tons of mercury that has to be safely sequestered before the mercury threat from dental amalgams really takes care of itself.

Mr. BURTON. Would the chairman yield?

Mr. KUCINICH. Of course, I will yield to my friend.

Mr. BURTON. Let me just cite some facts regarding the voluntary effort of dentists to come up with these separators and put them in their offices.

In the Seattle, King County Dental Society, they conducted a study and they found after 6 years, after 6 years—it was a voluntary program—24 dental offices out of 900 decided to go along with the separators. That is your voluntary program, 24 out of 900, and that is why.

Dr. MACKERT. That was at the very beginning of the availability of amalgam separators. There were mistakes made on both sides.

We have learned from those mistakes, and then we look at Minnesota which was a different situation where 87 percent of dentists complied voluntarily.

Mr. KUCINICH. I thank the gentleman for bringing that up.

Now I just want to ask Dr. Mackert again, how long would it take? Just give me an estimate.

How long would it take for dentists to eventually replace dental fillings with more than 1,000 tons of mercury? Would it be 10 years, 20 years, 30 years? How long would that take, do you think?

Dr. MACKERT. I don't think there is any way to predict that.

Mr. KUCINICH. A very long time, I imagine.

Is it a long time? Do you think it would take a long time to replace it?

Dr. MACKERT. Are you saying that if we started literally trying to do this tomorrow? How long would it take?

Mr. KUCINICH. Yes, how long would it take if you started tomorrow and you really made a concerted effort?

Dr. MACKERT. Or are you talking about fillings wearing out and needing to be replaced?

Mr. KUCINICH. Just all those, you know the normal process and pattern of people's fillings breaking down and needing replacement, dental accidents, things like that.

Dr. MACKERT. I don't know how we could estimate that, but we make an attempt.

Mr. KUCINICH. It would take a long time, though. See, what I am trying to get at is it is going to be a long time before the problem takes care of itself. So I just would like you to think about this with the ADA because I remember seeing your testimony here that you said it was a shrinking problem that would basically take care of itself.

With the point that Mr. Burton made, what were those numbers again, Mr. Burton?

Mr. BURTON. Twenty-four out of 900.

Mr. KUCINICH. If the problem takes care of itself, how is it going to take care of itself if the dentists don't help?

Dr. MACKERT. Well, as I said, that was at the very beginning of the development of amalgam separators, and we didn't know very much about them at that point.

The situation is we have generated lots of information about their use and installation. We have made efforts to make it easier for dentists to know how to install separators.

Mr. KUCINICH. You do want to do something about this, don't you?

Dr. MACKERT. Yes, we do, and we will. We are.

Mr. BURTON. Mr. Chair.

Mr. KUCINICH. Sure, of course, Mr. Burton. It is your time.

Mr. BURTON. Let me just thank you for yielding.

That study went on from 1995 to 2000. It was 6 or 7 years ago. Has it changed a great deal since then? Do you have any statistical data on showing how many voluntarily decided to go along with the separators?

Dr. MACKERT. I mentioned the case in Minnesota.

Mr. BURTON. I am talking about nationwide. We have 50 States.

Dr. MACKERT. There are, as far as I know, about 15,000 separators in use currently. There are 10 States that have laws on the books or have passed legislation which is not yet effective.

Mr. BURTON. Mr. Bender, do you have the statistics on that?

Mr. BENDER. I have an estimate from one amalgam manufacturer that approximately 56 percent of dentists in the United States have amalgam separators today.

Mr. BURTON. Five, and that includes the States that have some kind of mandatory requirement?

Mr. BENDER. That is correct.

Most of the Northeast States, although very admirable that I am from the Northeast, but we are very small States. The States with the big populations like California, Pennsylvania, the Great Lakes States, none of those States have those requirements. So we are talking about a relatively small part of the overall population that has those mandates.

I might add that in each State where we have proposed legislation the ADA has fought us tooth and nail to oppose any kind of mandatory programs, and they have consistently done that for the last 5 years.

Mr. BURTON. Thank you.

Thank you, Mr. Chairman.

Mr. KUCINICH. To Dr. Mackert, on your testimony, on page 2, you say that, well, I will start with page 1: "I don't want to overlook the obvious, so I will define what we are here to discuss. Dental amalgam is an alloy made by combining silver, copper, tin and zinc with mercury. It has been studied and reviewed extensively and, based on the best available science, dentists continue to rely on it as a safe and effective option for treating dental decay."

Would you concede that science is an ongoing process of an accumulation knowledge that causes people to evaluate and then reevaluate certain hypotheses that lend to certain conclusions and that the progress of science inevitably means that things that maybe you did yesterday, you don't do today?

Dr. MACKERT. Well, science is knowledge, and we have knowledge of the studies that have been done. We have looked at this issue. There have been two large studies published last year in JAMA that looked at the effects of amalgam on children, and both of these studies concluded.

Mr. KUCINICH. What about the environment?

Dr. MACKERT. Well, you know we have the numbers here from the EPA 2002 report. There is dental mercury is a half of 1 percent of the total mercury entering the environment. If we eliminate dental mercury, we will still have 99.5 percent of the mercury currently entering the environment after dental mercury is eliminated.

Mr. KUCINICH. Let me just say that I appreciate your being here, and some of my closest friends are dentists based on the childhood I had. So I appreciate the work that dentists do. It is important.

You know we are dealing with something here that basically is a technology that you are stuck with. I mean this is it, and this is what you use.

If all of a sudden this huge environmental movement starts moving up about mercury contamination here and there, I would imag-

ine that dentists do real well when they are not sitting in the chair, and so you are in the chair today. I am not trying to pull teeth. I am just trying to get some answers.

I want to go to Mr. Bender.

Now, you have testified because Dr. Mackert pointed out, look, this is what the EPA says, not quite so bad, but you have testified that the actual environmental emissions of mercury from source of dental mercury is somewhere between seven and more than nine tons per year. That is a lot higher than EPA's estimate of about 1.5 tons per year.

Your number is an estimate. EPA's number is an estimate. Why should we believe your estimate is any more valid than the U.S. EPA's?

Mr. BENDER. Well, first of all, because the model that my consultant was using to project that estimate was based on an EPA Region 5 scientist's approach, and so we are not pulling these numbers out of thin air. We are actually following what the EPA scientist is using for an approach.

The other point I think that is important to point out here is that there has been a lot of talk about mercury in the water, and that was the focus in 2003. I think it seems like one of the criteria that EPA uses is mercury releases to the air, and I think this testimony today demonstrated very clearly that in the case of dental mercury there is a significant doubt about the EPA numbers and there is a range of numbers that are out there.

It also seems that EPA and the Congress are motivated by mercury air release issues, and so I would submit that it is time to take another look at the air releases and not base it on 2002 or 2004.

Mr. KUCINICH. Let's assume your estimate is closer to reality. What then can we say about the significance of dentist use of mercury as a source of mercury pollution of the environment?

Mr. BENDER. Well, it is compared to the 50 tons that we are talking about from the coal-fired power plants, we are talking about a 10 ton number which is very significant.

Mr. KUCINICH. Is that significant in terms of the potential bioaccumulation?

Mr. BENDER. It absolutely is and in terms of the methylation of mercury which gets into the fish that people eat.

Mr. KUCINICH. If actual emission are between 7 and 9 tons, you have estimated that some 31 tons of mercury from dentists' offices are calculated to go into emissions and waste. Where does it all go and where does the difference between the emissions and the total go?

Mr. BENDER. As we detail in our extensive testimony, there are several avenues. Clearly, the one that rises to the top is cremation, and the new estimates are over three tons per year. If you were to just do a simple mass balance and that is really what has been lacking from all these equations, the mercury that goes in has to go somewhere.

The question is, where does it go and how does it get there, and a large question is how much goes into the air?

Mr. KUCINICH. Well, we have a persistent toxin we are talking about here. What safe way is there to dispose of mercury to prevent it from getting out into the environment?

Mr. BENDER. I am sorry.

Mr. KUCINICH. What is a safe way to dispose of mercury to prevent it from being released into the environment?

Mr. BENDER. Well, in the case of crematoria, it is a rather difficult situation because if you were to require these control devices on crematoria, then you would be closing down all the small crematoria in the country. So I would submit the long term answer is to stop using dental mercury.

Mr. KUCINICH. You have said previously it is far preferable to keep mercury from reaching the wastewater plant in terms of mercury reduction. Can you spell out for us from least cost per ton emitted to most, what are the policy options for reducing mercury emissions from dental use of mercury?

Mr. BENDER. Oh, absolutely, the first step is installation of amalgam separators in combination with best management practices. We have seen example after example where when the dentists are required to put in amalgam separators and once they comply with that requirement, that we are seeing a 50 percent reduction, and we are talking about $100 a month per dentist.

Mr. KUCINICH. I am going to just conclude with this comment, and I want to go back to Dr. Mackert because I think what we need to do is to look at this from the standpoint of having the ADA countenance this advancing science and the data that is available with respect to effect in air.

I would imagine that when somebody trained to be a dentist years ago, they weren't thinking about mercury emissions from crematoriums. It just doesn't seem to me that would necessarily be something in the books. I don't know.

I am not a dentist, but it would seem to me that you are in an area of effects that may not be something that had really years ago been of great concern and significance, but now we know that there are impacts.

So what I would just respectfully suggest to you—knowing that America has the best dentistry, has people who are really committed to their patients, has dentists who really care about the health of people because, after all, you are doctors—that you take into account this advancing science and, as Mr. Burton pointed out, to look at the potential that participating in a mandatory program might actually be to further strengthening public confidence in dentists, which I am sure is already high but helping to secure it.

So thank you, sir.

Mr. Burton and then we are going to conclude the hearing.

Mr. BURTON. Yes. I just have one comment about this study that took place in Seattle where only 24 out of 900 dentists voluntarily put those separators in.

There were articles and paid advertisements in the Seattle, King County Dental Journal. There were seven different editions that were mailed to all members of the society. There was a guidebook sent out. There were presentations and workshops at dental conventions within that area.

There were cash rebates from companies that were selling the amalgam separators. There were newspaper articles acknowledging the "green" dentists. There was an outreach to dental supply companies. There was a curriculum prepared for the dental assistant-hygienist training programs and technical assistance visits to dental offices.

And, only 24 out of 900 voluntarily complied. So I think they were pretty well informed about it.

The other thing I would like to say about it is when the ADA certifies something for a company, a new product, a new kind of amalgam, do they get any kind of a fee for that? Does the ADA get any kind of a fee if they certify from a company that their product gets their stamp of approval?

Dr. MACKERT. I am sorry. The seal program now only applies to over-the-counter products anyway. There is no seal program for professional products.

Mr. BURTON. They don't get any fee for anything except over-the-counter?

Dr. MACKERT. That is correct. They do not anymore.

There was a program that was run by far and away, primarily at the expense of dentists through paying their dues. The ADA charged a small fee for all materials, not just amalgam but any product just to help defray some of the cost of laboratory analyses that had to be done in certifying these products. But, as I pointed out, that is not done anymore.

Mr. BURTON. It is not done anymore?

Dr. MACKERT. No.

Mr. BURTON. Did they ever have a patent on the amalgam?

Dr. MACKERT. The ADA has about 70, last time I checked, about 77 patents. I point out that the ADAD developed the white.

Mr. BURTON. Do any of them involve amalgams at all?

Dr. MACKERT. The two, over 30 years ago, did. They were never licensed by the ADA. The ADA never made any money on these patents.

In contrast, the ADA has, and I have the numbers. I can get them for you, but they not only invented the white filling material that is a primary alternative. That was developed by Ray Bowen who is an ADA scientist.

Mr. BURTON. I would like, if you would just submit for the record, any patents they have and any fees that they get for any product that they give their stamp of approval on.

Dr. MACKERT. OK.

Mr. BURTON. I really want to thank all of you for waiting so long. I know the chairman feels the same way I do.

I really would appreciate if you could submit for the record. I would like to personally see all those statistics you have.

Mr. KUCINICH. I want to thank the gentleman from Indiana for his contributions to this area of inquiry by the U.S. Congress. You have been on this for years. You have really made a major contribution as a Member of Congress to further investigating this.

I am Dennis Kucinich, Chairman of the Domestic Policy Subcommittee of the Oversight and Government Reform Committee. This has been a hearing on the Environmental Risks of and Regulatory Response to Mercury Dental Fillings.

I want to thank each and every one of our witnesses for their patience and their participation in this. This committee will continue its oversight of this matter, and I am sure our members of the staff will be in touch with you. Thank you very much.

This committee stands adjourned.

[Whereupon, at 6:45 p.m., the subcommittee was adjourned.]

[The prepared statement of Hon. Elijah E. Cummings and additional information submitted for the hearing record follows:]

FOR THE RECORD ONLY

CONGRESSMAN ELIJAH E. CUMMINGS OF MARYLAND
OPENING STATEMENT

"ENVIRONMENTAL RISKS AND REGULATORY RESPONSE TO MERCURY DENTAL FILLINGS"

DOMESTIC POLICY SUBCOMMITTEE
OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

WEDNESDAY, NOVEMBER 14, 2007
2154 RAYBURN HOB – 2:00 P.M.

Mr. Chairman,

Thank you for holding this vitally important hearing to examine the environmental impact of mercury dental fillings.

As you know, Congress has extensively examined the health effects of using mercury for dental fillings, but the environmental impact has received less attention.

Whereas significant controversy surrounds the conversation about whether mercury fillings are safe for humans, we have reached a consensus on the environmental aspect.

We know that mercury is a dangerous substance when introduced into the environment without necessary precautions—and we know that dental offices are the third largest user of mercury.

To be sure, the dental industry has been ahead of the curve in this arena.

The American Dental Association has provided its members with excellent guidance on how best to dispose of the substance.

I have some concern, however, about whether the government agencies responsible for overseeing mercury pollution have kept pace with private industry.

Specifically, the Environmental Protection Agency seems unwilling to recognize the clear findings of the latest science on the effects of mercury in the environment.

Further, the Food and Drug Administration has been negligent in its responsibility to analyze the impact for the purposes of approving dental mercury fillings as a medical device.

Thank you again, Mr. Chairman, for holding this important hearing.

I look forward to the testimonies of today's witnesses and I yield back the remainder of my time.

ELIJAH E. CUMMINGS
Member of Congress

CUMMINGS QUESTIONS

"ENVIRONMENTAL RISKS AND REGULATORY RESPONSE TO MERCURY DENTAL FILLINGS"

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
SUBCOMMITTEE ON DOMESTIC POLICY

Questions for EPA

M. King, I am concerned about the fact that the Environmental Protection Agency does not appear to recognize the environmental impact of dental mercury fillings. In fact, the only dental-specific initiative is the EPA's "gray bag" program, which is a voluntary program to encourage dentists to collect mercury before it enters the wastewater stream. The American Dental Association has promoted a more progressive approach than this.

- Why is the EPA behind the curve?

- Does the EPA regularly reassess its regulations when new technologies become available? If so, why has this not been the case for dental mercury fillings?

- What will the EPA do in the future with regards to dental fillings?

Questions for FDA

Dr. Alderson, I am concerned that the Food and Drug Administration has classified dental mercury fillings as a

medical device that is safe for human use, without appropriate consideration of the environmental impact.

- Is this standard practice? Does FDA usually approve medical devices without considering the environmental impact?

- After what you have heard today, do you think the FDA ought to reassess its policy?

What the ADA has done

Mr. Mackert, I am impressed with the fact that the American Dental Association has been very aggressive in its efforts to minimize the environmental impact of mercury dental fillings disposal—even more aggressive than the federal government, it would seem.

- Why has the ADA been attuned to this issue?

- To what extent are dentists in compliance with the ADA recommendations? Is statutory language necessary?

The impact of dental mercury fillings

I understand that while dental mercury fillings make up the third largest use of mercury, they represent a small proportion overall. Further, as new technologies arise, dentists are using mercury less and less. How large is this problem in real terms?

AN ASSESSMENT OF MERCURY IN THE FORM OF AMALGAM IN DENTAL WASTEWATER IN THE UNITED STATES

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Abstract. An assessment was conducted of the discharge from dental facilities of mercury in the form of amalgam to surface waters in the United States. Two pathways were examined – effluent from publicly owned treatment works (POTWs) and air emissions from sewage sludge incinerators (SSIs). The annual use of mercury in the form of amalgam in the U.S. is approximately 35.2 tons (31.9 metric tons). It was estimated that 29.7 tons (26.9 metric tons) of mercury in the form of amalgam are annually discharged to the internal wastewater systems of dental facilities during amalgam placements and removals. Based on the partial capture of this amalgam in conventional chair-side traps and vacuum filters, the discharge of mercury in the form of amalgam from dental facilities to POTWs was estimated to be 6.5 tons (5.9 metric tons). The discharge of mercury to surface water via POTW effluents and SSI emissions was estimated to total approximately 0.4 tons (0.4 metric tons). A cost-effectiveness analysis determined that the annual cost to the dental industry to reduce mercury discharges through the use of amalgam separators would range from $380 million to $1.14 billion per ton.

Keywords: amalgam separator, biosolids, dental amalgam, dentistry, mercury, publicly owned treatment works, wastewater

1. Introduction

Amalgams (often referred to as silver fillings) have been the primary restorative material used by dentists in the United States for over 150 years (Yuming *et al.*, 1998). Amalgam has historically contained approximately 50% by weight mercury (Anusavice, 2003). Due to the growing concern regarding mercury as a persistent, bioaccumulative, and toxic (PBT) substance, the use of mercury in many industries and products in the United States has decreased substantially since the early 1980s (USEPA, 1997; Sznopek and Goonan, 2000). Although the available data indicate that the use of mercury in dental amalgams has also decreased during this period, the dental industry remains one of the largest consumers of mercury in the United States (ADA, 2002; Sznopek and Goonan, 2000).

The placement and removal of dental amalgams generates small amounts of amalgam particles in a dental facility's wastewater. This wastewater flows through a chair-side trap and, in the majority of dental facilities, a filter that protects the vacuum pump, prior to being discharged. Although chair-side traps and vacuum

filters capture amalgam particles in the dental wastewater stream, some particles remain in the wastewater (MCES and MDA, 2001). Because the majority of dental facilities in the United States are connected to sewerage systems, this wastewater is primarily received and managed by publicly owned treatment works (POTWs). The concern regarding mercury as a PBT in the United States has prompted reductions in mercury discharges to surface waters from point sources, including POTWs. Therefore, the dental industry is currently facing increasing regulatory scrutiny at the national, state, and local levels regarding the mercury content of dental wastewater (AMSA, 2002).

Through the early 1990s, little data existed to accurately estimate the use of amalgam in dentistry and the resulting mercury content of dental wastewater. Researchers noted that the relative contribution of dental offices to the mercury load is not well documented and that the data on the amount of the different mercury contaminated waste categories produced in dentistry are sparse (Fan *et al.*, 1997; Arenholt-Bindslev and Larsen, 1996). Because of this lack of data, researchers recognized that initial assessments were dominated by rough estimates and assumptions (Arenholt-Bindslev, 1992; Arenholt-Bindslev and Larsen, 1996). Over the past several years, a number of studies have been conducted on the use of mercury in the dental industry and the attendant mercury content of dental wastewater, resulting in the generation of a substantial volume of data.

The objectives of the present study were to assess, through a comprehensive review of the available data, (1) the quantity of mercury used in amalgam in the United States, (2) the amount of mercury in the form of amalgam discharged from dental facilities to surface waters via POTW effluent and mercury emitted from sewage sludge incinerators (SSI), and (3) the cost-effectiveness of reducing these discharges through the installation and use of amalgam separators in dental facilities. This study was limited to the discharge of mercury in the form of amalgam to surface waters via the primary pathways of POTW effluent and mercury emissions from SSIs.

It was recognized that additional indirect pathways may exist for the discharge of mercury to the environment due to its use in dental amalgam. Other indirect pathways may include the volatilization of mercury from land-applied biosolids and the leaching of mercury from landfills. The scope of the present assessment was specifically to examine the discharge of mercury in POTW effluent and emissions from SSIs. However, in the course of conducting this assessment, a number of studies were identified that the authors believe provide initial or preliminary data to support that these indirect pathways are minimal sources of mercury.

Key among these is the highly bound form of mercury in the amalgam, which also plays a role in the calculations presented throughout this publication. The calculations presented herein assume that mercury remains in the form of amalgam throughout the wastewater conveyance and treatment process. This assumption is based on studies conducted by Kunkel *et al.* in 1996 and Okabe *et al.* in 2003, among others. Kunkel *et al.* studied the potential release of mercury from amalgam in aerobic and anaerobic wastewater treatment systems and did not detect soluble

mercury, even when amalgam particles were introduced into the systems at concentrations on the order of 1,000 times the expected concentration of POTW influents. Okabe *et al.* evaluated the release of mercury from amalgam into continuously replenished water and acidic solutions (pH = 1) over 1 month and identified slow release rates that decreased exponentially over time. Preliminary calculations based on these release rates and the anticipated size and shape of discharged amalgam particles indicate that an insignificant fraction of mercury is released from dental amalgam in the tested solutions. Although more work is needed in this area, the authors have reasonably assumed that that the significant fraction of mercury in dental amalgam remains amalgamated through the wastewater conveyance and treatment process. As a result, mercury in the form of amalgam particles that are land-applied with POTW biosolids or landfilled are still relatively immobile as compared to many other sources of mercury (for example, background levels of mercury in soils).

Beyond the highly bound form of the mercury in the amalgam particles, other factors are likely to limit the quantity of mercury reaching surface waters from land-applied and landfilled amalgam particles. These include the reaction and fixation of any mercury released from amalgam particles with other compounds in soil and waste matrices, the application of additional layers of biosolids over land-applied amalgam particles over time, and the containment provided by landfill covers and leachate collection systems. Accordingly, the authors focused on direct discharges of mercury in the form of amalgam to surface waters and the incineration and ultimate deposition of mercury from amalgam particles present in biosolids as the primary pathways during this assessment.

2. Use, Capture, and Discharge of Mercury in the Form of Amalgam

2.1. Use of Mercury in the Form of Amalgam

The assessment focused on identifying and evaluating the mercury discharges to surface waters in the United States from the use of amalgam by general dentists and specialists in private practice. According to surveys conducted by the ADA, the United States dental industry comprised 166,611 active, licensed dentists in 2001. Approximately 92%, or 153,116, of these dentists were in private practice, with the remainder consisting of professors, graduate students, and federal employees. General dentists account for 122,320 of the dentists in private practice (ADA, 2002). Surveys conducted by product manufacturers indicate that approximately 76% of general dentists reported using amalgam in 2001, down from 88% in 1997 (White, 2001). It was estimated, therefore, that 92,957 (76% of 122,320) general dentists in private practice in the United States currently use amalgam.

According to the ADA, pediatric dentists, prosthodontists, and endodontists were the only specialists that reported using amalgam in 2001. These dentists

constituted 10,739 of the 30,804 specialists in private practice in the United States (ADA, 2002). No data were available regarding the fraction of these specialists that used amalgam. It was therefore conservatively assumed that all 10,739 of these specialists used amalgam in their practice.

The ADA estimated that a total of approximately 71 million restorations were conducted using amalgam in 1999, down 29% from the 99.5 million amalgam restorations estimated by the ADA in 1990 (Berthold, 2002). The ADA's estimate correlated well with most recent estimates of mercury use in dentistry conducted by the USGS, which identified a decrease of 30% from 1990 to 1996 (Sznopek and Goonan, 2000). According to the ADA, general dentists performed approximately 66.3 million of the 71 million amalgam procedures conducted in 1999, and pediatric dentists, prosthodontists, and endodontists performed the remaining 4.7 million procedures (Berthold, 2002).

Based on the data presented above, it was estimated that general dentists that use amalgam annually perform an average of 713 amalgam placements per dentist, and the pediatric dentists, prosthodontists, and endodontists annually perform an average of 440 amalgam placements per specialist. The amalgam placement rate estimated for general dentists correlated well with data collected in the early to mid-1990s by various domestic municipalities, including the Municipality of Metropolitan Seattle, Washington; the Metropolitan Council Environmental Services (MCES) in Minneapolis-St. Paul, Minnesota; and the Western Lake Superior Sanitary District (WLSSD) in Duluth, Minnesota. The annual placement rates reported by these municipalities for general dentists averaged approximately 710 amalgam placements per general dentist when adjusted for the decrease in amalgam use throughout the 1990s (Municipality of Metropolitan Seattle, 1993; MCES, 1995; WLSSD, 1992). No comparable data for specialists were identified.

Stone *et al.* (2001) reported the average mercury content per double spill of amalgam to be approximately 450 mg. Combined with the 71 million restorations reported by the ADA in 1999, it was estimated that the United States dental industry currently uses approximately 35.2 tons (31.9 metric tons) of mercury in the form of amalgam each year. This quantity correlates well with the USGS' most recent estimate of mercury consumption by the dental industry of 34.2 tons (31 metric tons) in 1996 (Sznopek and Goonan, 2000). Given the decrease in amalgam use in recent years, it was recognized that the use of 35.2 tons (31.9 metric tons) provided a conservative, upper-bound estimate of the current, annual consumption of mercury by the dental industry in the United States.

2.2. Release of Mercury in the Form of Amalgam to Dental Wastewater

The mercury used as amalgam by the dental industry is primarily placed in teeth as a restorative material. However, dentists commonly triturate excess amalgam

during each procedure to ensure that sufficient mixed amalgam is available to complete the restoration of the tooth prior to the hardening of the amalgam. The leftover amalgam from this process is often identified as "non-contact" amalgam because it has not been in contact with a patient's mouth. The Florida Center for Solid and Hazardous Waste Management (1997); Arenholt-Bindlsev (1992); and Barron (2001) estimated that 15% to 50% of the amalgam triturated for placement is collected by dentists and recycled as non-contact amalgam. Barron's estimate of 25% was used as an approximate average of the percentages reported in the literature. Applying this percentage, it was estimated that 8.8 tons (8 metric tons) of the mercury used by the dental industry in the United States becomes non-contact amalgam. The remaining approximately 26.4 tons (24 metric tons) of mercury is used in amalgam placements, for an average of approximately 340 mg of mercury used per placement. Barron (2001) estimated that 9% of amalgam, or about 30 mg of mercury per placement, is ultimately discharged to the internal wastewater systems of dental facilities during amalgam placements, such that only 310 mg is actually placed in the tooth. This percentage was applied to the estimated 26.4 tons (24 metric tons) of mercury used in amalgam placements to estimate that approximately 2.4 tons (2.2 metric tons) of mercury are annually discharged as amalgam particles to the internal wastewater systems of dental facilities in the United States during amalgam placements.

Recent data were not available regarding the number of amalgams removed by the dental industry. However, five municipal studies that had evaluated amalgam removal rates in the early to mid-1990s were identified, including the three studies noted previously by the Municipality of Metropolitan Seattle, Washington (1993); MCES (1995); and WLSSD (1992), and two studies conducted by the City of San Francisco (Rourke, 1993) and the Massachusetts Water Resources Authority (Bering, 1997). These studies reported amalgam removal rates on daily and weekly bases; therefore, data regarding the work schedule of the dental industry was obtained from the ADA in order to compare annual rates. For 1999, the ADA reported that the average dentist spent 1,600 h per year conducting patient examinations and restorative procedures, and worked an average of 48 weeks per year (ADA, 2001). Normalizing the data from the available studies, the average amalgam removal rate was approximately 710 removals per general dentist per year. Data were not available regarding the removal rate for specialists. It was estimated, therefore, that specialists remove amalgams at a rate similar to the placement rate of approximately 440 amalgams per specialist per year. Further, it was assumed that all of the general dentists, pediatric dentists, prosthodontists, and endodontists in the United States removed amalgam in their practices. Considering the numbers of active general dentists and specialists estimated above and their respective removal rates, it was estimated that approximately 91.5 million amalgam removals are currently conducted in the United States each year.

The USGS estimated the average life of a dental amalgam as approximately 8–9 years in its evaluations of the cycling of mercury as a commodity in the United

States (Sznopek and Goonan, 2000). As a result, it was anticipated that the amalgam placement rates of 1990 would generally approximate the amalgam removal rates for 1999 (i.e., the typical amalgam placed in 1990 would likely be removed in approximately 1999 for replacement with an amalgam or composite). According to the ADA, 99.5 million amalgam placements were conducted by general dentists in 1990 (Berthold, 2002). This generally correlates with the 91.5 million amalgam removals estimated from the municipal studies.

The mass of amalgam originally placed in a tooth will be greater than that ultimately removed from the tooth at the end of the amalgam's useful life due to losses associated with wear. Barron (2001) estimated that 90% of the mercury originally placed in amalgam is present at the time of removal. With an estimated amalgam life of 8–9 years, this percentage was in general agreement with the annual mercury loss rates predicted by Skare (1995) and the United States Agency for Toxic Substances and Disease Registry (ATSDR, 1999). When applied to the estimated average mass of mercury originally placed as amalgam (310 mg), this percentage indicated that the average amalgam would contain approximately 280 mg of mercury when removed from the tooth. This estimate was slightly lower than the results of a study of amalgam conducted by Watson *et al.* (2002). During the study, amalgam was removed from 152 human and dentoform teeth. Although the age of the removed amalgam was not identified during the study, the data indicated that an average of approximately 320 mg mercury was present in each removed amalgam.

Each amalgam currently removed by dentists in the United States was estimated to contain an average of 300 mg of mercury based on the studies conducted by Barron (2001) and Watson *et al.* (2002). Combined with the estimated 91.5 million amalgam removals conducted each year, it was estimated that approximately 30.3 tons (27.5 metric tons) of mercury in the form of amalgam are removed annually. Barron (2001) estimated that 90% of mercury in the form of amalgam is released to the internal wastewater systems of dental facilities during the removal procedures. Therefore, it was estimated that approximately 27.2 tons (24.7 metric tons) of mercury in the form of amalgam are annually discharged to the internal wastewater systems of dental facilities during removal procedures.

By summing the discharge estimates for both amalgam placements (2.4 tons or 2.2 metric tons) and removals (27.3 tons or 24.8 metric tons), it was estimated that a total of approximately 29.7 tons (26.9 metric tons) of mercury in the form of amalgam are discharged to the internal wastewater systems of dental facilities in the United States each year.

2.3. Capture of Mercury in the Form of Amalgam in Dental Facilities

Dental wastewater generated from restorative procedures flows through a chair-side trap and, in the majority of dental facilities, a filter that protects the vacuum pump,

prior to discharge (MCES and MDA, 2001). Drummond *et al.* (1995) identified a capture efficiency for chair-side traps of 60% based on sampling data, while Naleway *et al.* (1994) estimated that chair-side traps capture 75% of amalgam in dental wastewater based on particle size distribution studies. An average chair-side trap capture efficiency of 68% was selected based on the capture efficiencies reported by these studies.

Based on studies conducted in Minneapolis-St. Paul, Minnesota, the MCES and MDA reported that approximately 71% to 88% of the surveyed dental facilities were equipped with vacuum filters (MCES, 1995; MCES and MDA, 2001). These estimates are similar to those reported in a study conducted by Watson *et al.* (2002), which estimated that approximately 90% to 95% of dental facilities in Ontario, Canada were equipped with vacuum filters. Approximately 80% of the dental facilities in the United States were estimated to be equipped with vacuum filters based on the average of the results of the MCES and MDA studies.

In 2001, the MCES and MDA conducted a detailed evaluation of the efficiency of vacuum filters in capturing amalgam particles that pass a chair-side trap, and identified an overall capture efficiency of 42%. Particle size distribution studies conducted by Batchu *et al.* (1995) and Cailas *et al.* (1994) indicated that capture efficiencies for vacuum filters range from 25% to 50%. An average vacuum filter capture efficiency of 40% was estimated based on the average of the capture efficiencies identified from these studies.

The industry-wide capture efficiency of mercury in the form of amalgam was calculated using the data identified in the literature for the capture of chair-side traps and vacuum filters. Dental facilities equipped with both a chair-side trap and vacuum filter were estimated to capture approximately 81% of the amalgam particles in dental wastewater due to the combined capture of both devices, while dental facilities equipped with only a chair-side trap were estimated to capture 68% of the amalgam particles. An estimated 80% of the dental facilities in the United States are equipped with both chair-side traps and vacuum filters and 20% are equipped with chair-side traps only. A weighted average was utilized to estimate an industry-wide capture efficiency for dental facilities in the United States of approximately 78%. This capture efficiency assumes that dentists manage chair-side traps and vacuum filters appropriately, as has been emphasized by the ADA in recent years through education and outreach efforts and recently updated ADA best management practices for amalgam waste (ADA, 2004).

The industry-wide capture efficiency of 78% was applied to the estimated 29.7 tons (26.9 metric tons) of mercury annually discharged in the form of amalgam to the internal wastewater systems in dental facilities to estimate the mass of mercury captured each year. Based on this capture efficiency, it was estimated that chair-side traps and vacuum filters capture approximately 23.2 tons (21 metric tons) of mercury in the form of amalgam, and that the dental industry discharges

approximately 6.5 tons (5.9 metric tons) of mercury in the form of amalgam each year.

2.4. Capture of Mercury in the Form of Amalgam in POTWs

In the United States, the wastewater generated by dental facilities is discharged to either POTWs or septic systems. The Maine Dental Association recently conducted a survey of its constituents, and estimated that 86% of the dentists in Maine discharged wastewater to POTWs and that the remainder is discharged to septic systems (F. Miliano, personal communication). Little additional data regarding this distribution was identified from a review of the literature. In order to be conservative in the estimate of mercury loading to POTWs, it was assumed that all of the dental facilities in the United States discharge to POTWs.

A review of the open literature was conducted to identify POTW capture efficiencies for mercury and mercury in the form of amalgam. Although substantial data were identified regarding the capture of mercury by POTWs, little data was identified for the capture of mercury in the form of amalgam. The capture of a particle, such as amalgam, by a POTW is largely a function of particle density and size (Tchobanoglous and Burton, 1991). The density of amalgam is approximately 10 times that of water (Fan *et al.*, 2002b). Analyses of the particle size distribution of amalgam generated from dental procedures conducted by the American, Dutch, and German Dental Associations in support of the development of a representative amalgam sample for International Organization for Standardization (ISO) Standard 11143 have indicated that amalgam particles are generally larger than the other forms of mercury captured in POTWs. These analyses determined that approximately 98% of the particles generated from amalgam placements and removals are larger than 5 μm (ISO, 1999). In comparison, a study of mercury entering a POTW in St. Paul, Minnesota reported that 85% of the mercury entering the POTW from all sources was associated with particle sizes greater than 5 μm (Balogh and Liang, 1995). Although these data indicate a higher POTW capture efficiency for mercury in the form of amalgam than for other forms of mercury, it was conservatively estimated that all forms of mercury are captured at the same efficiency.

A number of recent studies have reported mercury capture efficiencies for POTWs ranging from 95% to 99%. The most comprehensive of these studies was conducted by AMSA (2002), and included of a review of 15 POTWs ranging in capacity from approximately 4 million gallons per day (MGD) to 375 MGD. The AMSA study identified an average mercury capture efficiency for POTWs of 95%. Independent studies conducted by the MCES in 1995 and 1998 identified mercury capture efficiencies for three POTWs of 96%, 98%, and 99%, respectively (Balogh and Liang, 1995; Balogh and Johnson, 1998). Based on the comprehensive data reported in the AMSA study, an average POTW capture efficiency of 95% for mercury and mercury in the form of amalgam was used.

2.5. DISCHARGE OF MERCURY TO SURFACE WATERS

The average POTW capture efficiency of 95% was applied to the estimated 6.5 tons (5.9 metric tons) of mercury annually discharged in the form of amalgam to POTWs to estimate that approximately 6.2 tons (5.6 metric tons) of mercury in the form of amalgam are annually captured by the POTWs. Approximately 0.3 tons (0.3 metric tons) of mercury in the form of amalgam are discharged by POTWs to surface waters.

Particles captured in POTWs are either removed with the grit solids or biosolids. Grit solids are typically removed from the wastewater stream through the use of horizontal-flow, aerated, or vortex grit chambers (Tchobanoglous and Burton, 1991). A study conducted by the MCES in 1998 identified mercury capture efficiencies for aerated and vortex grit chambers of 7% and 48%, respectively (Balogh and Johnson, 1998). These data were compared with a theoretical capture analysis for amalgam of approximately 20% in a horizontal-flow grit chamber based on design specifications reported by Tchobanoglous and Burton (1991) and the amalgam particle size distribution identified by ISO (1999). Based on these data and personal communication from AMSA (K. Kirk, personal communication), it was estimated that 25% of mercury in the form of amalgam captured by POTWs is transferred to the grit solids, and that 75% is transferred to the biosolids. This distribution was applied to the estimated 6.2 tons (5.6 metric tons) of mercury in the form of amalgam that is captured by POTWs to estimate that approximately 1.6 tons (1.5 metric tons) of mercury is transferred to the grit solids and 4.6 tons (4.2 metric tons) to the biosolids.

Approximately 22% of the biosolids generated in the United States are managed through incineration in SSIs (USEPA, 1999). Applying this percentage, it was estimated that approximately 1 ton (0.9 metric ton) of mercury in the form of amalgam present in biosolids is annually incinerated by SSIs. The emissions from SSIs are treated by wet scrubber systems to control particulate emissions, and capture some particulate forms of mercury. From approximately 1988 to 1995, the United States Environmental Protection Agency (USEPA) developed representative emissions factors for SSIs, commonly referred to as AP-42 factors, the average of which represented a mercury capture efficiency for SSI emission controls of about 79% (USEPA, 1995). This capture efficiency was used for SSIs to estimate that approximately 0.2 tons (0.2 metric tons) of mercury from dental amalgam is annually emitted to the atmosphere from SSIs as a result of the incineration of biosolids.

In 1997, the USEPA estimated that approximately one-third of the mercury emissions originating from the United States were deposited within the country (USEPA, 1997). This percentage was used to estimate that less than 0.1 tons (0.1 metric tons) of the mercury is annually deposited in the United States from the incineration of biosolids containing amalgam. It was conservatively estimated that all this mercury will enter surface waters. This deposition estimate was combined

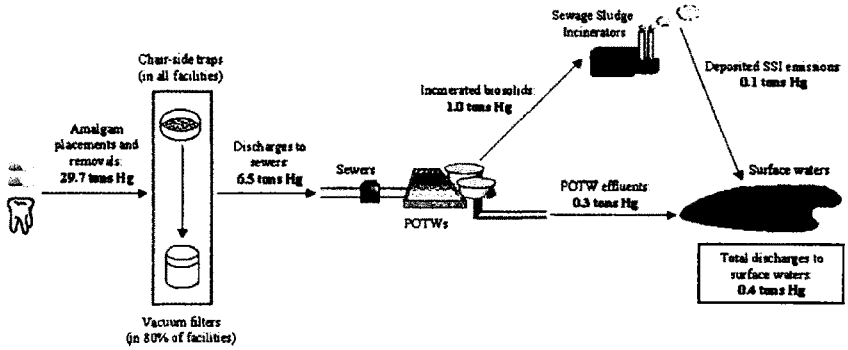

Figure 1. Summary of the fate of mercury used as amalgam in the United States.

with the discharge estimate for POTW effluents of approximately 0.3 tons (0.3 metric tons) to estimate that approximately 0.4 tons (0.4 metric tons) of mercury from dental facilities are annually entering surface waters in the United States via POTW effluents and SSI emissions.

Figure 1 summarizes the results of this assessment.

3. Cost-Effectiveness Analysis

The cost-effectiveness analysis focused on identifying the unit cost of reducing the discharge of mercury through the use of amalgam separators at dental facilities. The costs associated with the purchase, installation, and operation of amalgam separators were identified from a review of recent studies, as well as vendor quotes. The effectiveness of separators was evaluated as the incremental capture attained by the separator beyond that already attained by chair-side traps and, where present, vacuum filters. The behavior of the amalgam fraction not captured by the separators in the receiving POTWs was evaluated in order to determine the actual reduction in discharges to surface waters via the POTW effluent and SSI emission pathways. Due to the limited data regarding this behavior, two scenarios of incremental POTW capture were considered in the final cost-effectiveness calculations.

3.1. Cost of Amalgam Separation Equipment

From 2000 to 2002, the ADA, the MCES and MDA, and the Palo Alto RWQCP conducted studies of the costs associated with utilizing amalgam separation equipment in dental facilities in the United States (Fan *et al.*, 2002a; MCES and MDA, 2001; Johnson, 2000). The results of these studies were reviewed and supplemented with commercial vendor quotes to estimate the current cost of purchasing and operating

TABLE I
Summary of amalgam separator purchase and operating costs

Vendor	Model	Type	Purchase price	Annual operating costs
AB Dental Trends, Inc.	890–1000	Sedimentation, filtration, ion exchange	$1,190	$476
	890–4000	Sedimentation, filtration, ion exchange	$1,650	$610
	890–6000	Sedimentation, filtration, ion exchange	$667	$441
	A 1000	Sedimentation	$750	$1,150
Air Techniques, Inc.	Durr 7800/7801	Centrifuge	$4,000	$495
Avprox, Inc.	Asdex filter	Filtration	$215	$1,360
DRNA	BullfroHg	Sedimentation	$0	$1,200
	MRU	Sedimentation, filtration, ion exchange	$0	$1,800
Maximum Separation Systems, Inc.	MSS 2000	Sedimentation	$3,000	$596
Metasys	ECO II	Sedimentation	$260	$428
R&D Services	Amalgam collector	Sedimentation	$350	$540
Rebec Environmental	RME 2000	Sedimentation	$1,895	$474
SolmeteX	Hg5	Sedimentation, filtration, ion exchange	$695	$496

an amalgam separator for the average dental facility in the United States. Table I summarizes the separator purchase and operating costs estimated for the cost-effectiveness analysis.

Based on a review of the cost studies and vendor quotes, it was estimated that the cost to purchase and install an amalgam separator(s) would typically range from roughly $1,000 to $2,000 per dental facility. It was estimated that the cost to operate the separator(s) would typically range from $700 to $1,000 per dental facility per year.

In order to prepare a conservative estimate of the nationwide costs associated with amalgam separators, only the installation and operation of separators in those dental facilities operated by general dentists were considered in the cost calculations. In 2001, the ADA reported that approximately 66% of all dentists in private practice in the United States maintained a solo practice, and that the remaining 34% of dentists worked in practices staffed by an average of 2.9 dentists per facility (ADA, 2001). These percentages were applied to the 122,320 general dentists that manage amalgam (through placements and/or removals) to estimate that amalgam procedures are currently conducted in approximately 95,066 dental facilities in the United States.

The range of costs for the purchase and installation of amalgam separators of approximately $1,000 to $2,000 per dental facility were applied to the estimated 95,066 dental facilities in the United States to calculate an estimated capital cost for the installation of amalgam separators in these facilities of approximately $95 million to $190 million. Similarly, the operation and maintenance of separators in these dental facilities was estimated to require approximately $67 million to $95 million per year. For the purposes of the cost-effectiveness analysis, the capital cost was spread evenly over a 10-year assumed separator life to estimate an annual cost of approximately $76 million to $114 million for the purchase, installation, and operation of amalgam separators in dental facilities in the United States.

3.2. Performance of Amalgam Separators

The MCES and MDA recently completed a 2-year study on the capture efficiency of amalgam separators in several dental facilities located in Minnesota. This study identified incremental capture efficiencies for amalgam separators of approximately 94% beyond the capture already achieved in facilities equipped with chair-side traps and 89% beyond the capture achieved in facilities equipped with both chair-side traps and vacuum filters (MCES and MDA, 2001).

The ADA recently conducted a bench study of the amalgam capture efficiency of 12 amalgam separators in accordance with ISO Standard 11143. From the study, the ADA identified an average overall amalgam capture efficiency of 99%. However, the amalgam sample utilized in these studies was prepared in accordance with the ISO standard, and consisted of amalgam particles ranging up to 3,150 μm in size, 60% by mass of which were greater than 500 μm in diameter (Fan *et al.*, 2002b; ISO, 1999). As noted, dental facilities in the United States are equipped with chair-side traps that have pore sizes of 700 μm, and many are also equipped with vacuum filters that have pore sizes ranging from 210 μm to 400 μm. Therefore, had the ADA's tests been conducted in actual dental facilities, much of the ISO amalgam sample utilized in the tests would have been captured by the chair-side traps and vacuum filters prior to entering the amalgam separators. As a result, the incremental amalgam capture efficiency achieved from the use of the separators in these dental facilities would be less than 99%.

In order to determine the incremental capture efficiency of the amalgam separators tested by the ADA under ISO Standard 11143, the fate of a 100-mg representative ISO amalgam sample was considered. As discussed previously, it was estimated that 80% of the dental facilities in the United States are equipped with both chair-side traps and vacuum filters, for which average capture efficiencies of 68% and 40%, respectively, were identified in the open literature. In those dental facilities equipped with both a chair-side trap and vacuum filter, an estimated 68 mg of the ISO amalgam sample would be captured in the chair-side trap, with approximately 32 mg passing on to the vacuum filter. The incremental capture of the vacuum filter, at 40%, would retain approximately 13 mg of the 32 mg of amalgam

that passed the chair-side trap. Therefore, an estimated 81 mg of the original amalgam sample would be captured from the combination of the chair-side trap and vacuum filter. The remaining 19 mg of the amalgam sample would pass on to the amalgam separator, which would capture some portion of the 19 mg. According to the ADA sampling results, if the entire 100 mg sample were run through the amalgam separator at the average 99% ISO capture efficiency, the separator would not have captured 1 mg of the sample. This 1 mg would consist of the smallest and most difficult amalgam particles to capture, and, having passed the chair-side trap and vacuum filter, would be part of the 19 mg left under this illustration. Therefore, the ADA data indicate that, in a typical dental facility equipped with both a chair-side trap and vacuum filter, the average amalgam separator would capture 18 mg of the 19 mg of amalgam that reached the device, for an incremental capture efficiency of approximately 95%. Similarly, in the estimated 20% of dental facilities that are only equipped with chair-side traps, approximately 68 mg of the ISO amalgam sample would be captured in the chair-side trap, with about 32 mg passing on to the amalgam separator. In these dental facilities, the separator would capture 31 mg of the 32 mg that reached the device, for an incremental capture efficiency of approximately 97%.

Based on the MCES and MDA study and the ADA bench tests, an average incremental capture efficiency for the use of amalgam separators of approximately 95% was used in the cost-effectiveness analysis. At this efficiency, amalgam separators would reduce the estimated discharge of 6.5 tons (5.9 metric tons) of mercury in the form of amalgam to POTWs in the United States to approximately 0.3 tons (0.3 metric tons). As noted, this 0.3 tons would consist of the smallest and most difficult amalgam particles to capture. Amalgam separators primarily employ the same physical processes to remove amalgam particles as the processes utilized at POTWs to remove particulates (i.e., sedimentation and centrifugation), and can generally be expected to remove the same types of amalgam particles. Indeed, the amalgam capture efficiencies identified for both POTWs and separators from the open literature are both approximately 95%. Therefore, it is unlikely that a significant amount, if any, of the 0.3 tons of mercury in the form of amalgam particles not captured by amalgam separators would subsequently be captured by the downstream POTWs (i.e., the 0.3 tons of mercury in the form of amalgam not captured by the separators would consist of the same 0.3 tons that is already estimated not to be captured by POTWs). Under this scenario, the only benefit attained through the use of separators would be the virtual elimination of the deposition to surface waters of an estimated 0.1 tons (0.1 metric tons) of mercury from the incineration of amalgam in SSIs in the United States, at an estimated annual cost of reduction of approximately $760 million to $1.14 billion per ton.

A second scenario of the potential reductions in mercury discharges from the use of amalgam separators was considered for the purposes of the cost-effectiveness analysis. AMSA is currently conducting a study to evaluate whether separators have an effect on the mercury discharged in POTW effluents. From this study, AMSA

has generated some preliminary data regarding average mercury concentrations in the effluent from the POTWs operated by the City of Wichita, Kansas. Although the data appear relatively inconclusive, AMSA has reported that the use of amalgam separators reduced mercury effluent concentrations from the City of Wichita's POTWs by approximately 29% (C. Hornback, personal communication). Despite the preliminary nature of this data, a hypothetical situation was considered for the cost-effectiveness analysis in which the use of amalgam separators decreased the mercury concentrations in the effluent from POTWs nationwide by approximately 30%. Assuming this hypothetical situation, the mercury discharges from POTWs to surface waters in the United States would be reduced by at most 0.2 tons (0.2 metric tons) per year, at an annual cost of reduction of approximately $380 million to $570 million per ton.

4. Discussion

The results of the present study correspond well with independent estimates of mercury use by the dental industry in the United States, the mercury discharged in the form of amalgam to POTWs, and the mercury emitted from SSIs as a result of the incineration of biosolids. The estimate of the use of mercury in amalgam by the dental industry of 35.2 tons (31.9 metric tons) per year from this assessment generally agrees with the USGS' most recent estimate of 34.2 tons (31 metric tons) per year. It is noted, however, that the USGS' estimate was prepared in 1996, while the estimate from the present study was intended to represent the current use of mercury in amalgam. Due to the decreased use of amalgam in the 1990s, the 35.2-ton (31.9-metric ton) estimate from this assessment may be an overly conservative one.

The estimate that approximately 6.5 tons (5.9 metric tons) of mercury in the form of amalgam is discharged to POTWs from dental facilities in the United States generally agrees with the results of POTW influent studies conducted by AMSA in 2002 and the USEPA in 1996. The AMSA study identified an average mercury concentration in POTW influents of approximately 225 ng/L (AMSA, 2002). The USEPA estimated that, in 1996, the total wastewater flow to POTWs was approximately 32 billion gallons per day (1.4 million liters per second) (USEPA, 1999). Based on forecasting methods used by the USEPA for the Clean Water Needs Survey, it was estimated that the current flow of wastewater to POTWs has increased since 1996 to approximately 36 billion gallons per day (1.6 million liters per second). At an average mercury concentration of approximately 225 ng/L, this flow rate equates to a total mercury load to POTWs of approximately 12.3 tons (11.2 metric tons) per year. At approximately 6.5 tons (5.9 metric tons), the present study's estimate of the discharge of mercury as amalgam from dental facilities to POTWs corresponds to approximately half of the estimated total mercury load to POTWs in the United States. This percentage is slightly higher than the dental contribution estimated by AMSA of approximately 35 to 40% (K. Kirk, personal

communication). This is to be expected considering the conservative assumptions used in this assessment, particularly that all dental facilities discharge to POTWs.

Similarly, the estimate that approximately 0.3 tons (0.3 metric tons) of mercury in the form of amalgam is annually discharged to surface waters in the United States via POTW effluents also agrees with the data collected during AMSA's 2002 study. AMSA identified an average mercury concentration in POTW effluents of approximately 12 ng/L. When applied to the estimated wastewater flow rate of 36 billion gallons per day, this equates to a total discharge of mercury to surface waters via POTW effluents of approximately 0.6 tons (0.5 metric tons). When an estimated dental contribution of approximately half is applied to this total discharge estimate, the resulting 0.3 tons (0.3 metric tons) attributable to dental facilities agrees with the 0.3-ton discharge estimate from the present study.

Finally, the estimate of the emission of mercury as amalgam from SSIs also correlates well with estimates of total SSI emissions. The USEPA estimated that a total of approximately 0.9 tons (0.8 metric tons) of mercury were emitted from SSIs in 1994 (USEPA, 1997). At that time, the USEPA estimated the mercury concentration of biosolids as approximately 5.2 parts per million (ppm) (USEPA, 1995). According to AMSA, the concentration of mercury in biosolids currently ranges from approximately 1 ppm to 3 ppm (K. Kirk, personal communication). Assuming an average mercury concentration of approximately 2 ppm, the total mercury emissions from SSIs can be estimated at approximately 0.4 tons (0.4 metric tons) of mercury per year. When a dental contribution of approximately half is applied to this total emissions estimate, the resulting 0.2 tons (0.2 metric tons) of emissions associated with the use of mercury as amalgam agrees with the 0.2-ton emissions estimate from the present study.

Figure 2 illustrates the correlation of the results of this assessment with the data obtained from the AMSA and USEPA studies.

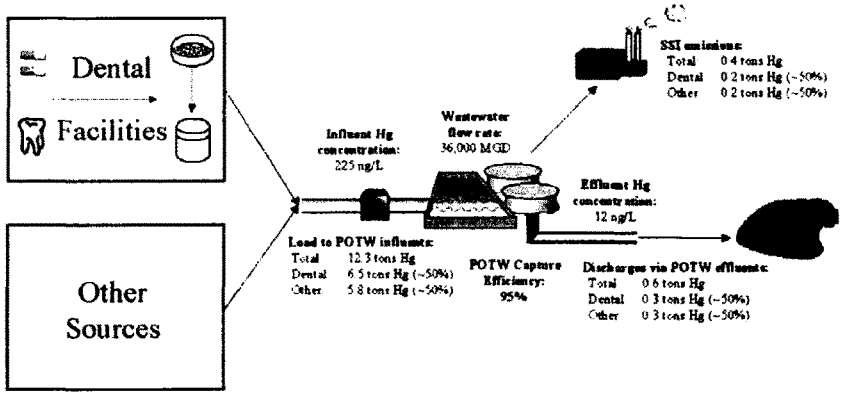

Figure 2. Summary of the flow of total mercury and mercury from dental amalgam in the United States.

5. Conclusions

An assessment was conducted to quantify the use of mercury in the form of amalgam by the dental industry in the United States and to estimate the discharge of that mercury from dental facilities to surface waters via POTW effluents and SSI emissions. The annual use of mercury as amalgam by the dental industry in the United States was estimated at approximately 35.2 tons (31.9 metric tons). It was estimated that approximately 29.7 tons (26.9 metric tons) of mercury in the form of amalgam are annually discharged to the internal wastewater systems of dental facilities during amalgam placements and removals. Due to the partial capture of this amalgam in conventional chair-side traps and vacuum filters, the discharge of mercury in the form of amalgam from dental facilities to POTWs was estimated at 6.5 tons (5.9 metric tons), or approximately half of the estimated total mercury load to POTWs throughout the United States. The discharge of mercury from dental facilities to the surface waters of the United States via POTW effluent and SSI emissions were estimated to total approximately 0.4 tons (0.4 metric tons). When approximately half of the total mercury in POTW influents, POTW effluents, and SSI emissions was attributed to wastewater discharges associated with the use of mercury as amalgam in dental facilities, the results of the present study correlated well with data from studies conducted by AMSA and the USEPA. A cost-effectiveness analysis based on these results determined that the annual unit cost to reduce these mercury discharges through the use of amalgam separators would range from $380 million to $1.14 billion per ton.

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If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through *http://www.regulations.gov*, your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: October 24, 2007.

Richard B. Ossias,

Associate General Counsel.

[FR Doc. E7–21321 Filed 10–29–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2006–0771; FRL–8486–3]

RIN 2040–AE89

Notice of Availability of Preliminary 2008 Effluent Guidelines Program Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability of Preliminary 2008 Effluent Guidelines Program Plan.

SUMMARY: EPA establishes national, technology-based regulations known as effluent guidelines and pretreatment standards to reduce pollutant discharges from categories of industry discharging directly to waters of the United States or discharging indirectly through Publicly Owned Treatment Works (POTWs). The Clean Water Act (CWA) sections 301(d), 304(b), 304(g), and 307(b) require EPA to annually review these effluent guidelines and pretreatment standards. This notice presents EPA's 2007 review of existing effluent guidelines and pretreatment standards. It also presents EPA's evaluation of indirect dischargers without categorical pretreatment standards to identify potential new categories for pretreatment standards under CWA sections 304(g) and 307(b). This notice also presents the Preliminary 2008 Effluent Guidelines Program Plan ("preliminary 2008 Plan"), which, as required under CWA section 304(m), identifies any new or existing industrial categories selected for effluent guidelines rulemaking and provides a schedule for such rulemaking. CWA section 304(m) requires EPA to biennially publish such a plan after public notice and comment. EPA is soliciting comment on its preliminary 2008 Plan and on its 2007 annual review of existing effluent guidelines and pretreatment standards and industrial categories not currently regulated by effluent guidelines and pretreatment standards.

DATES: If you wish to comment on any portion of this notice, EPA must receive your comments by December 31, 2007.

ADDRESSES: Submit your comments, data and information for the 2007 annual review of existing effluent guidelines and pretreatment standards and the preliminary 2008 Plan, identified by Docket ID No. EPA–HQ–OW–2006–0771, by one of the following methods:

(1) *www.regulations.gov.* Follow the on-line instructions for submitting comments.

(2) *E-mail: OW-Docket@epa.gov*, Attention Docket ID No. EPA–HQ–OW–2006–0771.

(3) *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 4203M, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OW–2006–0771. Please include a total of 3 copies.

(4) *Hand Delivery:* Water Docket, EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. EPA–HQ–OW–2006–0771. Such deliveries are only accepted during the Docket's normal hours of operation and special arrangements should be made.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2006–0771. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you

consider to be CBI or otherwise protected through regulations.gov or e-mail. The federal regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the index at *www.regulations.gov*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *www.regulations.gov* or in hard copy at the Water Docket in the EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

The following key document provides additional information about EPA's annual reviews and the Preliminary 2008 Effluent Guidelines Program Plan: "Technical Support Document for the Preliminary 2008 Effluent Guidelines Program Plan," EPA–821R–07–007, DCN 04247, October 2007.

FOR FURTHER INFORMATION CONTACT: Mr. Carey A. Johnston at (202) 566–1014 or *johnston.carey@epa.gov*.

SUPPLEMENTARY INFORMATION:

How is this document organized?

The outline of this notice follows.

I. General Information

A. Does This Action Apply to Me?

This notice provides a statement of the Agency's effluent guidelines review and planning processes and priorities at this time, and does not contain any regulatory requirements.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting Confidential Business Information.* Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible.
- Make sure to submit your comments by the comment period deadline identified.

II. Legal Authority

This notice is published under the authority of the CWA, 33 U.S.C. 1251, et seq., and in particular sections 301(d), 304(b), 304(g), 304(m), 306, and 307(b), 33 U.S.C. 1311(d), 1314(b), 1314(g), 1314(m), 1316, and 1317.

III. What Is the Purpose of This Federal Register Notice?

This notice presents EPA's 2007 review of existing effluent guidelines and pretreatment standards under CWA sections 301(d), 304(b), 304(g) and 307(b). This notice also provides EPA's preliminary thoughts concerning its 2008 annual reviews under CWA sections 301(d), 304(b), 304(g) and 307(b) and solicits comments, data and information to assist EPA in performing these reviews. It also presents EPA's evaluation of indirect dischargers without categorical pretreatment standards to identify potential new categories for pretreatment standards under CWA sections 304(g) and 307(b). This notice also presents the preliminary 2008 Effluent Guidelines Program Plan ("preliminary 2008 Plan"), which, as required under CWA section 304(m), identifies any new or existing industrial categories selected for effluent guidelines rulemaking and provides a schedule for such rulemaking. CWA section 304(m) requires EPA to biennially publish such a plan after public notice and comment.

IV. Background

A. What Are Effluent Guidelines and Pretreatment Standards?

The CWA directs EPA to promulgate effluent limitations guidelines and standards ("effluent guidelines") that reflect pollutant reductions that can be achieved by categories or subcategories of industrial point sources using technologies that represent the appropriate level of control. See CWA sections 301(b)(2), 304(b), 306, 307(b), and 307(c). For point sources that introduce pollutants directly into the waters of the United States (direct dischargers), the effluent limitations guidelines and standards promulgated

by EPA are implemented through National Pollutant Discharge Elimination System (NPDES) permits. See CWA sections 301(a), 301(b), and 402. For sources that discharge to POTWs (indirect dischargers), EPA promulgates pretreatment standards that apply directly to those sources and are enforced by POTWs and State and Federal authorities. See CWA sections 307(b) and (c).

1. Best Practicable Control Technology Currently Available (BPT)—CWA Sections 301(b)(1)(A) & 304(b)(1)

EPA defines Best Practicable Control Technology Currently Available (BPT) effluent limitations for conventional, toxic, and non-conventional pollutants. Section 304(a)(4) designates the following as conventional pollutants: Biochemical oxygen demand (BOD_5), total suspended solids, fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501). EPA has identified 65 pollutants and classes of pollutants as toxic pollutants, of which 126 specific substances have been designated priority toxic pollutants. See Appendix A to part 423. All other pollutants are considered to be non-conventional.

In specifying BPT, EPA looks at a number of factors. EPA first considers the total cost of applying the control technology in relation to the effluent reduction benefits. The Agency also considers the age of the equipment and facilities, the processes employed, and any required process changes, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements), and such other factors as the EPA Administrator deems appropriate. See CWA section 304(b)(1)(B). Traditionally, EPA establishes BPT effluent limitations based on the average of the best performance of facilities within the industry of various ages, sizes, processes, or other common characteristics. Where existing performance is uniformly inadequate, BPT may reflect higher levels of control than are currently in place in an industrial category if the Agency determines that the technology can be practically applied.

2. Best Conventional Pollutant Control Technology (BCT)—CWA Sections 301(b)(2)(E) & 304(b)(4)

The 1977 amendments to the CWA required EPA to identify effluent reduction levels for conventional pollutants associated with Best Conventional Pollutant Control Technology (BCT) for discharges from existing industrial point sources. In addition to considering the other factors specified in section 304(b)(4)(B) to establish BCT limitations, EPA also considers a two part "cost-reasonableness" test. EPA explained its methodology for the development of BCT limitations in 1986. See 51 FR 24974 (July 9, 1986).

3. Best Available Technology Economically Achievable (BAT)—CWA Sections 301(b)(2)(A) & 304(b)(2)

For toxic pollutants and non-conventional pollutants, EPA promulgates effluent guidelines based on the Best Available Technology Economically Achievable (BAT). See CWA section 301(b)(2)(A), (C), (D) and (F). The factors considered in assessing BAT include the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, non-water quality environmental impacts, including energy requirements, and other such factors as the EPA Administrator deems appropriate. See CWA section 304(b)(2)(B). The technology must also be economically achievable. See CWA section 301(b)(2)(A). The Agency retains considerable discretion in assigning the weight accorded to these factors. BAT limitations may be based on effluent reductions attainable through changes in a facility's processes and operations. Where existing performance is uniformly inadequate, BAT may reflect a higher level of performance than is currently being achieved within a particular subcategory based on technology transferred from a different subcategory or category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

4. New Source Performance Standards (NSPS)—CWA Section 306

New Source Performance Standards (NSPS) reflect effluent reductions that are achievable based on the best available demonstrated control technology. New sources have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent controls attainable through the application of the best available demonstrated control technology for all pollutants (*i.e.*, conventional, non-conventional, and priority pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

5. Pretreatment Standards for Existing Sources (PSES)—CWA Section 307(b)

Pretreatment Standards for Existing Sources (PSES) are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly-owned treatment works (POTWs), including sludge disposal methods at POTWs. Pretreatment standards for existing sources are technology-based and are analogous to BAT effluent limitations guidelines.

The General Pretreatment Regulations, which set forth the framework for the implementation of national pretreatment standards, are found at 40 CFR part 403.

6. Pretreatment Standards for New Sources (PSNS)—CWA Section 307(c)

Like PSES, Pretreatment Standards for New Sources (PSNS) are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers have the opportunity to incorporate into their facilities the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

B. What Are EPA's Review and Planning Obligations Under Sections 301(d), 304(b), 304(g), 304(m), and 307(b)?

1. EPA's Review and Planning Obligations Under Sections 301(d), 304(b), and 304(m)—Direct Dischargers

Section 304(b) requires EPA to review its existing effluent guidelines for direct dischargers each year and to revise such regulations "if appropriate." Section 304(m) supplements the core requirement of section 304(b) by requiring EPA to publish a plan every two years announcing its schedule for performing this annual review and its schedule for rulemaking for any effluent guidelines selected for possible revision as a result of that annual review. Section 304(m) also requires the plan to identify categories of sources discharging non-trivial amounts of toxic or non-conventional pollutants for which EPA has not published effluent limitations guidelines under section 304(b)(2) or NSPS under section 306. See CWA section 304(m)(1)(B); S. Rep. No. 50, 99th Cong., 1st Sess. (1985); WQA87

Leg. Hist. 31 (indicating that section 304(m)(1)(B) applies to "non-trivial discharges."). Finally, under section 304(m), the plan must present a schedule for promulgating effluent guidelines for industrial categories for which it has not already established such guidelines, providing for final action on such rulemaking not later than three years after the industrial category is identified in a final Plan.[1] See CWA section 304(m)(1)(C). EPA is required to publish its preliminary Plan for public comment prior to taking final action on the plan. See CWA section 304(m)(2).

In addition, CWA section 301(d) requires EPA to review every five years the effluent limitations required by CWA section 301(b)(2) and to revise them if appropriate pursuant to the procedures specified in that section. Section 301(b)(2), in turn, requires point sources to achieve effluent limitations reflecting the application of the best available technology economically achievable (for toxic pollutants and non-conventional pollutants) and the best conventional pollutant control technology (for conventional pollutants), as determined by EPA under sections 304(b)(2) and 304(b)(4), respectively. For nearly three decades, EPA has implemented sections 301 and 304 through the promulgation of effluent limitations guidelines, resulting in regulations for 56 industrial categories. *See E.I. du Pont de Nemours & Co.* v. *Train*, 430 U.S. 113 (1977). Consequently, as part of its annual review of effluent limitations guidelines under section 304(b), EPA is also reviewing the effluent limitations they contain, thereby fulfilling its obligations under sections 301(d) and 304(b) simultaneously.

2. EPA's Review and Planning Obligations Under Sections 304(g) and 307(b)—Indirect Dischargers

Section 307(b) requires EPA to revise its pretreatment standards for indirect dischargers "from time to time, as control technology, processes, operating methods, or other alternatives change." See CWA section 307(b)(2). Section 304(g) requires EPA to annually review these pretreatment standards and revise them "if appropriate." (Although section 307(b) only requires EPA to revise existing pretreatment standards "from time to time," section 304(g) requires an annual review. Therefore, EPA meets its 304(g) and 307(b) requirements by reviewing all industrial categories subject to existing categorical pretreatment standards on an annual basis to identify potential candidates for revision.

Section 307(b)(1) also requires EPA to promulgate pretreatment standards for pollutants not susceptible to treatment by POTWs or that would interfere with the operation of POTWs, although it does not provide a timing requirement for the promulgation of such new pretreatment standards. EPA, in its discretion, periodically evaluates indirect dischargers not subject to categorical pretreatment standards to identify potential candidates for new pretreatment standards. The CWA does not require EPA to publish its review of pretreatment standards or identification of potential new categories, although EPA is exercising its discretion to do so in this notice.

EPA intends to repeat this publication schedule for future pretreatment standards reviews (*e.g.*, EPA will publish the 2008 annual pretreatment standards review in the notice containing the Agency's 2008 annual review of existing effluent guidelines and the final 2008 Plan). EPA intends that these contemporaneous reviews will provide meaningful insight into EPA's effluent guidelines and pretreatment standards program decision-making. Additionally, by providing a single notice for these and future reviews, EPA hopes to provide a consolidated source of information for the Agency's current and future effluent guidelines and pretreatment standards program reviews.

V. EPA's 2007 Annual Review of Existing Effluent Guidelines and Pretreatment Standards Under CWA Sections 301(d), 304(b), 304(g), and 307(b)

A. What Process Did EPA Use To Review Existing Effluent Guidelines and Pretreatment Standards Under CWA Section 301(d), 304(b), 304(g), and 307(b)?

1. Overview

In its 2007 annual review, EPA reviewed all industrial categories subject to existing effluent limitations guidelines and pretreatment standards, representing a total of 56 point source categories and over 450 subcategories. This review consisted of a screening level review of all existing industrial categories based on the hazard associated with discharges from each category and other factors identified by EPA as appropriate for prioritizing effluent guidelines and pretreatment standards for possible revision. EPA used this review to confirm the identification of the four industrial categories prioritized for further review in the final 2006 Effluent Guidelines Program Plan (December 21, 2006; 71 FR 76644) and to list the industrial categories currently regulated by existing effluent guidelines that cumulatively comprise 95% of the reported hazard (reported in units of toxic-weighted pound equivalent or TWPE).

As reported in the final 2006 Effluent Guidelines Program Plan (December 21, 2006; 71 FR 76644), EPA also continued or began work on four detailed studies as part of the 2007 annual review: Steam Electric Power Generating (Part 423), Coal Mining (Part 434), Oil and Gas Extraction (Part 435) (only to assess whether to include coalbed methane extraction as a new subcategory), and Hospitals (Part 460).[2]

Together, these reviews discharged EPA's obligations to annually review both existing effluent limitations guidelines for direct dischargers under CWA sections 301(d) and 304(b) and existing pretreatment standards for indirect dischargers under CWA sections 304(g) and 307(b).

Based on this review and prior annual reviews, and in light of the ongoing effluent guidelines rulemakings and detailed studies currently in progress, EPA is not identifying any existing categories for effluent guidelines rulemaking at this time.

2. How did EPA's 2006 annual review influence its 2007 annual review of point source categories with existing effluent guidelines and pretreatment standards?

In view of the annual nature of its reviews of existing effluent guidelines and pretreatment standards, EPA believes that each annual review can and should influence succeeding annual reviews, *e.g.*, by indicating data gaps, identifying new pollutants or pollution reduction technologies, or otherwise highlighting industrial categories for additional scrutiny in subsequent years. For example, during its 2005 and 2006

[1] EPA recognizes that one court—the U.S. District Court for the Central District of California—has found that EPA has a duty to *promulgate* effluent guidelines within three years for new categories identified in the Plan. *See NRDC et al.* v. *EPA*, 437 F.Supp.2d 1137 (C.D. Ca. 2006). However, EPA continues to believe that the mandatory duty under section 304(m)(1)(C) is limited to providing a *schedule* for taking final action in effluent guidelines rulemaking—not necessarily promulgating effluent guidelines—within three years, and has appealed this decision.

[2] Based on available information, hospitals consist mostly of indirect dischargers for which EPA has not established pretreatment standards. As discussed in Section VII.B, EPA is including hospitals in its review of the Health Services Industry, a potential new category for pretreatment standards. As part of that process, EPA will review the existing effluent guidelines for the few direct dischargers in the category.

annual reviews EPA started a detailed study of the Steam Electric Power Generating (Part 423) category. At the conclusion of the 2006 annual review EPA indicated that it would continue the detailed study of the Steam Electric Power Generating (Part 423) category and begin detailed studies for the following three industrial categories: Coal Mining (Part 434), Oil and Gas Extraction (Part 435) (only to assess whether to include coalbed methane extraction as a new subcategory); and Hospitals (Part 460) (which is part of the Health Services Industry detailed study). In addition, EPA identified two other industrial categories, Ore Mining and Dressing (Part 440) and Textile Mills (Part 410), at the conclusion of the 2006 annual review as candidates for "preliminary category reviews" in the 2007 review based on the toxic discharges reported to the Toxics Release Inventory (TRI) and Permit Compliance System (PCS). These are categories for which EPA lacks sufficient data to determine whether revision would be appropriate and for which EPA is performing a further assessment of pollutant discharges before starting a detailed study. This assessment provides an additional level of quality assurance on the reported pollutant discharges and number of facilities that represent the majority of toxic-weighted pollutant discharges. EPA published the findings from its 2006 annual review with its final 2006 Plan (December 21, 2006; 71 FR 76644), making the data collected available for public comment. Docket No. EPA–HQ–OW–2004–0032. EPA used the findings, data and comments on the 2006 annual review to inform its 2007 annual review. The 2007 review also built on the previous reviews by continuing to use the screening methodology, incorporating some refinements to assigning discharges to categories and updating toxic weighting factors used to estimate potential hazards of toxic pollutant discharges.

3. What actions did EPA take in performing its 2007 annual reviews of existing effluent guidelines and pretreatment standards?

a. Screening-Level Review

The first component of EPA's 2007 annual review consisted of a screening-level review of all industrial categories subject to existing effluent guidelines or pretreatment standards. As a starting point for this review, EPA examined screening-level data from its 2007 annual reviews. In its 2007 annual reviews, EPA focused its efforts on collecting and analyzing data to identify industrial categories whose pollutant discharges potentially pose the greatest hazard to human health or the environment because of their toxicity (*i.e.*, highest estimates of toxic-weighted pollutant discharges). In particular, EPA ranked point source categories according to their discharges of toxic and non-conventional pollutants (reported in units of toxic-weighted pound equivalent or TWPE), based primarily on data from TRI and PCS. EPA calculated the TWPE using pollutant-specific toxic weighting factors (TWFs). Where data are available, these TWFs reflect both aquatic life and human health effects. For each facility that reports to TRI or PCS, EPA multiplies the pounds of discharged pollutants by pollutant-specific TWFs. This calculation results in an estimate of the discharged toxic-weighted pound equivalents, which EPA then uses as its estimate of the hazard posed by these toxic and non-conventional pollutant discharges to human health or the environment. For the 2007 annual reviews, EPA used the most recent PCS and TRI data (2004). The full description of EPA's methodology for the 2007 screening-level review is presented in the Technical Support Document (TSD) for the preliminary 2008 Plan (*see* DCN 04247) and in the Docket (*see* EPA–HQ–OW–2006–0771) accompanying this notice.

EPA is continuously investigating and solicits comment on how to improve its analyses. In particular, EPA recently conducted a peer review of the TWF methodology and the Agency's use of TWFs in effluent guidelines program planning. An independent panel of scientific experts was asked to provide comment on the appropriateness of the TWF calculations and the quality and hierarchy of the data used in developing individual TWFs. EPA is currently in the process of reviewing and responding to the peer reviewer's comments. EPA is also in the process of updating the following document, Draft Toxic Weighting Factor Development in Support of CWA 304(m) Planning Process, EPA–HQ–OW–2004–0032–1634, to address some of the peer reviewers concerns. EPA plans to release the peer review report with the Agency's response as soon as it's completed, but no later than when the final 2008 304(m) Plan is released. EPA also is exploring how best to communicate the uncertainty inherent with incomplete data regarding individual TWFs. EPA will continue to update individual TWFs as new information becomes available.

EPA also developed a quality assurance project plan (QAPP) for its use of TRI and PCS data in the 2007 annual review to document the type and quality of data needed to make the decisions in this annual review and to describe the methods for collecting and assessing those data (*see* DCN 04422). EPA used the following document to develop the QAPP for this annual review: "EPA Requirements for QA Project Plans (QA/R–5), EPA–240–B01–003." Using the QAPP as a guide, EPA performed extensive quality assurance checks on the data used to develop estimates of toxic-weighted pollutant discharges (*i.e.*, verifying 2004 discharge data reported to TRI and PCS) to determine if any of the pollutant discharge estimates relied on incorrect or suspect data. For example, EPA contacted facilities and permit writers to confirm and, as necessary, correct TRI and PCS data for facilities that EPA had identified in its screening-level review as the significant dischargers of nutrients and of toxic and non-conventional pollution.

Based on this methodology, EPA prioritized for potential revision industrial categories that offered the greatest potential for reducing hazard to human health and the environment. EPA assigned those categories with the lowest estimates of toxic-weighted pollutant discharges a lower priority for revision (*i.e.*, industrial categories marked "(3)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice).

In order to further focus its inquiry during the 2007 annual review, EPA assigned a lower priority for potential revision to categories for which effluent guidelines had been recently promulgated or revised, or for which effluent guidelines rulemaking was currently underway (*i.e.*, industrial categories marked "(1)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice). For example, EPA excluded facilities that are associated with the Chlorine and Chlorinated Hydrocarbon (CCH) Manufacturing effluent guidelines rulemaking (formerly known as the "Vinyl Chloride and Chlor-Alkali Manufacturing" effluent guidelines rulemaking) currently underway from its 2006 hazard assessment of the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) and Inorganic Chemicals point source categories to which CCH facilities belong.

Additionally, EPA applied less scrutiny to industrial categories for which EPA had promulgated effluent guidelines or pretreatment standards within the past seven years. EPA chose

seven years because this is the time it customarily takes for the effects of effluent guidelines or pretreatment standards to be fully reflected in pollutant loading data and TRI reports (in large part because effluent limitations guidelines are often incorporated into NPDES permits only upon re-issuance, which could be up to five years after the effluent guidelines or pretreatment standards are promulgated). Because there are 56 point source categories (including over 450 subcategories) with existing effluent guidelines and pretreatment standards that must be reviewed annually, EPA believes it is important to prioritize its review so as to focus on industries where changes to the existing effluent guidelines or pretreatment standards are most likely to be needed. In general, industries for which effluent guidelines or pretreatment standards have recently been promulgated are less likely to warrant such changes. However, in cases where EPA becomes aware of the growth of a new industrial activity within a category for which EPA has recently revised effluent guidelines or pretreatment standards, or where new concerns are identified for previously unevaluated pollutants discharged by facilities within the industrial category, EPA would apply more scrutiny to the category in a subsequent review. EPA identified no such instance during the 2007 annual review.

EPA also applied a lower priority for potential revision at this time to categories for which EPA lacked sufficient data to determine whether revision would be appropriate. For industrial categories marked "(5)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice, EPA lacks sufficient information at this time on the magnitude of the toxic-weighted pollutant discharges associated with these categories. EPA will seek additional information on the discharges from these categories in the next annual review in order to determine whether a detailed study is warranted. EPA typically performs a further assessment of the pollutant discharges before starting a detailed study of an industrial category. This assessment ("preliminary category review") provides an additional level of quality assurance on the reported pollutant discharges and number of facilities that represent the majority of toxic-weighted pollutant discharges. See the appropriate section in the TSD for the preliminary 2008 Plan (DCN 04247) for EPA's data needs for these industrial categories.

For industrial categories marked "(4)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice, EPA had sufficient information on the toxic-weighted pollutant discharges associated with these categories to start or continue a detailed study of these industrial categories in the 2007 annual review. EPA intends to use the detailed study to obtain information on hazard, availability and cost of technology options, and other factors in order to determine if it would be appropriate to identify the category for possible effluent guidelines revision. In the 2007 annual review, EPA began or continued detailed studies of four such categories.

As part of its 2007 annual review, EPA also considered the number of facilities responsible for the majority of the estimated toxic-weighted pollutant discharges associated with an industrial activity. Where only a few facilities in a category accounted for the vast majority of toxic-weighted pollutant discharges (*i.e.*, categories marked "(2)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice), EPA applied a lower priority for potential revision. EPA believes that revision of individual permits for such facilities may be more effective than a revised national effluent guidelines rulemaking. Individual permit requirements can be better tailored to these few facilities and may take considerably less time and resources to establish than a national effluent guidelines rulemaking. The Docket accompanying this notice lists facilities that account for the vast majority of the estimated toxic-weighted pollutant discharges for particular categories (*see* DCN 04247). For these facilities, EPA will consider identifying pollutant control and pollution prevention technologies that will assist permit writers in developing facility-specific, technology-based effluent limitations on a best professional judgment (BPJ) basis. For example, EPA developed and distributed a 2007 technical document to NPDES permit writers in order to support the development of effluent limitations for facilities in the dissolving kraft (Subpart A) and dissolving sulfite (Subpart D) subcategories of the pulp and paper point source category (40 CFR Part 430) (*see* DCN 04167). As of the beginning of 2006, there were four affected facilities in these two subcategories, two in Florida and one each in Georgia and Washington. EPA indicated in the final 2006 Plan (*see* December 21, 2006; 71 FR 76651–76652) that it would provide support to permit writers in establishing facility-specific effluent limits for these subcategories based on their Best Professional Judgment (BPJ) in lieu of finalizing its 1993 effluent guidelines rulemaking (*see* December 17, 1993; 58 FR 44078). In future annual reviews, EPA also intends to re-evaluate each category based on the information available at the time in order to evaluate the effectiveness of the BPJ permit-based support.

EPA received comments in previous biennial planning cycles urging the Agency to encourage and recognize voluntary efforts by industry to reduce pollutant discharges, especially when the voluntary efforts have been widely adopted within an industry and the associated pollutant reductions have been significant. EPA agrees that industrial categories demonstrating significant progress through voluntary efforts to reduce hazard to human health or the environment associated with their effluent discharges would be a comparatively lower priority for effluent guidelines or pretreatment standards revision, particularly where such reductions are achieved by a significant majority of individual facilities in the industry. Although during this annual review EPA could not complete a systematic review of voluntary pollutant loading reductions, EPA's review did indirectly account for the effects of successful voluntary programs because any significant reductions in pollutant discharges should be reflected in discharge monitoring and TRI data, as well as any data provided directly by commenters, that EPA used to assess the toxic-weighted pollutant discharges.

As was the case in previous annual reviews, EPA was unable to gather the data needed to perform a comprehensive screening-level analysis of the availability of treatment or process technologies to reduce toxic pollutant wastewater discharges beyond the performance of technologies already in place for all of the 56 existing industrial categories. However, EPA believes that its analysis of hazard is useful for assessing the effectiveness of existing technologies because it focuses on the amount and significance of pollutants that are still discharged following existing treatment. Therefore, by assessing the hazard associated with discharges from all existing categories in its screening-level review, EPA was indirectly able to assess the possibility that further significant reductions could be achieved through new pollution control technologies for these categories. In addition, EPA directly assessed the availability of technologies for certain industries that were prioritized for a more in-depth review as a result of the screening level analysis. See DCN 04247.

Similarly, EPA could not identify a suitable screening-level tool for comprehensively evaluating the affordability of treatment or process technologies because the universe of facilities is too broad and complex. EPA could not find a reasonable way to prioritize the industrial categories based on readily available economic data. In the past, EPA has gathered information regarding technologies and economic achievability through detailed questionnaires distributed to hundreds of facilities within a category or subcategory for which EPA has commenced rulemaking. Such information-gathering is subject to the requirements of the Paperwork Reduction Act (PRA), 33 U.S.C. 3501, *et seq.* The information acquired in this way is valuable to EPA in its rulemaking efforts, but the process of gathering, validating and analyzing the data can consume considerable time and resources. EPA does not think it appropriate to conduct this level of analysis for all point source categories in conducting an annual review. Rather, EPA believes it is appropriate to set priorities based on hazard and other screening-level factors identified above, and to directly consider the availability and affordability of technology only in conducting the more in-depth reviews of prioritized categories. For these prioritized categories, EPA may conduct surveys or other PRA-governed data collection activities in order to better inform the decision on whether effluent guidelines are warranted. Additionally, EPA is working to develop tools for directly assessing technological and economic achievability as part of the screening-level review in future annual reviews under section 301(d), 304(b), and 307(b) (*see* EPA–HQ–OW–2004–0032–2344). EPA solicits comment on how to best identify and use screening-level tools for assessing technological and economic achievability on an industry-specific basis as part of future annual reviews.

In summary, through its screening level review, EPA focused on those point source categories that appeared to offer the greatest potential for reducing hazard to human health or the environment, while assigning a lower priority to categories that the Agency believes are not good candidates for effluent guidelines or pretreatment standards revision at this time. This enabled EPA to concentrate its resources on conducting more in-depth reviews of certain industries prioritized as a result of the screening level analysis, as discussed below (*see* section V.A.3.b and c).

b. Further Review of Prioritized Categories

In the publication of the final 2006 Plan EPA identified two additional categories with potentially high TWPE discharge estimates for further investigation ("preliminary category review") in the 2007 annual review: Ore Mining and Dressing (Part 440) and Textile Mills (Part 410) (*i.e.*, EPA identified these categories with "(5)" in the column entitled "Findings" in Table V–1, Page 76657 of the final 2006 Plan). From its 2007 annual review, EPA is identifying the Centralized Waste Treatment (Part 437) and Waste Combustors (Part 444) categories for preliminary category reviews in the 2008 annual review.

In conducting these preliminary category reviews EPA uses the same types of data sources used for the detailed studies but in less depth. EPA typically performs a further assessment of the pollutant discharges before starting a detailed study of an industrial category. This assessment provides an additional level of quality assurance on the reported pollutant discharges and number of facilities that represent the majority of toxic-weighted pollutant discharges. EPA may also develop a preliminary list of potential wastewater pollutant control technologies before conducting a detailed study. EPA is not conducting a detailed study for these categories at this time because EPA needs additional information regarding these industries to determine whether a detailed study is warranted.

c. Detailed Study of Four Categories

In addition to conducting a screening-level review of all existing categories, EPA started or continued detailed studies of four categories: Steam Electric Power Generating (Part 423), Coal Mining (Part 434), Oil and Gas Extraction (Part 435) (only to assess whether to include coalbed methane extraction as a new subcategory), and Hospitals (Part 460) (which is part of the Health Services Industry detailed study). For these industries, EPA gathered and analyzed additional data on pollutant discharges, economic factors, and technology issues during its 2007 annual review. EPA examined: (1) Wastewater characteristics and pollutant sources; (2) the pollutants discharged from these sources and the toxic weights associated with these discharges; (3) treatment technology and pollution prevention information; (4) the geographic distribution of facilities in the industry; (5) any pollutant discharge trends within the industry; and (6) any relevant economic factors.

EPA is relying on many different sources of data including: (1) The 2002 U.S. Economic Census; (2) TRI and PCS data; (3) contacts with reporting facilities to verify reported releases and facility categorization; (4) contacts with regulatory authorities (states and EPA regions) to understand how category facilities are permitted; (5) NPDES permits and their supporting fact sheets; (6) monitoring data included in facility applications for NPDES permit renewals (Form 2C data); (7) EPA effluent guidelines technical development documents; (8) relevant EPA preliminary data summaries or study reports; (9) technical literature on pollutant sources and control technologies; (10) information provided by industry including industry conducted survey and sampling data; and (11) stakeholder comments (*see* DCN 04247). Additionally, in order to evaluate available and affordable treatment technology options for the coalbed methane extraction industry sector, EPA intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for its review and approval prior to publication of the final 2008 Plan.

d. Public Comments

EPA's annual review process considers information provided by stakeholders regarding the need for new or revised effluent limitations guidelines and pretreatment standards. To that end, EPA established a docket for its 2007 annual review at the time of publication of the final 2006 Plan to provide the public with an opportunity to submit additional information to assist the Agency in its 2007 annual review. These public comments are in the supporting docket (EPA–HQ–OW–2006–0771, *www.regulations.gov*) and summarized in the TSD for the preliminary 2008 Plan (*see* DCN 04247).

B. What Were EPA's Findings From its 2007 Annual Review for Categories Subject to Existing Effluent Guidelines and Pretreatment Standards?

1. Screening-Level Review

In its 2007 screening level review, EPA considered hazard—and the other factors described in section A.3.a. above—in prioritizing effluent guidelines for potential revision. See Table V–1 in section V.B.4 of today's notice for a summary of EPA's findings with respect to each existing category; see also the TSD for the preliminary 2008 Plan ("TSD"). Out of the categories subject only to the screening level review in 2007, EPA is not identifying any for effluent guidelines rulemaking

at this time, based on the factors described in section A.3.a above and in light of the effluent guidelines rulemakings and detailed studies in progress.

In the 2007 annual review EPA listed the industrial categories currently regulated by existing effluent guidelines that cumulatively comprise 95% of the reported hazard (reported in units of toxic-weighted pound equivalent or TWPE). The TSD presents a summary of EPA's review of these eleven industrial categories (*see* DCN 04247).

2. Detailed Studies

In its 2007 annual review, EPA started or continued detailed studies of four industrial point source categories with existing effluent guidelines and pretreatment standards: Steam Electric Power Generating (Part 423), Coal Mining (Part 434), and Oil and Gas Extraction (Part 435) (only to assess whether to include coalbed methane extraction as a new subcategory), and Hospitals (Part 460) (which is part of the Health Services Industry detailed study). EPA is investigating whether the pollutant discharges reported to TRI and PCS for 2004 accurately reflect the current discharges of the industry. EPA is also analyzing the reported pollutant discharges, and technology innovation and process changes in these industrial categories. Additionally, EPA is considering whether there are industrial activities not currently subject to effluent guidelines or pretreatment standards that should be included with these existing categories, either as part of existing subcategories or as potential new subcategories. EPA will use these detailed studies to determine whether EPA should identify in the final 2008 Plan (or a future Plan) any of these industrial categories for possible revision of their existing effluent guidelines and pretreatment standards. EPA's reviews of three of these four categories are described below and its review of hospitals is described in section VII.B (Health Services Industry detailed study).

a. Steam Electric Power Generating (Part 423)

The Steam Electric Power Generating effluent guidelines (40 CFR 423) apply to a subset of the electric power industry, namely those facilities "primarily engaged in the generation of electricity for distribution and sale which results primarily from a process utilizing fossil-type fuel (coal, oil, or gas) or nuclear fuel in conjunction with a thermal cycle employing the steam water system as the thermodynamic medium." See 40 CFR 423.10. EPA's most recent revisions to the effluent guidelines and standards for this category were promulgated in 1982 (*see* November 19, 1982; 47 FR 52290).

EPA previously found that facilities in the Steam Electric Power Generating point source category collectively discharge relatively high amounts of toxic pollutants (as measured in toxic-weighted pound equivalents (TWPE)). See Tables 5–3 and 5–4 of the TSD for the final 2006 Plan, EPA–HQ–OW–2004–0032–2782, and Section 5.4.4.7 of the TSD for the final 2004 Plan, EPA–HQ–OW–2003–0074–1346 through 1351. The 2007 annual review again identified this category as the second-largest discharger of toxic pollutants (*see* DCN 04247). EPA also determined that PCS and TRI data provide an incomplete picture of the wastewaters generated by the regulated steam electric industry. For example, EPA anticipates greater amounts of nitrogen compounds, selenium, and other metals, most of which are not regulated by the effluent guidelines, and therefore, may not be reported to TRI or PCS, in steam electric wastewaters as a result of the increasing use of air pollution controls (*see* Interim Detailed Study Report for the Steam Electric Power Generating Point Source Category, November 2006, EPA–HQ–OW–2004–0032–2781). Consequently, EPA focused on supplementing its review of PCS and TRI data for this category with additional data collection as described below and in the supporting docket (*see* DCN 04247).

The detailed study for the Steam Electric Power Generating point source category is mainly focused on: (1) Characterizing the mass and concentrations of pollutants in wastewater discharges from coal-fired steam electric facilities; and (2) identifying the pollutants that comprise a significant portion of the category's TWPE discharge estimate and the corresponding industrial operation. Waste streams of particular interest include cooling water, fly ash and bottom ash wastes, coal pile runoff, and discharges from wet air pollution control devices [*e.g.*, wet flue gas desulfurization (FGD)]. EPA's previous annual reviews have identified that: (1) The TWPE discharge estimate for this category is predominantly driven by the metals present in wastewater discharges; and (2) the waste streams contributing the majority of these metals are associated with ash handling and wet FGD systems (*see* EPA–HQ–OW–2004–0032–2781). Other potential sources of metals include coal pile runoff, metal/chemical cleaning wastes, coal washing, and certain low volume wastes. EPA is collecting data for the detailed study through facility inspections, wastewater sampling, a data request that was sent to a limited number of companies, and various secondary data sources (*see* DCN 04711).

EPA is conducting wastewater sampling of ash ponds and FGD wastewater treatment systems at several steam electric facilities. Samples collected are being analyzed for metals and classical pollutants, such as total suspended solids and nitrogen. EPA selected the plants for sampling based on characteristics and process configurations of interest. Factors taken into consideration include the type of fuel, type of wet FGD systems in operation, fly ash handling practices, nitrogen oxides (NO_X) controls (*e.g.*, selective catalytic reduction systems), and wastewater treatment technologies. See the following document for information about the sample collection methodologies, analytes of interest, and laboratory analytical methods: "Generic Sampling and Analysis Plan for Coal-Fired Steam Electric Power Plants," DCN 04296.

EPA also collected facility specific information using a data request conducted under authority of CWA section 308 (*see* DCN 04711). EPA sent this data request to nine companies that operate a number of coal-fired power plants with wet FGD systems. The data request complements the wastewater sampling effort as it collects facility-specific information about wastewaters EPA is not sampling. Additionally, the data request collects detailed information about wastewater generation rates and management practices for wastewaters included in EPA's sampling program. The data request seeks information on selected wastewater sources, air pollution controls, wastewater management and treatment practices, water reuse/recycle, and treatment system capital and operating costs.

b. Coal Mining (Part 434)

As discussed in the "Notice of Availability of Final 2006 Effluent Guidelines Program Plan" EPA is conducting a detailed study during the 2007 and 2008 annual reviews to evaluate the merits of comments by states, industry, and a public interest group that urged revisions to pollutant limitations in the Coal Mining effluent guidelines (40 CFR Part 434) (*see* December 21, 2006; 71 FR 76644–76667). The Interstate Mining Compact Commission, which represents mining agencies in 35 states, together with a few individual state agencies, and a few

mining companies, asked EPA to remove the current manganese limitations and allow permittees to employ best management practices as necessary to reduce manganese discharges based on the quality of receiving waterbodies.

The public interest group, the Environmental Law and Policy Center, asked EPA to place greater controls on coal mining discharges of sulfates, chlorides, mercury, cadmium, manganese, selenium, and other unspecified pollutants.

State and industry commentors cited the following factors in support of their comments: (1) New, more stringent coal mining reclamation bonding requirements on post-closure discharges; (2) evidence that current manganese limitations are more stringent than necessary to protect aquatic life; (3) perception that high cost of manganese treatment is causing permittees to default on their post-closure bonds; and (4) perception that treatment with chemical addition may complicate permit compliance, especially after a mine is closed. The public interest group referenced a study by EPA Region 5 on potential adverse impacts of the discharge of sulfates on aquatic life (*see* DCN 2487).

EPA initiated the Coal Mining Detailed Study in January 2007. The study follows the framework presented in the Detailed Study Plan, a draft of which the Agency placed into the docket (see DCN 2488) during the Fall of 2006. EPA revised and finalized the Detailed Study Plan in April 2007 to reflect public comments. The study will evaluate treatment technologies, costs, and pollutant discharge loads, as well as the effects of manganese and other pollutants on aquatic life. The study will also address the question of whether bonds are being forfeited because of the cost of manganese treatment by examining bonding and trust fund requirements, past bond forfeiture rates, future potential bond forfeiture rates, and the issues related to state assumption of long-term water treatment responsibilities for mines where the bonds have been forfeited. As outlined in the Detailed Study Plan, EPA has framed study questions based on public comment, identified data sources to help answer the study questions, developed a methodology for estimating treatment costs and discharge loads, and initiated data collection activities with the Interstate Mining Compact Commission, state agencies, and the Office of Surface Mining, Reclamation, and Enforcement within the U.S. Department of the Interior.

The Coal Mining Detailed Study consists of several interim products which will be summarized in the 2008 final report: An industry financial profile which will include information about the types and locations of mines, ownership, and revenues; a summary of state and federal permitting requirements; a summary of bonding and trust fund requirements for control of water discharges from post-mining sites; an analysis of bond forfeiture and the consequences for the states; an analysis of treatment technologies, costs, and pollutant discharge loads; and an environmental summary of the aquatic life effects of manganese and other pollutants.

During 2007, EPA plans to complete data collection, complete the industry financial profile, begin analysis of bonding and trust fund issues, and begin analysis of treatment costs and discharge loads. During 2008, EPA will complete analysis of bonding and trust fund issues, complete estimates of treatment costs and discharge loads, complete its analysis of bond defaults, complete the summary of environmental impacts, and complete the final report.

EPA will use the results of the Coal Mining Detailed Study, which will be summarized in the 2008 annual review, to help decide appropriate regulatory steps.

c. Oil and Gas Extraction (Part 435) (Only To Assess Whether To Include Coalbed Methane Extraction as a New Subcategory)

As discussed in the 2006 annual review, EPA is conducting a detailed study of the coalbed methane industry to determine whether to revise the effluent guidelines for the Oil and Gas Extraction category to include limits for this potential new subcategory (*see* December 21, 2006; 71 FR 76656). The coalbed methane (CBM) industrial sector is an important part of the Nation's domestic source of natural gas. In 2004, CBM accounted for about 10.4% of the total U.S. natural gas production and is expanding in multiple basins across the Nation. Currently, the Department of Energy's Energy Information Administration (EIA) expects CBM production to remain an important source of domestic natural gas over the next few decades. Based on Bureau of Land Management (BLM) and States' projections this will likely involve over 100,000 CBM wells. The growth in the CBM industrial sector can be explained by the decrease in drilling and transmission costs in getting the CBM to market, clarity of gas ownership, and the increase of long-term natural gas prices. See Section 6 of the TSD for the final 2006 Plan, EPA–HQ–OW–2004–0032–2782, December 2006. EPA identified the CBM extraction industry as a potential new subcategory of the Oil and Gas Extraction category (40 CFR 435) in the 2006 annual review (*see* December 21, 2006; 71 FR 76656).

Coalbed methane (CBM) extraction requires removal of large amounts of water from underground coal seams before CBM can be released. CBM wells have a distinctive production history characterized by an early stage when large amounts of water are produced to reduce reservoir pressure which in turn encourages release of gas; a stable stage when quantities of produced gas increase as the quantities of produced water decrease; and a late stage when the amount of gas produced declines and water production remains low (*see* EPA–HQ–OW–2004–0032–1904). The quantity and quality of water that is produced in association with CBM development will vary from basin to basin, within a particular basin, from coal seam to coal seam, and over the lifetime of a CBM well.

Pollutants often found in these wastewaters include chloride, sodium, sulfate, bicarbonate, fluoride, iron, barium, magnesium, ammonia, and arsenic. Total dissolved solids (TDS) and electrical conductivity (EC) are bulk parameters used for quantifying the total amount of dissolved solids in a wastewater and that may also be used to quantify and control the amount of pollutants in CBM produced waters. Equally important in preventing environmental damage is controlling the sodicity of the CBM produced waters. Sodicity is often quantified as the sodium adsorption ratio (SAR), which is expressed as the ratio of sodium ions to calcium and magnesium ions, and is an important factor in controlling the produced water's suitability for irrigation and its potential for degrading soils. All of these parameters can potentially affect environmental impacts as well as potential beneficial uses of CBM produced water.

Impacts to surface water from discharges of CBM produced waters can be severe depending upon the quality of the CBM produced waters. Saline discharges have variable effects depending on the biology of the receiving stream. Some waterbodies and watersheds may be able to absorb the discharged water while others are sensitive to large amounts of low-quality CBM water. For example, large surface waters with sufficient dilution capacity or marine waters are less sensitive to saline discharges than smaller freshwater surface waters. Discharge of

these CBM produced waters may also cause erosion and in some cases irreversible soil damage from elevated TDS concentrations and SAR values. This may limit future agricultural and livestock uses of the water and watershed.

Currently, regulatory controls for CBM produced waters vary from State to State and permit to permit (*see* EPA–HQ–OW–2004–0032–2782, 2540). There is very limited permit information (*e.g.*, effluent limits, restrictions) in PCS and TRI for this industrial sector. Consequently, EPA is gathering additional information from State NPDES permit programs and industry on the current regulatory controls across the different CBM basins.

EPA indicated in the 2006 annual review that it will need to gather more specific information as part of a detailed review of the coalbed methane industry in order to determine whether it would be appropriate to conduct a rulemaking to potentially revise the effluent guidelines for the Oil and Gas Extraction category to include limits for CBM. In particular, EPA will need to collect technical, economic, and environmental data from a wide range of CBM operations (*e.g.*, geographical differences in the characteristics of CBM-produced waters, current regulatory controls, potential environmental impacts, availability and affordability of treatment technology options). Accordingly, EPA intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for its review and approval under the Paperwork Reduction Act (PRA), 33 U.S.C. 3501, et seq. EPA is working with stakeholders in the design of this industry survey (*see* DCN 04247). EPA solicits comment on the potential scope and methodology of this ICR. See section IX.C for a list of questions that EPA will use to develop the ICR. EPA expects to distribute the ICR in late summer of 2008.

EPA is also collecting discharge related information from five site visit trips to support this detailed study (*see* DCN 04247), and collecting data from other secondary sources to supplement its current understanding of the CBM industrial sector. EPA is specifically gathering data on available and affordable beneficial use and treatment technology options, and potential impacts of CBM produced water discharges. A summary of the data collected for this detailed study is provided in the TSD for the 2007 annual review.

3. Results of Preliminary Category Reviews

During the 2006 annual review, EPA identified two categories with potentially high TWPE discharge estimates for preliminary category review: Ore Mining and Dressing (Part 440) and Textile Mills (Part 410) (*i.e.*, EPA identified these categories with "(5)" in the column entitled "Findings" in Table V–1, Page 76657 of the final 2006 Plan). EPA concluded its preliminary category review of the Textile Mills category in the 2007 annual review and has determined that the Textile Mills category is not among those industrial categories currently regulated by existing effluent guidelines that cumulatively comprise 95% of the reported hazard (reported in units of toxic-weighted pound equivalent or TWPE) (*see* DCN 04247). As such, it has a low priority for effluent guideline revision at this time. EPA has yet to complete its preliminary category review of the Ore Mining and Dressing category. Section IX of this notice and the TSD lists the data and information that EPA would like to collect on the pollutant discharges and potential treatment technology options for the Ore Mining and Dressing category in order to complete this preliminary category review.

Additionally and as noted above, EPA identified two additional categories for preliminary category review as a result of the 2007 annual review: Centralized Waste Treatment (Part 437) and Waste Combustors (Part 444). EPA applied less scrutiny to these categories in the 2002, 2004, and 2006 biennial planning cycles as EPA effluent guidelines and pretreatment standards for these categories were promulgated in 2000. As discussed in section V.A.3.a, EPA generally applies less scrutiny to industrial categories for which EPA has promulgated effluent guidelines or pretreatment standards within the past seven years of the current biennial review. However, because this seven year period has elapsed and because of the relative high hazard ranking of these categories, EPA plans to conduct a preliminary category review of both categories in its 2008 annual review. Section IX and the TSD list data and information that EPA would like to collect on the pollutant discharges and potential treatment technology options for these two categories in order to complete these preliminary category reviews.

EPA is not identifying any of these three categories (Ore Mining and Dressing, Centralized Waste Treatment, and Waste Combustors) for an effluent guidelines rulemaking in this preliminary 2008 Plan. However, EPA is identifying these categories for new or on-going preliminary category reviews in the 2008 annual review (*i.e.*, these categories are marked with "(5)" in the "Findings" column in Table V–1 in section V.B.4 of today's notice). The docket accompanying this notice presents a summary of EPA's findings on these three industrial categories (*see* DCN 04247).

4. Summary of 2007 Annual Review Findings

In its 2007 annual review, EPA reviewed all categories subject to existing effluent guidelines and pretreatment standards in order to identify appropriate candidates for revision. Based on this review, and in light of effluent guidelines rulemakings and detailed studies currently in progress, EPA is not identifying any existing categories for effluent guidelines rulemaking. EPA is, however, conducting detailed studies for four existing categories: Steam Electric Power Generating, Coal Mining, Oil and Gas Extraction (only with respect to coalbed methane), and Hospitals (part of the Health Services Industry detailed study).

A summary of the findings of the 2007 annual review is presented below in Table V–1. This table uses the following codes to describe the Agency(s findings with respect to each existing industrial category.

(1) Effluent guidelines or pretreatment standards for this industrial category were recently revised or reviewed through an effluent guidelines rulemaking, or a rulemaking is currently underway.

(2) Revising the national effluent guidelines or pretreatment standards is not the best tool for this industrial category because most of the toxic and non-conventional pollutant discharges are from one or a few facilities in this industrial category. EPA will consider assisting permitting authorities in identifying pollutant control and pollution prevention technologies for the development of technology-based effluent limitations by best professional judgment (BPJ) on a facility-specific basis.

(3) Not identified as a hazard priority based on data available at this time (*e.g.*, not among industries that cumulatively comprise 95% of reported hazard in TWPE units).

(4) EPA intends to continue a detailed study of this industry in its 2008 annual review to determine whether to identify the category for effluent guidelines rulemaking.

(5) EPA is continuing or initiating a preliminary category review because incomplete data are available to determine whether to conduct a detailed study or identify for possible revision. EPA typically performs a further assessment of the pollutant discharges before starting a detailed study of the industrial category. This assessment provides an additional level of quality assurance on the reported pollutant discharges and number of facilities that represent the majority of toxic-weighted pollutant discharges. EPA may also develop a preliminary list of potential wastewater pollutant control technologies before conducting a detailed study. See the appropriate section in the TSD (DCN 04247) for EPA's data needs for industries in this category.

TABLE V–1.—FINDINGS FROM THE 2007 ANNUAL REVIEW OF EFFLUENT GUIDELINES AND PRETREATMENT STANDARDS CONDUCTED UNDER SECTION 301(D), 304(B), 304(G), AND 307(B)

No.	Industry category (listed alphabetically)	40 CFR Part	Findings†
1	Aluminum Forming	467	(3)
2	Asbestos Manufacturing	427	(3)
3	Battery Manufacturing	461	(3)
4	Canned and Preserved Fruits and Vegetable Processing	407	(3)
5	Canned and Preserved Seafood Processing	408	(3)
6	Carbon Black Manufacturing	458	(3)
7	Cement Manufacturing	411	(3)
8	Centralized Waste Treatment	437	(5)
9	Coal Mining‡	434	(1) and (4)
10	Coil Coating	465	(3)
11	Concentrated Animal Feeding Operations (CAFO)	412	(1)
12	Concentrated Aquatic Animal Production	451	(1)
13	Copper Forming	468	(3)
14	Dairy Products Processing	405	(3)
15	Electrical and Electronic Components	469	(3)
16	Electroplating	413	(1)
17	Explosives Manufacturing	457	(3)
18	Ferroalloy Manufacturing	424	(3)
19	Fertilizer Manufacturing	418	(3)
20	Glass Manufacturing	426	(3)
21	Grain Mills	406	(3)
22	Gum and Wood Chemicals	454	(3)
23	Hospitals[3]	460	(4)
24	Ink Formulating	447	(3)
25	Inorganic Chemicals‡‡	415	(1) and (3)
26	Iron and Steel Manufacturing	420	(1)
27	Landfills	445	(3)
28	Leather Tanning and Finishing	425	(3)
29	Meat and Poultry Products	432	(1)
30	Metal Finishing	433	(1)
31	Metal Molding and Casting	464	(3)
32	Metal Products and Machinery	438	(1)
33	Mineral Mining and Processing	436	(3)
34	Nonferrous Metals Forming and Metal Powders	471	(3)
35	Nonferrous Metals Manufacturing	421	(3)
36	Oil and Gas Extraction††	435	(1) and (4)
37	Ore Mining and Dressing	440	(5)
38	Organic Chemicals, Plastics, and Synthetic Fibers‡‡	414	(1) and (3)
39	Paint Formulating	446	(3)
40	Paving and Roofing Materials (Tars and Asphalt)	443	(3)
41	Pesticide Chemicals	455	(2)
42	Petroleum Refining	419	(3)
43	Pharmaceutical Manufacturing	439	(1)
44	Phosphate Manufacturing	422	(3)
45	Photographic	459	(3)
46	Plastic Molding and Forming	463	(3)
47	Porcelain Enameling	466	(3)
48	Pulp, Paper, and Paperboard	430	(2)
49	Rubber Manufacturing	428	(3)
50	Soaps and Detergents Manufacturing	417	(3)
51	Steam Electric Power Generating	423	(4)
52	Sugar Processing	409	(3)
53	Textile Mills	410	(3)
54	Timber Products Processing	429	(3)
55	Transportation Equipment Cleaning	442	(3)
56	Waste Combustors	444	(5)

[3] Based on available information, hospitals consist mostly of indirect dischargers for which EPA has not established pretreatment standards. As discussed in Section VII.D, EPA is including hospitals in its review of the Health Services Industry, a potential new category for pretreatment standards. As part of that process, EPA will review the existing effluent guidelines for the few direct dischargers in the category.

† Note: The descriptions of the "Findings" codes are presented immediately prior to this table.

‡ Note: Two codes ("(1)" and "(4)") are used for this category as both codes are applicable to this category and do not overlap. The first code ("(1)") refers to the recent effluent guidelines rulemaking (January 23, 2002; 67 FR 3370), which created two new subcategories [Coal Remining (Subpart G) and Western Alkaline Coal (Subpart H)]. The second code ("(4)") refers to the on-going detailed study described above that is examining the issues identified by commenters to the preliminary 2006 Plan, which are different from those addressed in the previous rulemaking.

† † Note: Two codes ("(1)" and "(4)") are used for this category as both codes are applicable to this category and do not overlap. The first code ("(1)") refers to the recent effluent guidelines rulemaking (January 22, 2001; 66 FR 6850), which established BAT limitations and NSPS for non-aqueous drilling fluids. The second code ("(4)") refers to the on-going detailed study described above that is examining the issues identified by commenters to the preliminary 2006 Plan, which are different from those addressed in the previous rulemaking.

‡ ‡ Note: Two codes ("(1)" and "(3)") are used for this category as both codes are applicable to this category and do not overlap. The first code ("(1)") refers to the on-going effluent guidelines rulemaking for the Chlorinated Hydrocarbon (CCH) manufacturing sector, which includes facilities currently regulated by the OCSPF and Inorganics effluent guidelines. The second code ("(3)") indicates that the remainder of the facilities in these two categories do not represent a hazard priority at this time.

VI. EPA's 2008 Annual Review of Existing Effluent Guidelines and Pretreatment Standards Under CWA Sections 301(d), 304(b), 304(g), and 307(b)

As discussed in section V and further in section VIII, EPA is coordinating its annual reviews of existing effluent guidelines and pretreatment standards under CWA sections 301(d), 304(b), 307(b), and 304(g) with the publication of preliminary Plans and biennial Plans under section 304(m). Public comments received on EPA's prior reviews and Plans helped the Agency prioritize its analysis of existing effluent guidelines and pretreatment standards during the 2007 review. The information gathered during the 2007 annual review, including the identification of data gaps in the analysis of certain categories with existing regulations, in turn, provides a starting point for EPA's 2008 annual review. See Table V–1 in section V.B.4 of today's notice. In 2008, EPA intends to again conduct a screening-level analysis of all 56 categories and compare the results against those from previous years. EPA will also conduct further review of the industrial categories currently regulated by existing effluent guidelines that cumulatively comprise 95% of the reported hazard (reported in units of toxic-weighted pound equivalent or TWPE). Additionally, EPA intends to continue detailed studies of the following categories with existing effluent guidelines and pretreatment standards: Steam Electric Power Generating (Part 423), Coal Mining (Part 434), Oil and Gas Extraction (Part 435) (only to assess whether to include coalbed methane extraction as a new subcategory) and Hospitals (Part 460) (which is part of the Health Services Industry detailed study). EPA is identifying three categories (Ore Mining and Dressing, Centralized Waste Treatment, and Waste Combustors) for a preliminary category review in the 2008 annual review. EPA invites comment and data on the four detailed studies, the three preliminary category reviews, and all remaining point source categories.

VII. EPA's Evaluation of Categories of Indirect Dischargers Without Categorical Pretreatment Standards To Identify Potential New Categories for Pretreatment Standards

A. EPA's Evaluation of Pass Through and Interference of Toxic and Non-conventional Pollutants Discharged to POTWs

All indirect dischargers are subject to general pretreatment standards (40 CFR 403), including a prohibition on discharges causing "pass through" or "interference." See 40 CFR 403.5. All POTWs with approved pretreatment programs must develop local limits to implement the general pretreatment standards. All other POTWs must develop such local limits where they have experienced "pass through" or "interference" and such a violation is likely to recur. There are approximately 1,500 POTWs with approved pretreatment programs and 13,500 small POTWs that are not required to develop and implement pretreatment programs.

In addition, EPA establishes technology-based national regulations, termed "categorical pretreatment standards," for categories of industry discharging pollutants to POTWs that may pass through, interfere with or otherwise be incompatible with POTW operations. CWA section 307(b). Generally, categorical pretreatment standards are designed such that wastewaters from direct and indirect industrial dischargers are subject to similar levels of treatment. EPA has promulgated such pretreatment standards for 35 industrial categories.

Historically, for most effluent guidelines rulemakings, EPA determines the potential for "pass through" by comparing the percentage of the pollutant removed by well-operated POTWs achieving secondary treatment with the percentage of the pollutant removed by wastewater treatment options that EPA is evaluating as the bases for categorical pretreatment standards (January 28, 1981; 46 FR 9408).

The term "interference" means a discharge which, alone or in conjunction with a discharge or discharges from other sources, both: (1) Inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and (2) therefore is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation) or of the prevention of sewage sludge use or disposal in compliance with applicable regulations or permits. See 40 CFR 403.3(i). To determine the potential for "interference," EPA generally evaluates the industrial indirect discharges in terms of: (1) The compatibility of industrial wastewaters and domestic wastewaters (*e.g.*, type of pollutants discharged in industrial wastewaters compared to pollutants typically found in domestic wastewaters); (2) concentrations of pollutants discharged in industrial wastewaters that might cause interference with the POTW collection system, the POTW treatment system, or biosolids disposal options; and (3) the potential for variable pollutant loadings to cause interference with POTW operations (*e.g.*, batch discharges or slug loadings from industrial facilities interfering with normal POTW operations).

If EPA determines a category of indirect dischargers causes pass through or interference, EPA would then consider the BAT and BPT factors (including "such other factors as the Administrator deems appropriate") specified in section 304(b) to determine whether to establish pretreatment standards for these activities. Examples of "such other factors" include a consideration of the magnitude of the hazard posed by the pollutants discharged as measured by: (1) The total annual TWPE discharged by the industrial sector; and (2) the average TWPE discharge among facilities that discharge to POTWs. Additionally, EPA would consider whether other regulatory tools (*e.g.*, use of local limits under Part 403) or voluntary measures would better control the pollutant discharges from this category of indirect dischargers. For example, EPA relied on a similar evaluation of "pass through potential" in its prior decision not to

promulgate national categorical pretreatment standards for the Industrial Laundries industry. See 64 FR 45071 (August 18, 1999). EPA noted in this 1999 final action that, "While EPA has broad discretion to promulgate such [national categorical pretreatment] standards, EPA retains discretion not to do so where the total pounds removed do not warrant national regulation and there is not a significant concern with pass through and interference at the POTW." See 64 FR 45077 (August 18, 1999).

EPA reviewed TRI data in order to identify industry categories without categorical pretreatment standards that are discharging pollutants to POTWs that may pass through, interfere with or otherwise be incompatible with POTW operations (*see* DCN 04247). This review did not identify any such industrial categories. EPA also evaluated stakeholder comments and pollutant discharge information in the previous annual reviews to inform this review. In particular, commenters on the 2004 and 2006 annual reviews raised concerns about discharges of emerging pollutants of concern such as endocrine disruptors and mercury discharges from dentists and health service facilities and urged EPA to consider establishing effluent guidelines and pretreatment standards for such discharges. In response to these comments, EPA investigated the Health Services Industry in its 2006 annual review and found that it did not have readily available information to make an informed decision on the potential for "pass through" or "interference." Consequently, EPA identified this industrial category for detailed study in its 2007 and 2008 annual reviews. EPA also solicits comment and data on all industrial sectors not currently subject to categorical pretreatment standards for its 2008 review. Finally, EPA solicits comment on methods for aggregating pollutant discharge data collected by pretreatment programs to further inform its future review of industry categories without categorical pretreatment standards.

B. Health Services Industry Detailed Study

The Health Services Industry includes establishments engaged in various aspects of human health (*e.g.* hospitals, dentists, long-term care facilities) and animal health (*e.g.*, veterinarians). Health services establishments fall under SIC major group 80 "Health Services" and industry group 074 "Veterinary Services." According to the 2002 Census, there are over 475,000 facilities in the Health Services Industry (*see* EPA–HQ–OW–2004–0032–1615). EPA is including the following sectors within the Health Services Industry in its detailed study: Offices and Clinics of Dentists; Doctors and Mental Health Practitioners; Nursing and Personal Care Facilities (long-term care facilities); Hospitals and Clinics; Medical Laboratories and Diagnostic Centers; and Veterinary Care Services (*see* August 29, 2005; 70 FR 51054).

All these sectors require services to be delivered by trained professionals for the purpose of providing health care and social assistance for individuals or animals. These entities may be free standing or part of a hospital or health system and may be privately or publicly owned. The services can include diagnostic, preventative, cosmetic, and curative health services.

The vast majority of establishments in the health services industries are not subject to categorical limitations and standards. In 1976, EPA promulgated 40 CFR 460 which only applies to direct discharging hospitals with greater than 1,000 occupied beds. Part 460 did not establish pretreatment standards for indirect discharging facilities.

In evaluating the health services industries to date, EPA has found little readily available information. Both PCS and TRI contain sparse information on health care service establishments. For 2002, PCS only has data for two facilities which are considered "major" sources of pollutants and only Federal facilities in the healthcare industry are required to report to TRI. In 1989, EPA published a Preliminary Data Summary (PDS) for the Hospitals Point Source Category (*see* EPA–HQ–OW–2004–0032–0782). Also, EPA's Office of Enforcement and Compliance Assistance (OECA) published a Healthcare Sector Notebook in 2005 (*see* EPA–HQ–OW–2004–0032–0729). In addition, industry and POTWs have conducted studies to estimate pollutant discharges for some portions of this industry (e.g., dentists) (*see* EPA–HQ–OW–2004–0032–0772).

Based on preliminary information, major pollutants of concern in discharges from health care service establishments include solvents, mercury, pharmaceuticals, endocrine-disrupting compounds (EDCs), and biohazards (*e.g.*, items contaminated with blood) (*see* EPA–HQ–OW–2004–0032–0729). The majority of the mercury originates from the following sources: amalgam used in dental facilities and medical equipment, laboratory reagents, and cleaning supplies used in healthcare facilities (*see* EPA–HQ–OW–2004–0032–0038 and 2391). EPA found little to no quantitative information on wastewater discharges of emerging pollutants of concern such as pharmaceuticals and EDCs but was able to identify some information on biohazards (*see* DCN 04274).

As described above, the Health Services Industry is expansive and contains approximately half a million facilities. Because of the size and diversity of this category and other resource constraints, EPA decided to focus its detailed study on certain subcategories of dischargers. EPA selected its focus areas, for the most part, to respond to stakeholder concerns. The focus areas are:

- *Dental mercury:* EPA is focusing its evaluation on mercury discharges from the offices and clinics of dentists due to the potential hazard and bioaccumulative properties associated with mercury.
- *Unused pharmaceuticals:* EPA is focusing its evaluation on unused or leftover pharmaceuticals from health service facilities due to the growing concern over the discharge of pharmaceuticals into water and the potential environmental effects.

Unused pharmaceuticals include dispensed prescriptions that patients do not use as well as materials that are beyond their expiration dates. It includes both human and veterinary drugs (including certain pesticides such as flea, tick, and lice controls). As a point of clarification, the term "unused pharmaceuticals" does not include excreted pharmaceuticals. In particular, EPA is evaluating disposed unused pharmaceutical practices from the following sectors:

- Physicians offices
- Nursing and personal care facilities (including long-term care facilities);
- Veterinary care services; and
- Hospitals and clinics.

The Agency notes that it has an overall interest in mercury reduction and on July 5, 2006, issued a report titled, "EPA's Roadmap for Mercury," (*see* DCN 03035). Among other things, EPA's report highlights mercury sources and describes progress to date in addressing mercury sources. Similarly, assessing pharmaceuticals in wastewater is part of the Agency's Strategic Plan (2006–2011) to meet its goals of clean and safe water, (*see http://www.epa.gov/ocfo/plan/plan.htm*). EPA is concerned about pharmaceuticals in the environment and is working on this issue in many different areas. Currently, the Agency is: (1) Developing analytical methods to measure pharmaceuticals in wastewater and biosolids; (2) studying the health and ecological effects of

pharmaceuticals on aquatic life and their occurrence in fish; and (3) engaged in determining the significance of consumer disposal of drugs to wastewater. Additionally, the Agency is considering amending its hazardous waste regulations to add hazardous pharmaceuticals to the universal waste system to facilitate its oversight of the disposal of pharmaceutical waste (40 CFR 273) (*see* RIN 2050–AG39, April 30, 2007; 72 FR 23170).

While stakeholders and EPA are concerned about EDC discharges, EPA has found only limited data on EDCs. In order to fill in some of these data gaps, in conjunction with its Health Services Industry detailed study, EPA is conducting a POTW study that, among other things, has the goal of developing wastewater analytical methods for certain pollutants, characterizing the presence of chemicals such as surfactants and pharmaceuticals in POTW wastewaters and evaluating POTW treatment technology effectiveness in reducing such pollutant discharges. To the extent that the results of the POTW studies become available during the term of this Health Services Industry detailed study, EPA will include relevant information in this study.

The Health Services Study is described in more detail in *EPA's Draft Detailed Study Plan for the Health Services Industry* (*see* DCN 05067) and *Overview of EPA's Detailed Study of the Health Services* (*see* DCN 05080). As explained there, EPA is researching the following questions/topics as they relate to disposal of mercury and unused pharmaceuticals into municipal sewer systems:

- What are the current industry practices in regards to disposal of unused pharmaceuticals and mercury? To what extent are each of these practices applied? What factors drive current practices?
- Are there federal, state, or local requirements or guidance for disposal of unused pharmaceuticals and/or mercury? What are these requirements?
- How are control authorities currently controlling (or not) disposal of unused pharmaceuticals and mercury via wastewater?
- To what extent do POTWs report pass through or interference problems related to unused pharmaceuticals or mercury discharges?
- What technologies are available: (1) As alternatives to wastewater disposal; and (2) to control pollutant discharges. Is there any qualitative or quantitative information on their efficiency?
- What Best Management Practices (BMPs) are used as alternatives to wastewater disposal and/or to control discharges and is there any qualitative or quantitative information on their efficiency?
- Is there any quantitative or qualitative information on the costs associated with identified technologies and/or BMPs?

1. Dental Mercury

Across the United States, states and municipal wastewater treatment plants (publicly owned treatment works (POTWs)) are working toward the goal of reducing discharges of mercury into collection systems. Many studies have been conducted in an attempt to identify the sources of mercury entering these collection systems. According to the 2002 *Mercury Source Control and Pollution Prevention Program Final Report* prepared for the National Association of Clean Water Agencies (NACWA), dental clinics are the main source of mercury discharges to POTWs. The American Dental Association (ADA) estimated in 2003 that 50% of mercury entering POTWs was contributed by dental offices.

EPA estimates there are approximately 130,000 dental offices in the United States—almost all of which discharge their wastewater exclusively to POTWs. Mercury in dental wastewater originates from waste particles associated with the placement and removal of amalgam fillings. Most dental offices currently use some type of basic filtration system to reduce the amount of mercury solids passing into the sewer system. However, best management practices and the installation of amalgam separators may reduce discharges even further.

Some states, regions, and POTWs have already implemented or are considering alternatives to reduce mercury discharges from dental offices. For example, a number of states have enacted legislation requiring the installation and operation of amalgam separators or use of best management practices (*see* DCN 04668). EPA Region 5 published guidance for permitting dental mercury discharges (*see* DCN 05024). The ADA has also adopted and published best management practices for its members. On October 2, 2007, the ADA updated its best management practices to include the use of amalgam separators (*see* DCN 05087). See DCN 04668 for a compilation of the information EPA has collected to date on existing guidance and requirements for dental mercury.

In 2007, EPA has focused its efforts on collecting and compiling information on current mercury discharges from dental offices, best management practices (BMPs), and control technologies such as amalgam separators. For control technologies and BMPs, EPA has looked at the frequency with which each is currently used; their effectiveness in reducing discharges to POTWs; and the capital and annual costs associated with their installation and operation (*see* DCN 04851 and 04852). EPA encourages all stakeholders to review the information collected to date and provide additional information, if available. EPA is particularly interested in quantitative information on the effectiveness and costs of implementing best management practices.

At this time, EPA does not know if its investigation will lead to the development of national, categorical pretreatment standards for dental mercury discharges. While this is a possibility, EPA is aware of a number of successful local programs and has identified that there are many opportunities for pollution prevention and adoption of BMPs without federal regulation. It appears that the dental industry is already actively working towards voluntarily reducing its mercury discharges.

2. Unused Pharmaceuticals

Stakeholders have expressed concern over the discharge of pharmaceuticals into water and its environmental effects. Recent studies have indicated the presence of pharmaceuticals in waters of the U.S. See Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, USGS Fact Sheet FS–027–02, June 2002 (*see* DCN 04854). Recent studies have also shown the presence of pharmaceuticals directly downstream of POTWs (*see* DCN 05071). To date, EPA has found little quantitative information on the origin of pharmaceuticals in municipal wastewaters. There is even less data on the quantity of pharmaceuticals entering and leaving wastewater treatment plants. The discharge of pharmaceuticals to these treatment plants, with few exceptions, is not currently regulated or monitored.

Health Services Industry facilities (*e.g.*, hospitals, veterinarians, doctors, and long-term care facilities) may dispose of unused, expired, and unwanted medications ("unused pharmaceuticals") down the drain or toilet, which then may pass through the POTW and on to surface waters. Given this concern, EPA plans to collect information from the Health Services Industry to better understand pharmaceutical discharges to POTWs and to make informed decisions. POTWs are not specifically designed to remove the wide range of

pharmaceuticals, and often the treatment plant removal efficiencies are unknown. The full spectrum of pharmaceuticals occurring in POTW effluent is not yet known, and for those that are present, the POTW removal efficiency is a function of the treatment technology employed and will vary from drug to drug. As a result, unused pharmaceuticals may have the potential to cause interference or to pass through municipal wastewater treatment plants.

In order to obtain further quantitative information on unused pharmaceuticals in Health Service Industry wastewaters, EPA plans to send a data request to targeted long-term care facilities, hospitals, and veterinarians. EPA is interested in obtaining the records facilities keep to track disposal of unused pharmaceuticals and their quantities. EPA especially wants to know how much and how often unused pharmaceuticals are disposed of via the sink or toilet, and what drives such practices.

There are best management practices (BMPs) and alternatives to disposing of pharmaceuticals into POTWs via sinks and toilets. Alternative disposal options include hazardous waste incinerators, regulated medical waste incinerators, and non-hazardous landfills (i.e., trash). Also, there are pharmacy take back programs via the mail and physical drop off locations (*e.g.*, reverse distribution brokers or centers). These take back programs are typically only available for pharmaceuticals that have not been sold and are not available to consumers. EPA is exploring the utility of take back programs and has given a grant to the University of Maine Center on Aging to devise, implement and evaluate a mail back plan for consumers to return unused over the counter and prescription medications. A network of 75 distribution points located at pharmacies will provide for mailer pick up and drop offs. Informational materials for pharmacists, staff and consumers regarding the mailers will be developed and distributed. In addition, the pilot will test the effectiveness of an educational campaign about the hazards to life, health, and the environment posed by improper storage and disposal of unused mediations.

Many of the current disposal practices are driven by Federal requirements or guidance. In addition to Federal rules, there are state and local policies that influence disposal of unused pharmaceuticals. EPA will continue to evaluate disposal alternatives in context of the existing requirements which affect disposal decisions.

At this time, EPA does not have enough information to know if this study will lead to the development of a national, categorical pretreatment standard for unused pharmaceuticals. While this is a possibility, EPA is gathering information on pollution prevention opportunities and BMPs that may provide a reasonable alternative to federal regulation. To aid EPA in its assessment of unused pharmaceuticals from the Health Services Industry, EPA requests comment on current practices. See section IX.

VIII. The Preliminary 2008 Effluent Guidelines Program Plan Under Section 304(m)

In accordance with CWA section 304(m)(2), EPA is publishing this preliminary 2008 Plan for public comment prior to this publication of the final 2008 Plan.

A. EPA's Schedule for Annual Review and Revision of Existing Effluent Guidelines Under Section 304(b)

1. Schedule for 2007 and 2008 Annual Reviews Under Section 304(b)

As noted in section IV.B, CWA section 304(m)(1)(A) requires EPA to publish a Plan every two years that establishes a schedule for the annual review and revision, in accordance with section 304(b), of the effluent guidelines that EPA has promulgated under that section. This preliminary 2008 Plan announces EPA's schedule for performing its section 304(b) reviews. The schedule is as follows: EPA will coordinate its annual review of existing effluent guidelines under section 304(b) with its publication of the preliminary and final Plans under CWA section 304(m). In other words, in odd-numbered years, EPA intends to complete its annual review upon publication of the preliminary Plan that EPA must publish for public review and comment under CWA section 304(m)(2). In even-numbered years, EPA intends to complete its annual review upon the publication of the final Plan. EPA's 2007 annual review is the review cycle ending upon the publication of this preliminary 2008 Plan.

EPA is coordinating its annual reviews under section 304(b) with publication of Plans under section 304(m) for several reasons. First, the annual review is inextricably linked to the planning effort, because the results of each annual review can inform the content of the preliminary and final Plans, *e.g.*, by identifying candidates for ELG revision for which EPA can schedule rulemaking in the Plan, or by calling to EPA's attention point source categories for which EPA has not promulgated effluent guidelines. Second, even though not required to do so under either section 304(b) or section 304(m), EPA believes that the public interest is served by periodically presenting to the public a description of each annual review (including the review process employed) and the results of the review. Doing so at the same time EPA publishes preliminary and final plans makes both processes more transparent. Third, by requiring EPA to review all existing effluent guidelines each year, Congress appears to have intended that each successive review would build upon the results of earlier reviews. Therefore, by describing the 2007 annual review along with the preliminary 2008 Plan, EPA hopes to gather and receive data and information that will inform its reviews for 2008 and the final 2008 Plan.

2. Schedule for Possible Revision of Effluent Guidelines Promulgated Under Section 304(b)

EPA is currently conducting rulemakings to potentially revise existing effluent guidelines and pretreatment standards for the following categories: Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) and Inorganic Chemicals (to address discharges from Vinyl Chloride and Chlor-Alkali facilities identified for effluent guidelines rulemaking in the final 2004 Plan, now termed the "Chlorine and Chlorinated Hydrocarbon (CCH) manufacturing" rulemaking) and Concentrated Animal Feeding Operations (rulemaking on BCT technology options for controlling fecal coliform and new source performance standards). EPA emphasizes that identification of the rulemaking schedules for these effluent guidelines does not constitute a final decision to revise the guidelines. EPA may conclude at the end of the formal rulemaking process—supported by an administrative record and following an opportunity for public comment—that effluent guidelines revisions are not appropriate for these categories. EPA is not scheduling any other existing effluent guidelines for rulemaking at this time.

B. Identification of Potential New Point Source Categories Under CWA Section 304(m)(1)(B)

The final Plan must also identify categories of sources discharging non-trivial amounts of toxic or non-conventional pollutants for which EPA has not published effluent limitations guidelines under section 304(b)(2) or new source performance standards (NSPS) under section 306. See CWA section 304(m)(1)(B); S. Rep. No. 99–50,

Water Quality Act of 1987, Leg. Hist. 31 (indicating that section 304(m)(1)(B) applies to "non-trivial discharges"). The final Plan must also establish a schedule for the promulgation of effluent guidelines for the categories identified under section 304(m)(1)(B), providing for final action on such rulemaking not later than three years after the identification of the category in a final Plan.[4] See CWA section 304(m)(1)(C).

EPA is currently conducting rulemakings to determine whether to establish effluent guidelines for three potential new categories (*see* September 2, 2004; 69 FR 53705). Two of these categories—Airport Deicing Operations and Drinking Water Treatment—were identified as potential new categories in the final 2004 Plan. EPA initiated rulemaking for the third category—Construction and Development—because it was directed to do so by a district court order. *NRDC et al.* v. *EPA*, No. 04–8307, order (C.D. Ca., December 6, 2006). Although EPA respectfully disagrees with this decision, and does not believe that it is required to promulgate effluent guidelines for this potential new category, EPA is conducting the rulemaking ordered by the court pending appeal of the Court's decision. For the reasons discussed below, EPA is not at this time proposing to identify any other potential new categories for effluent guidelines rulemaking and therefore is not scheduling effluent guidelines rulemaking for any such categories in this preliminary Plan.

In order to identify industries not currently subject to effluent guidelines, EPA primarily used data from TRI and PCS. Facilities with data in TRI and PCS are identified by a four-digit SIC code (*see* DCN 04247). EPA performs a crosswalk between the TRI and PCS data, identified with the four digit SIC code, and the 56 point source categories with effluent guidelines or pretreatment standards to determine if a four-digit SIC code is currently regulated by existing effluent guidelines (*see* DCN 04247). EPA also relied on comments received on its previous 304(m) plans to identify potential new categories. EPA then assessed whether these industrial sectors not currently regulated by effluent guidelines meet the criteria specified in section 304(m)(1)(B), as discussed below.

First, section 304(m)(1)(B) specifically applies only to "categories of sources" for which EPA has not promulgated effluent guidelines. Because this section does not define the term "categories," EPA interprets this term based on the use of the term in other sections of the Clean Water Act, legislative history, and Supreme Court case law, and in light of longstanding Agency practice. As discussed below, these sources indicate that the term "categories" refers to an industry as a whole based on similarity of product produced or service provided, and is not meant to refer to specific industrial activities or processes involved in generating the product or service. EPA therefore identifies in its biennial Plan only those new industries that it determines are properly considered stand-alone "categories" within the meaning of the Act—not those that are properly considered potential new subcategories of existing categories based on similarity of product or service.

The use of the term "categories" in other provisions of the CWA indicates that a "category" encompasses a broad array of industrial operations related by similarity of product or service provided. For example, CWA section 306(b)(1)(A) provides a list of "categories of sources" (for purposes of new source performance standards) that includes "pulp and paper mills," "petroleum refining," "iron and steel manufacturing," and "leather tanning and finishing." These examples suggest that a "category" is intended to encompass a diversity of facilities engaged in production of a similar product or provision of a similar service. *See also* CWA section 402(e) and (f) (indicating that "categories" are comprised of smaller subsets such as "class, type, and size"). In the effluent guidelines program, EPA uses these factors, among others, to define "subcategories" of a larger industrial category.

The legislative history of later amendments to CWA section 304 indicates that Congress was aware that there was a distinction between "categories" and "subcategories" in effluent guidelines. *See Leg. Hist: Senate Committee on Environment and Public Works, A Legislative History of the Clean Water Act of 1977*, prepared by the Environmental Policy Division of the Congressional Research Service of the Library of Congress (Comm. Print 1978) at 455 (indicating that BAT calls for the examination of "each industry category or subcategory"). *See also Chemical Manufacturers' Association* v. *EPA*, 470 U.S. 116, 130 (1985) (interpreting this legislative history as "admonish[ing] [EPA] to take into account the diversity within each industry by establishing appropriate subcategories."). Therefore, in light of Congress' awareness of the distinction between categories and subcategories, EPA reasonably assumes that Congress' use in 1987 of the term "categories" in section 304(m)(1)(B) was intentional. If Congress had intended for EPA to identify potential new subcategories in the Plan, it would have said so. Congress' direction for EPA to identify new "categories of sources" cannot be read to constrain EPA's discretion over its internal planning processes by requiring identification of potential new "subcategories" in the Plan. *See Norton* v. *Southern Utah Wilderness Alliance et al*, 124 S Ct. 2373, 2383 (2004) (finding that a statutory mandate must be sufficiently specific in order to constrain agency discretion over its internal planning processes).

Moreover, the distinction between a category and a subcategory has long been recognized by the Supreme Court. In *Chemical Manufacturers' Association* v. *EPA*, the Court recognized that categories are "necessarily rough-hewn" (*id.* at 120) and that EPA establishes subcategories to reflect "differences among segments of the industry" based on the factors that EPA must consider in establishing effluent limitations. *Id.* at 133, n. 24. *See also Texas Oil and Gas Assn.* v. *EPA*, 161 F.3d 923, 939 (5th Cir. 1998) ("The EPA is authorized—indeed, is required—to account for substantial variation within an existing category * * * of point sources."). Indeed, the effluent guidelines considered by the Supreme Court in *Du Pont* case was divided into 22 subcategories, each with its own set of technology-based limitations, reflecting variations in processes and pollutants. *Id.* at 22 and nn. 9 and 10. *See also id.* at 132 (noting that legislative history "can be fairly read to allow the use of subcategories based on factors such as size, age, and unit processes.").

EPA's interpretation of the term "categories" is consistent with longstanding Agency practice. Pursuant to CWA section 304(b), which requires EPA to establish effluent guidelines for "classes and categories of point sources," EPA has promulgated effluent guidelines for 56 industrial "categories." Each of these "categories" consists of a broad array of facilities that produce a similar product or perform a similar service—and is broken down into smaller subsets, termed "subcategories," that reflect variations

[4] EPA recognizes that one court—the U.S. District Court for the Central District of California—has found that EPA has a duty to *promulgate* effluent guidelines within three years for new categories identified in the Plan. *See NRDC et al.* v. *EPA*, 437 F.Supp.2d 1137 (C.D. Ca. 2006). However, EPA continues to believe that the mandatory duty under section 304(m)(1)(c) is limited to providing a *schedule* for concluding the effluent guidelines rulemaking—not necessarily promulgating effluent guidelines—within three years, and has appealed this decision.

in the processes, treatment technologies, costs and other factors associated with the production of that product that EPA is required to consider in establishing effluent guidelines under section 304(b). For example, the "Pulp, Paper and Paperboard point source category" (40 CFR part 430) encompasses a diverse range of industrial facilities involved in the manufacture of a like product (paper); the facilities range from mills that produce the raw material (pulp) to facilities that manufacture end-products such as newsprint or tissue paper. EPA's classification of this "industry by major production processes used many of the statutory factors set forth in CWA Section 304(b), including manufacturing processes and equipment (*e.g.*, chemical, mechanical, and secondary fiber pulping; pulp bleaching; paper making); raw materials (*e.g.*, wood, secondary fiber, non-wood fiber, purchased pulp); products manufactured (*e.g.*, unbleached pulp, bleached pulp, finished paper products); and, to a large extent, untreated and treated wastewater characteristics (*e.g.*, BOD loadings, presence of toxic chlorinated compounds from pulp bleaching) and process water usage and discharge rates."[5] Each subcategory reflects differences in the pollutant discharges and treatment technologies associated with each process. Similarly, the "Iron and Steel Manufacturing point source category" (40 CFR part 420) consists of various subcategories that reflect the diverse range of processes involved in the manufacture of iron and steel, ranging from facilities that make the basic fuel used in the smelting of iron ore (subpart A—Cokemaking) to those that cast the molten steel into molds to form steel products (subpart F—Continuous Casting). An example of an industry category based on similarity of service provided is the Transportation Equipment Cleaning Point Source Category (40 CFR Part 442), which is subcategorized based on the type of tank (*e.g.*, rail cars, trucks, barges) or cargo transported by the tanks cleaned by these facilities, reflecting variations in wastewaters and treatment technologies associated with each.

Thus, EPA's first decision criterion asks whether a new industrial operation or activity in question is properly characterized as an industry "category" based on similarity of product produced or service provided, or whether it simply represents a variation (*e.g.* new process) among facilities generating the same product and is therefore properly characterized as a potential new subcategory. If it is properly considered a stand-alone category in its own right, EPA addresses it pursuant to sections 304(m)(1)(B) and (C). If EPA determines that it is a potential new "subcategory," EPA reviews the activity in its section 304(b) annual review of the existing categories in which it would belong, in order to determine whether it would be appropriate to revise the effluent guidelines for that category to include limits for the new subcategory.

As a practical matter, this approach makes sense. There are constantly new processes being developed within an industry category—new ways of making paper or steel, new ways of cleaning transportation equipment, new ways of extracting oil and gas, for example. These new processes are closely interwoven with the processes already covered by the existing effluent guidelines for the category—they often generate similar pollutants, are often performed by the same facilities, and their discharges can often be controlled by the same treatment technology. Therefore, it is more efficient for EPA to consider industry categories holistically by looking at these new processes when reviewing and revising the effluent guidelines for the existing category. The opposite approach could lead to a situation when EPA would do a separate effluent guidelines rulemaking every time a new individual process emerges without considering how these new technologies could affect BAT for related activities. In revising effluent guidelines, EPA often creates new subcategories to reflect new processes. For example, the effluent guidelines for the pesticides chemicals category (40 CFR part 455) did not originally cover refilling establishments because this process was developed after the limitations were first promulgated. When EPA revised the effluent guidelines for the Pesticides Chemicals category, EPA included refilling establishments as a new subcategory subject to the effluent limits for this category. The issue is not whether a guideline should be developed for a particular activity, but whether the analysis should occur in isolation or as part of a broader review.

To ensure appropriate regulation of such new subcategories prior to EPA's promulgation of new effluent guidelines for the industrial category to which they belong, under EPA's regulations at 40 CFR part 125.3(c), a permit writer is required to establish technology-based effluent limitations for these processes on a case by case, "Best Professional Judgment" (BPJ) basis, considering the same factors that EPA considers in promulgating categorical effluent limitations guidelines. These new processes are covered by these BPJ-based effluent guidelines until the effluent guidelines for the industrial category are revised to include limits for these new subcategories.

EPA's approach to addressing new industries is analogous to EPA's approach to addressing newly identified pollutants. When EPA identifies new pollutants associated with the discharge from existing categories, EPA considers limits for those new pollutants in the context of reviewing and revising the existing effluent guidelines for that category. For example, EPA revised effluent limitations for the bleached papergrade kraft and soda and papergrade sulfite subcategories within the Pulp, Paper, and Paperboard point source category (40 CFR 430) to add BAT limitations for dioxin, which was not measurable when EPA first promulgated these effluent guidelines and pretreatment standards and was not addressed by the pollutant control technologies considered at that time. See 63 FR 18504 (April 15, 1998).

In short, for the reasons discussed above, EPA believes that the appropriateness of addressing a new process or pollutant discharge is best considered in the context of revising an existing set of effluent guidelines. Accordingly, EPA analyzed similar industrial activities not regulated by existing regulations as part of its annual review of existing effluent guidelines and pretreatment standards.

The second criterion EPA considers when implementing section 304(m)(1)(B) also derives from the plain text of that section. By its terms, CWA section 304(m)(1)(B) applies only to industrial categories to which effluent guidelines under section 304(b)(2) or section 306 would apply, if promulgated. Therefore, for purposes of section 304(m)(1)(B), EPA would not identify in the biennial Plan any industrial categories comprised exclusively or almost exclusively of indirect discharging facilities regulated under section 307. For example, based on its finding that the Health Services Industry consists almost exclusively of indirect dischargers, EPA did not identify this industry in the 2008 Plan but instead will consider whether to adopt pretreatment standards for this industry in the context of its section 304(g)/307(b) review of indirect dischargers. Similarly, EPA would not identify in the Plan categories for which effluent guidelines do not apply, *e.g.*,

[5] U.S. EPA, 1997. *Supplemental Technical Development Document for Effluent Limitations Guidelines and Standards for the Pulp, Paper, and Paperboard Category*, Page 5–3, EPA–821–R–97–011, October 1997.

POTWs regulated under CWA section 301(b)(1)(B) or municipal storm water runoff regulated under CWA section 402(p)(3)(B).

Third, CWA section 304(m)(1)(B) applies only to industrial categories of sources that discharge toxic or non-conventional pollutants to waters of the United States. EPA therefore did not identify in the Plan industrial activities for which conventional pollutants, rather than toxic or non-conventional pollutants, are the pollutants of concern. In addition, even when toxic and non-conventional pollutants might be present in an industrial category's discharge, section 304(m)(1)(B) does not apply when those discharges occur in trivial amounts. EPA does not believe that it is necessary, nor was it Congressional intent, to develop national effluent guidelines for categories of sources that discharge trivial amounts of toxic or non-conventional pollutants and therefore pose an insignificant hazard to human health or the environment. See Senate Report Number 50, 99th Congress, 1st Session (1985); WQA87 Legislative History 31 (*see* DCN 03911). This decision criterion leads EPA to focus on those remaining industrial categories where, based on currently available information, new effluent guidelines have the potential to address a non-trivial hazard to human health or the environment associated with toxic or non-conventional pollutants.

Finally, EPA interprets section 304(m)(1)(B) to give EPA the discretion to identify in the Plan only those potential new categories for which an effluent guidelines rulemaking may be an appropriate tool. Therefore, EPA does not identify in the Plan all potential new categories discharging toxic and non-conventional pollutants. Rather, EPA identifies only those potential new categories for which it believes that effluent guidelines may be appropriate, taking into account Agency priorities, resources and the full range of other CWA tools available for addressing industrial discharges.

This interpretation is supported by the Supreme Court's decision in *Norton* v. *Southern Utah Wilderness Alliance et al.* (124 S. Ct. 2373, 2383 (2004)), which recognized the importance of agency discretion over its internal planning processes. Specifically, the Court in *Norton* held that a statute requiring an agency to "manage wilderness study areas . . . in a manner so as not to impair the suitability of such areas" was too broad to constrain the agency's discretion over its internal land use planning processes. *See also Fund for Animals et al.* v. *U.S. Bureau of Land Management*, No. 04–5359, 2006 U.S. App. LEXIS 21206 (D.C. Cir., August 18, 2006); *Center for Biological Diversity* v. *Veneman*, 394 F.3d 1108 (9th Cir. 2005) (both cases following *Norton* line of reasoning to find that statutory mandate was not sufficiently specific to constrain agency discretion over its internal planning processes). In this case, the statutory mandate at issue—establish technology-based effluent limits that take into account a range of factors including "such other factors as the Administrator deems appropriate"—also lacks the specificity to constrain the Agency's discretion over its effluent guidelines planning process. See CWA section 304(b)(2)(B). This broad statutory mandate gives EPA the discretion to identify in its section 304(m) Plan only those industrial categories for which it determines that effluent guidelines would be "appropriate" and to rely on other CWA tools—such as site-specific technology based limitations developed by permit writers on a BPJ basis—when it determines that such tools would be a more effective and efficient way of increasing the stringency of pollution control through NPDES permits.

Congress specifically accorded EPA with the discretion to choose the appropriate tool for pressing the development of new technologies, authorizing EPA to develop technology-based effluent limitations using a site-specific BPJ approach under CWA section 402(a)(1), rather than pursuant to an effluent guidelines rulemaking. See CWA section 301(b)(3)(B). Significantly, section 301(b)(3)(B) was enacted contemporaneously with section 304(m) and its planning process, suggesting that Congress contemplated the use of *both* tools, with the choice of tools in any given 304(m) plan left to the Administrator's discretion. The Clean Water Act requirement that EPA develop an effluent guidelines plan—when coupled with the broad statutory mandate to consider "appropriate" factors in establishing technology-based effluent limitations and the direction to establish such limitations either through effluent guidelines or site-specific BAT decision-making—cannot be read to constrain the Agency's discretion over what it includes in its plan.

Moreover, because section 304(m)(1)(C) requires EPA to complete an effluent guidelines rulemaking within three years of identifying an industrial category in a 304(m) Plan,[6] EPA believes that Congress intended to give EPA the discretion under section 304(m)(1)(B) to prioritize its identification of potential new industrial categories so that it can use available resources effectively. Otherwise, EPA might find itself conducting rushed, resource-intensive effluent guidelines rulemakings where none is actually needed for the protection of human health and the environment, or where such protection could be more effectively achieved through other CWA mechanisms. Considering the full scope of the mandates and authorities established by the CWA, of which effluent guidelines are only a part, EPA needs the discretion to promulgate new effluent guidelines in a phased, orderly manner, consistent with Agency priorities and the funds appropriated by Congress to execute them. By crafting section 304(m) as a planning mechanism, Congress has given EPA that discretion.

Like the land use plan at issue in *Norton*, EPA's plan is ultimately "a statement of choices and priorities." *See Norton* v. *Southern Utah Wilderness Alliance, et al.*, 124 S. Ct. 2373, 2383 (2004). By requiring EPA to publish its plan, Congress assured that EPA's priority-setting processes would be available for public viewing. By requiring EPA to solicit comments on preliminary plans, Congress assured that interested members of the public could contribute ideas and express policy preferences. EPA has given careful consideration and summarized its findings with respect to all industries suggested by commenters as candidates for inclusion in the Plan. Finally, by requiring publication of plans every two years, Congress assured that EPA would regularly re-evaluate its past policy choices and priorities (including whether to identify an industrial activity for effluent guidelines rulemaking) to account for changed circumstances. Ultimately, however, Congress left the content of the plan to EPA's discretion—befitting the role that effluent guidelines play in the overall structure of the CWA and their relationship to other tools for addressing water pollution.

[6] EPA recognizes that a recent district court held that section 304(m)(1)(c) requires EPA to promulgate effluent guidelines within three years for new categories identified in the Plan—not simply to conclude rulemaking in three years. *See NRDC et al.* v. *EPA*, 437 F.Supp.2d 1137 (C.D. Ca., 2006). EPA disagrees with this interpretation and has appealed this decision. If upheld on appeal, this decision would limit EPA's discretion regarding whether or not to promulgate effluent guidelines for new categories identified in the Plan. However, it would not affect EPA's discretion under section 304(m)(1)(B) to identify new industries in the Plan in the first place.

IX. Request for Comment and Information

A. EPA Requests Information on the Steam Electric Power Generating Category (Part 423)

EPA solicits public comments on the following areas of interest to support the Steam Electric Power Generating Detailed Study.

- *Integrated gasification combined cycle (IGCC) facilities.* EPA solicits comment on the wastewaters that may be generated or otherwise affected by the coal gasification process. What are the sources and characteristics of wastewaters generated by coal gasification and related processes at IGCC plants? How do these wastewaters compare to those of traditional coal-fired steam electric processes?
- *Treatment technologies for wastewaters from wet FGD systems.* EPA solicits information and data regarding the costs and effectiveness of available wastewater treatment technologies (*e.g.*, chemical precipitation) for wastewater from wet FGD systems (*e.g.*, capital and annual costs, pollutant removals). To help evaluate efficacy of the treatment technologies, EPA seeks both influent and effluent data from full scale or pilot applications. Data submitted should include details on the date samples were collected and analyzed, laboratory analytical methods used, and a description of the wastewater treatment system and sample collection points.
- *Ash pond management.* EPA solicits information that would help identify best management practices for ash ponds. For example, EPA is aware of information suggesting that managing pyritic wastes in ash ponds should be avoided because it can contribute to lowering pH of the ash pond impoundment, potentially liberating metals in ash sediments and elevating the level of metals released to surface waters. In addition, introducing certain other wastes such as coal pile runoff can substantially affect ash pond pH, similarly producing conditions that favor releasing metals present in ash pond sediments and suspended particulates. EPA solicits information on best management practices for minimizing the potential for such wastes to adversely impact ash pond operation and discharges.
- *Environmental assessments/impacts.* EPA solicits information on environmental assessments that have been conducted for discharges from steam electric power plants. In particular, EPA seeks information linking the environmental assessments to discharges of metals (*e.g.*, mercury, arsenic, selenium, boron, and magnesium), ammonia and other nitrogen compounds, phosphorus, or biocide residuals (*e.g.*, chlorinated or brominated compounds, or non-oxidizing chemical biocides). EPA also seeks more general information regarding the potential environmental hazard associated with discharges of these pollutants from steam electric power plants.

B. EPA Requests Information on the Coal Mining Category (Part 434)

EPA would appreciate any information to help address the following questions.

- To what degree are manganese discharges from coal mines causing environmental impairment? How would impacts change if the manganese limits were removed or made less stringent?
- How many companies have defaulted on their bonds because of post-mining manganese treatment costs?
- What is the potential for companies to default on their bonds in the future if the current manganese limit remains unchanged?
- To what extent have states had to assume long-term water treatment responsibilities for mines where the bonds have been forfeited? How are states managing these responsibilities?
- What is the prevalence of metals other than manganese, and other contaminants such as sulfates and chloride, in untreated mining wastewater? To what extent are other metals and contaminants removed by current manganese treatment practices? How significant are the impacts from other metals and contaminants?
- How successful are trust funds as alternatives to bonds for long-term manganese control from post-mining sites?
- To what extent are water discharge permits for post-mining operations based on state water quality standards rather than on EPA effluent limitations and guidelines?

C. EPA Requests Information on the Coalbed Methane Sector of the Oil and Gas Extraction Category (Part 435)

EPA is researching the following questions and topics as they relate to the quantity and toxicity of pollutants discharged and the environmental impacts of these discharges to support the Oil and Gas Extraction/Coal Bed Methane detailed study.

- What pollutants are typically discharged in CBM produced water?
- What is the toxicity of these pollutants to human health and the environment?
- What is the range of pollutant concentrations and CBM produced water flow rate?
- What CBM produced water pollutants are typically controlled through permit limits and what is the range of these permit limits?
- What are the observed and potential impacts of CBM produced water discharges on aquatic environments and communities, riparian zones, and other wetlands?
- How does the composition of CBM produced water change when discharged to normally dry draws or ephemeral streams?
- What is the potential for CBM produced water discharges to mobilize metals, soil nutrients, pesticides and other organic contaminants to surface waters?
- What CBM produced water pollutants are typically controlled through permit limits and what is the range of effluent limits?
- What are measures that can mitigate potential impacts to uses of surface waters for irrigation?

EPA is researching the following questions and topics as they relate to the potential technology options and beneficial use practices for this industrial sector.

- What are the current industry treatment technologies and beneficial use practices for CBM produced water?
- What are the potential beneficial use applications of CBM produced water and what are the corresponding criteria for such uses?
- What are the performances of these treatment technologies and beneficial use practices for reducing the potential impacts of CBM produced water discharges?
- What is the range of incremental annualized compliance costs associated with these technologies and practices? How do these costs differ between existing and new sources?
- What is the demonstrated use and economic affordability (*e.g.*, production losses, firm failures, employment impacts resulting from production losses and firm failures, impacts on small businesses) of these technologies across the different CBM basins?
- What are the types of non-water quality environmental impacts (including energy impacts) associated with the current industry treatment technologies and beneficial use practices for CBM produced water?

EPA is researching the following questions and topics as they relate to the expansion of CBM exploration and development and the affordability of potential technology options for this industrial sector.

- What is the near-term and long-term growth rate for this industry sector? Which CBM basins are likely to experience the most growth within the next ten years?
- What are the current industry drilling and infrastructure expansion plans for CBM exploration and development?
- What is the predicted range of CBM reserves across the different basins for different natural gas prices?
- What are the potential impacts on developing CBM reserves and operator profitability and rates of return on investment in response to any increased costs associated with potential industry treatment technologies and beneficial use practices for CBM produced water discharges?
- What is the difference between potential impacts on existing sources versus new sources?
- What percentage of CBM operators are considered small entities?

EPA is researching the following questions and topics as they relate to current regulatory controls.

- How do NPDES permit programs regulate CBM produced water discharges (*e.g.*, individual permits, general permits)?
- What is the BPJ basis for existing technology-based effluent limits for CBM produced water discharges?
- To what extent and how do current regulatory controls ensure the beneficial use of CBM produced water?

What other statutes might affect the ability to discharge, treat, or beneficially use CBM produced water (*e.g.*, SDWA, RCRA)?

D. EPA Requests Comments and Information on the Following as It Relates to Its Health Services Study

1. Dental Mercury

- In state and localities that have not established dental mercury guidance or requirements, what, if anything, do dental offices currently do to reduce mercury discharges associated with dental amalgam? Also, what annual costs are associated with these activities?
- EPA assumes that, at a minimum, all dental facilities have chairside traps and/or vacuum pump filters, and that they dispose of amalgam collected in these traps/filters as solid waste (*i.e.*, not subsequently rinsed down the drain). EPA solicits comment on this assumption.
- To what extent are the ADA recommended BMPs currently utilized in the dental industry? What is the effectiveness in reducing dental mercury associated with these BMPs and what are the annual costs?
- EPA solicits data on the effectiveness of BMP or amalgam separators in reducing mercury in POTW influent, effluent, and/or sludge. EPA is particularly interested in obtaining data from studies that measured mercury concentrations in POTW influent, effluent, and/or sludge before and after BMP or amalgam separation implementation.
- EPA solicits information on the cost and burden to POTWs of implementing state or local BMP or amalgam separator requirements. EPA is also interested in obtaining information on how POTWs have implemented such standards.
- EPA solicits comment on any known interference or pass through problems associated with dental mercury discharges.
- EPA solicits additional information on the effectiveness of voluntary local programs for reducing mercury discharges from dental facilities.

2. Unused Pharmaceuticals

- EPA solicits identification of any policies, procedures or guidelines that govern the disposal of unused pharmaceuticals from hospitals; offices of doctors and mental health practitioners; nursing, long-term care, re-habilitation, and personal care facilities; medical laboratories and diagnostic service facilities; and veterinary care facilities.
- EPA solicits information on the most likely sub-sectors within the Health Service sector that would accumulate unused pharmaceuticals for management and disposal.
- When applicable, to what extent are unused pharmaceuticals disposed according to the Resource Conservation and Recovery Act (RCRA)?
- EPA solicits comment and data on: (1) The main factors that drive current disposal practices; and (2) any barriers preventing the reduction or elimination of unused pharmaceuticals to POTWs and/or surface waters. In particular, EPA solicits comment on the extent that the Controlled Substances Act (21 U.S.C. 801 et. seq.) complicates the design of an efficacious solution to drug disposal?
- EPA solicits quantitative information or tracking sheets for the past year on the disposal of unused pharmaceuticals via the toilet, drain, or sewer.
- EPA solicits data on how control authorities are currently controlling disposal of unused pharmaceuticals via wastewater.
- EPA solicits information on any technologies or BMPs that are available to control or eliminate the disposal of unused pharmaceuticals to POTWs.
- EPA solicits qualitative and quantitative data on the effectiveness and annualized costs of the technologies or BMPs that health service facilities use to control or eliminate the discharge of unused pharmaceuticals from their wastewater. EPA is also interested in obtaining information on the current costs (including labor) associated with disposal of unused pharmaceuticals via the drain or toilet.
- EPA solicits any studies or information on the potential for unused pharmaceuticals disposed in non-hazardous landfills to contaminate underground resources of drinking water.

E. Preliminary Category Reviews for the 2008 Annual Review

EPA requests information on the industries for which it is continuing or initiating preliminary category reviews: Ore Mining and Dressing, Centralized Waste Treatment, and Waste Combustors (*i.e.*, industrial point source categories with existing effluent guidelines identified with "(5)" in the column entitled "Findings" in Table V–1 in section V.B.4 of today's notice). EPA will need to collect more information for the 2008 annual review. Specifically, EPA hopes to gather the following information:

- What toxic pollutants are discharged from these industries in non-trivial amounts on an industry and per-facility basis?
- What raw material(s) or process(es) are the sources of these pollutants?
- What technologies or management practices are available (technically and economically) to control or prevent the generation and/or release of these pollutants.

F. Data Sources and Methodologies

EPA solicits comments on whether EPA used the correct evaluation factors, criteria, and data sources in conducting its annual review and developing this preliminary Plan. EPA also solicits comment on other data sources EPA can use in its annual reviews and biennial planning process. Please see the docket for a more detailed discussion of EPA's analysis supporting the reviews in this notice (*see* DCN 04247).

G. BPJ Permit-Based Support

EPA solicits comments on whether and if so how, the Agency should provide EPA Regions and States with permit-based support instead of revising effluent guidelines (*e.g.*, when the vast majority of the hazard is associated with one or a few facilities). EPA solicits comment on categories for which the

Agency should provide permit-based support.

H. Identification of New Industrial Categories and Sectors

EPA solicits comment on the methodology for grouping industrial sectors currently not subject to effluent guidelines or pretreatment standards for review and prioritization, and the factors and measures EPA should consider for determining whether to identify such industries for a rulemaking. EPA solicits comment on other data sources and approaches EPA can use to identify industrial sectors currently not subject to effluent guidelines or pretreatment standards for review and prioritization.

I. Implementation Issues Related to Existing Effluent Guidelines and Pretreatment Standards

As a factor in its decision-making, EPA considers opportunities to eliminate inefficiencies or impediments to pollution prevention or technological innovation, or opportunities to promote innovative approaches such as water quality trading, including within-plant trading. Consequently, EPA solicits comment on implementation issues related to existing effluent guidelines and pretreatment standards.

Notice of Availability of Preliminary 2008 Effluent Guidelines Program Plan

J. EPA's Evaluation of Categories of Indirect Dischargers Without Categorical Pretreatment Standards To Identify Potential New Categories for Pretreatment Standards

EPA solicits comments on its evaluation of categories of indirect dischargers without categorical pretreatment standards. Specifically, EPA solicits wastewater characterization data (*e.g.*, wastewater volumes, concentrations of discharged pollutants), current examples of pollution prevention, treatment technologies, and local limits for all industries without pretreatment standards. EPA also solicits comment on whether there are industrial sectors discharging pollutants that cause interference issues that cannot be adequately controlled through the general pretreatment standards.

Dated: October 18, 2007.

Benjamin H. Grumbles,

Assistant Administrator for Water.

[FR Doc. E7–21310 Filed 10–29–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8488–8]

Clean Water Act Section 303(d): Availability of 20 Total Maximum Daily Loads (TMDL) in Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability for comment of the administrative record files for 20 TMDLs and the calculations for these TMDLs prepared by EPA Region 6 for waters listed in the Red and the Terrebonne Basins of Louisiana, under section 303(d) of the Clean Water Act (CWA). These TMDLs were completed in response to a court order in the lawsuit styled *Sierra Club, et al.* v. *Clifford, et al.*, No. 96–0527, (E.D. La.).

DATES: Comments must be submitted in writing to EPA on or before November 29, 2007.

ADDRESSES: Comments on the 20 TMDLs should be sent to Diane Smith, Environmental Protection Specialist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733 or e-mail: *smith.diane@epa.gov*. For further information, contact Diane Smith at (214) 665–2145 or fax 214.665.7373. The administrative record files for the 20 TMDLs are available for public inspection at this address as well. Documents from the administrative record files may be viewed at *http://www.epa.gov/earth1r6/6wq/npdes/tmdl/index.htm*, or obtained by calling or writing Ms. Smith at the above address. Please contact Ms. Smith to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Diane Smith at (214) 665–2145.

SUPPLEMENTARY INFORMATION: In 1996, two Louisiana environmental groups, the Sierra Club and Louisiana Environmental Action Network (plaintiffs), filed a lawsuit in Federal Court against the EPA, styled *Sierra Club, et al.* v. *Clifford, et al.*, No. 96–0527, (E.D. La.). Among other claims, plaintiffs alleged that EPA failed to establish Louisiana TMDLs in a timely manner. EPA proposes 15 of these TMDLs pursuant to a consent decree entered in this lawsuit.

EPA Seeks Comment on 20 TMDLs

By this notice EPA is seeking comment on the following 20 TMDLs for waters located within Louisiana basins:

Subsegment	Waterbody name	Pollutant
100404	Cypress Bayou Reservoir	Dissolved Oxygen.
100405	Black Bayou (including Black Bayou Reservoir)	Dissolved Oxygen.
120202	Bayou Black—Intracoastal Waterway to Houma	Nutrients and Dissolved Oxygen.
120204	Lake Verret and Grassy Lake	Nutrients and Dissolved Oxygen.
120304	Intracoastal Waterway—Houma to Larose	Nutrients and Dissolved Oxygen.
120401	Bayou Penchant—Bayou Chene to Lake Penchant	Dissolved Oxygen.
120403	Intracoastal Waterway—Bayou Boeuf Lake Penchant	Dissolved Oxygen.
120404		Dissolved Oxygen.
120405	Lake Hache, Lake Theriot	Nutrients and Dissolved Oxygen.
120406	Lake de Cade	Nutrients and Dissolved Oxygen.
120604	Bayou Blue—Intracoastal Waterway to boundary between segments 1206 and 1207.	Dissolved Oxygen.
120708	Lost Lake, Four League Bay	Nutrients and Dissolved Oxygen.
120709	Bayou Petite Caillou—From Houma Navigation Canal to Terrebonne Bay.	Nutrients and Dissolved Oxygen.

EPA requests that the public provide to EPA any water quality related data and information that may be relevant to the calculations for the 20 TMDLs. EPA will review all data and information submitted during the public comment period and revise the TMDLs where appropriate. EPA will then forward the TMDLs to the Louisiana Department of Environmental Quality (LDEQ). The LDEQ will incorporate the TMDLs into its current water quality management plan.

ADA.
American Dental Association
www.ada.org

BEST MANAGEMENT PRACTICES FOR AMALGAM WASTE

American Dental Association
October 2007

211 East Chicago Avenue, Chicago, Illinois 60611-2678

ADA.
American Dental Association
www.ada.org

Dental Amalgam Waste

Dental amalgam waste can be recycled to help prevent the release of mercury to the environment. Following the simple suggestions outlined in this document will help protect the environment.

Concern about the effects of mercury in the environment has increased over the years. Mercury in the environment is bioaccumulative, which means that it can build up in fish and cause health problems in humans and other animals that eat fish. Many state health professionals recommend limiting fish consumption, especially for children and pregnant women.

Mercury is a naturally occurring metal; however, about half of the mercury released to the environment comes from human activity. Of that amount, 53% is emitted from combustion of fuels for energy production and 34% is from the combustion of waste.[1] Sources associated with manufacturers and consumers make up the remaining 13%, with dentistry contributing less than one percent.

Some mercury released into the air eventually collects in the waterways, where it enters the food chain. As a precautionary measure, U.S. regulators typically assume that all or most of the mercury released into the air or surface water may accumulate in fish. According to the EPA in 2000, metals (mainly due to the detection of mercury in fish tissue samples) were the second most common pollutant impairing 3.2 million acres of the 17.3 million acres of assessed lakes (the assessed lakes comprised 43% of the total lake acres).[2]

Although mercury in the form of dental amalgam is stable, amalgam should ***not*** be disposed of in the garbage, infectious waste "red bag," or sharps container. Amalgam also should ***not*** be rinsed down the drain. These cautions are important because some communities incinerate municipal garbage, medical waste, and sludge from wastewater treatment plants. If amalgam waste ends up in one of these incinerated waste streams, the mercury can be released to the environment due to the high temperatures used in the incineration process. Increasingly, local communities are enacting restrictions on the incineration of wastes containing mercury.

The good news is that amalgam waste, kept separate from other waste, can be safely recycled. The mercury can be recovered from amalgam wastes through a distillation process and reused in new products. The ADA strongly recommends recycling as a best management practice for dental offices.

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[1] Office of Air Quality Planning and Standards, Office of Research and Development. Mercury Study Report to Congress. Volume II: An inventory of anthropogenic mercury emissions in the United States. Washington, D.C.: Environmental Protection Agency. Publication No. EPA-452/R-97-004. December 1997, p. ES-6.

[2] EPA. Quality of America's Lakes. http://www.epa.gov/owow/lakes/quality.html (accessed April 2007).

ADA.
American Dental Association
www.ada.org

The following information demonstrates how to manage and recycle dental amalgam waste to help protect the environment.

Glossary of Amalgam Waste Terms

- **Amalgam capture device** is an apparatus such as a chair side trap, vacuum pump filter or amalgam separator that collects amalgam particles.
- **Amalgam sludge** is a mixture of liquid and solid material that collects within vacuum pump filters, amalgam separators or other amalgam capture devices that may be used.
- **Contact amalgam** is amalgam that has been in contact with the patient. Examples are extracted teeth with amalgam restorations, carving scrap collected at chair side, and amalgam captured by chair side traps, filters, or screens.
- **Dental Best Management Practices** are a series of amalgam waste handling and disposal practices that include, but are not limited to, initiating bulk mercury collection programs, using chair side traps, amalgam separators compliant with ISO 11143[3] and vacuum collection, inspecting and cleaning traps, and recycling or using a commercial waste disposal service to dispose of the amalgam collected.
- **Empty amalgam capsules** are the individually dosed containers left over after mixing precapsulated dental amalgam.
- **Non-contact amalgam (scrap)** is excess mix leftover at the end of a dental procedure.

The ADA recommends against the use of bulk elemental mercury, also referred to as liquid or raw mercury, for use in the dental office. Since 1984, the ADA has recommended use of precapsulated amalgam alloy.

If you still have bulk elemental mercury in the office, you should recycle it. Check with a licensed recycler to determine whether they will accept bulk mercury. ***Do not*** pour bulk elemental mercury waste in the garbage, red bag or down the drain. You also should check with your state regulatory agency and municipality to find out if a bulk mercury collection program is available. Such bulk mercury collection programs provide an easy way to dispose of bulk mercury.

[3] International Standards Organization 11143:1999. Dental Equipment – Amalgam Separators.

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Steps for Recycling Amalgam Waste

1. Stock amalgam capsules in a variety of sizes to minimize the amount of amalgam waste generated.
2. Amalgam waste may be mixed with body fluids, such as saliva, or other potentially infectious material, so use personal protective equipment such as utility gloves, masks, and protective eyewear when handling it.
3. Contact an amalgam waste recycler about any special requirements that may exist in your area for collecting, storing and transporting amalgam waste.
   If you need to find a recycler, check with your city, county or local waste authority to see whether they have an amalgam waste recycling program.
4. Store amalgam waste in a covered plastic container labeled "Amalgam for Recycling" or as directed by your recycler. Your recycler may have its own requirements, so ask your recycler about containers and what may be placed in them.
5. Look for recyclers who comply with the ADA-ANSI standard. This standard is meant to encourage recycling.

Questions to Ask Your Amalgam Waste Recycler

Below is a list of questions you may want to ask your amalgam waste recycler. Note that not all recycling companies accept every type of amalgam waste, and the services offered by recyclers vary widely. The ADA recommends that you contact a recycler before recovering amalgam and ask about any specific handling instructions the recycler may have. Importantly, select a reputable company that complies with applicable federal and state law and provides adequate indemnification for its acts and omissions. Look for recyclers who comply with ANSI/ADA Specification 109: Procedures for Storing Dental Amalgam Waste and Requirements for Amalgam Waste Storage/Shipment Containers.[3] This standard is meant to encourage recycling.

Ask Your Recycler ...

- What kind of amalgam waste do you accept?
- Do your services include pick up of amalgam waste from dental offices? If not, can amalgam waste be shipped to you?
- Do you provide packaging for storage, pick up or shipping of amalgam waste?
- If packaging is not provided, how should the waste be packaged?
- What types of waste can be packaged together?
- Do you accept whole filters from the vacuum pump for recycling?
- Is disinfection required for amalgam waste?
- How much do your services cost?
- Do you pay for clean non-contact amalgam (scrap)?
- Do you accept extracted teeth with amalgam restorations?

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- Does your company have an EPA or applicable state license?
- Does the company use the proper forms required by the EPA and state agencies?
- Do your procedures comply with ANSI/ADA Specification 109: Procedures for Storing Dental Amalgam Waste and Requirements for Amalgam Waste Storage/Shipment Containers?[4]

[4]American Dental Association Council on Scientific Affairs. American National Standard/American Dental Association Specification No. 109. Procedures for storing dental amalgam waste and requirements for amalgam waste storage/shipment containers, 2006.

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Best Management Practices for Amalgam Waste

DO	DON'T
Do use precapsulated alloys and stock a variety of capsule sizes	***Don't*** use bulk mercury
Do recycle used disposable amalgam capsules	***Don't*** put used disposable amalgam capsules in biohazard containers, infectious waste containers (red bags) or regular garbage
Do salvage, store and recycle non-contact amalgam (scrap amalgam)	***Don't*** put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags) or regular garbage
Do salvage (contact) amalgam pieces from restorations after removal and recycle the amalgam waste	***Don't*** put contact amalgam waste in biohazard containers, infectious waste containers (red bags) or regular garbage
Do use chair-side traps, vacuum pump filters and amalgam separators to retain amalgam and recycle their contents.	***Don't*** rinse devices containing amalgam over drains or sinks
Do recycle teeth that contain amalgam restorations. (*Note:* Ask your recycler whether or not extracted teeth with amalgam restorations require disinfection)	***Don't*** dispose of extracted teeth that contain amalgam restorations in biohazard containers, infectious waste containers (red bags), sharps containers or regular garbage
Do manage amalgam waste through recycling as much as possible	***Don't*** flush amalgam waste down the drain or toilet
Do use line cleaners that minimize dissolution of amalgam	***Don't*** use bleach or chlorine-containing cleaners to flush wastewater lines

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Practical Guide to Integrating BMPs Into Your Practice

Non-contact (scrap) amalgam
• Place non-contact, scrap amalgam in wide-mouthed, container that is marked "Non-contact Amalgam Waste for Recycling." • Make sure the container lid is well sealed. • When the container is full, send it to a recycler.
Amalgam capsules
• Stock amalgam capsules in a variety of sizes. • After mixing amalgam, place the empty capsules in a wide-mouthed, airtight container that is marked "Amalgam Capsule Waste for Recycling." • Capsules that cannot be emptied should likewise be placed in a wide-mouthed, airtight container that is marked "Amalgam Capsule Waste for Recycling." • Make sure the container lid is well sealed. • When the container is full, send it to a recycler.
Disposable chair-side traps
• Open the chair-side unit to expose the trap. • Remove the trap and place it directly into a wide-mouthed, airtight container that is marked "Contact Amalgam Waste for Recycling." • Make sure the container lid is well sealed. • When the container is full, send it to a recycler. • Traps from dental units dedicated strictly to hygiene may be placed in with the regular garbage.
Reusable chair-side traps
• Open the chair-side unit to expose the trap. • Remove the trap and empty the contents into a wide-mouthed, airtight container that is marked "Contact Amalgam Waste for Recycling." • Make sure the container lid is well sealed. • When the container is full, send it to a recycler. • Replace the trap into the chair-side unit (Do ***not*** rinse the trap under running water as this could introduce dental amalgam into the waste stream.
Vacuum pump filters
• Change the filter according to the manufacturer's recommended schedule. *Note:* The following instructions assume that your recycler will accept whole filters; some recyclers require different handling of this material, so check with your recycler first. • Remove the filter. • Put the lid on the filter and place the sealed container in the box in which it was originally shipped. When the box is full, the filters should be recycled.
Amalgam separators
• Select an amalgam separator that complies with ISO 11143. • Follow the manufacturer's recommendations for maintenance and recycling procedures.
Line cleaners
• Use non-bleach, non-chlorine–containing line cleaners, which will minimize amalgam dissolution, such as those listed in the ***Additional Resources*** section of this document.

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Additional Resources

The following articles published in the *Journal of the American Dental Association* are available through the ADA Division of Science and also are available to ADA members online.

For information on proper mercury hygiene practices see "Dental Mercury Hygiene Recommendations". 2003:134(11);1498-9.

For information on choosing line cleaners that minimize the dissolution of mercury from amalgam see: "The effect of disinfectants and line cleaners on the release of mercury from amalgam" 2006:137(10);1419-25.

For information on amalgam separators see:

- "Laboratory evaluation of amalgam separators" 2002:133;577-89.
- "Evaluating amalgam separators using an international standard" 2006:137;999-1005.
- "Purchasing, installing and operating dental amalgam separators: Practical issues" 2003 134: 1054-65.

FOR THE RECORD ONLY

American Dental Association's Comments on FDA's Proposed Rule and Special Control Guidance on Dental Amalgam Products
May 21, 2002

Executive Summary

The American Dental Association ("ADA") submits these comments in support of the Food and Drug Administration's ("FDA" or "the Agency") proposed rule on dental amalgam products and draft guidance document entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA" (hereinafter "Draft Guidance"). The ADA is a not-for-profit organization representing its member dentists who number approximately 141,000.

The proposed rule and notice of availability of the Draft Guidance were published in the Federal Register on February 20, 2002 (67 *Fed. Reg.* 34 (2002)). ADA agrees with and supports FDA's proposal to:

- Issue a separate classification regulation for encapsulated amalgam alloy and dental mercury (hereinafter "encapsulated amalgams"), a preamendments device intended to be mixed in a single-use capsule to form filling material for the treatment of dental caries, as a class II device with special controls;
- Amend the existing classification for amalgam alloy, a class II preamendments device, by adding special controls; and
- Reclassify from class I (general controls) to class II with special controls dental mercury, a preamendments device intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth.

FDA has spent decades analyzing scientific literature on the safety of dental amalgam products. Studies, reports, and opinions from nearly every viable source on the topic have been reviewed by the Agency prior to its issuance of the proposed rule. ADA agrees with FDA that there exists no meritorious scientific evidence to indicate that the use of dental amalgam products

will result in adverse health effects. **The benefits of these products clearly outweigh their potential risks, and as such a uniform class II classification regulation with special controls is appropriate for encapsulated amalgam, amalgam alloy, and dental mercury**. The special controls specifically address the risks associated with these products for those with allergies to the ingredients in dental amalgam and for those occupationally exposed persons who may mishandle dental amalgam products. These special controls do adequately provide a reasonable assurance of the safety and effectiveness of the dental amalgam products. In addition, a formal evidentiary hearing on the proposed rule is not required or necessary, for such a hearing would not be in the public interest. Finally, the proposed rule should operate to preempt conflicting state laws and regulations regarding dental amalgam products.

FOR THE RECORD ONLY

American Dental Association's Comments on FDA's Proposed Rule and Special Control Guidance on Dental Amalgam Products
[Docket No. 01N-0067]

The American Dental Association ("ADA") submits these comments in support of the Food and Drug Administration's ("FDA" or "the Agency") proposed rule on dental amalgam products and draft guidance document entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA" (hereinafter "Draft Guidance"). The ADA is a not-for-profit organization representing its member dentists who number approximately 141,000.

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- Amend the existing classification for amalgam alloy, a class II preamendments device, by adding special controls; and

- Reclassify from class I (general controls) to class II with special controls dental mercury, a preamendments device intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth.

ADA takes the position that, pursuant to the Federal Food, Drug, and Cosmetic Act ("FDC Act") § 513 (a)(1)(B), the FDA is justified in implementing these proposed modifications to its regulations and that there is sufficient information to establish that the special controls described in: (1) the Draft Guidance; (2) the International Standards Organization's "(ISO) 1559:1995 Dental Materials – Alloys for Dental Amalgam" (hereinafter the "ISO Specifications"); and (3) the American National Standards Institute/American Dental Association's "Specification No. 6-1987 for Dental Mercury" (hereinafter the "ANSI/ADA Specifications") will provide a reasonable assurance of the safety and effectiveness of these three categories of devices.

The following comments first provide an overview as to the specific regulatory classification scheme the Agency is proposing with regard to dental amalgam products. The comments then address the scientific evidence that FDA has reviewed in accordance with a comprehensive methodological process to justify this regulatory action. Next, the comments discuss why, from a regulatory perspective, a uniform class II classification with special controls is the appropriate regulatory categorization for the dental amalgam products. The comments then describe why a hearing on this proposed rule is unnecessary. Next, the comments provide summaries of additional scientific evidence provided by ADA in support of the proposed rule. Finally, the comments address why the proposed rule should preempt conflicting state laws regarding dental amalgam products.

I. Overview

In light of the Agency's extensive scientific review related to dental mercury and amalgams outlined more fully below, the FDA has reconsidered its regulatory approach to dental amalgam products and is proposing to regulate these devices in a uniform manner as class II devices with special controls. The Agency may classify a device as class II with special controls if it determines that general controls alone will not provide the necessary reasonable assurance of safety and effectiveness. FDC Act § 513 (a)(1)(B). ADA fully supports the Agency's proposed classification scheme of dental amalgam products, which includes a separate classification regulation for encapsulated amalgams as well as the application of class II special controls to all three dental amalgam products that clearly provide a reasonable assurance of safety and effectiveness. As explained below, the concerns that have been raised in the scientific literature regarding the safe use of dental amalgam products are fully addressed by the Agency's proposed special controls.

Encapsulated Amalgams. Currently, encapsulated amalgams are not regulated as a separate medical device. Rather, they are regulated as class II devices under the amalgam alloy classification. FDA proposes to create a separate class II classification regulation for encapsulated amalgams with special controls. The proposed special controls would consist of conformance to voluntary industry standards described in the ISO Specifications, the ANSI/ADA Specifications, and FDA's Draft Guidance.

Dental Mercury. Dental Mercury is currently regulated as a class I device. FDA is proposing to reclassify dental mercury as a class II device with special controls. The proposed special controls would consist of conformance to voluntary industry standards described in the ANSI/ADA Specifications and FDA's Draft Guidance.

Amalgam Alloy. Amalgam alloy is currently regulated as a class II device. Currently, no performance standard or other special controls have been adopted for amalgam alloy. FDA proposes to amend the class II classification regulation of amalgam alloy to provide for special controls. The proposed special controls would consist of conformance to voluntary industry standards described in the ISO Specifications and FDA's Draft Guidance.

The proposed rule encompassing all three dental amalgam devices is clearly a more rigorous regulatory scheme than that which currently exists. ADA wholly agrees that encapsulated amalgams, amalgam alloy, and dental mercury should be uniformly classified as class II devices, and that the proposed special controls adequately address the risks associated with these devices. FDA and ADA, along with numerous other organizations described below, have conducted extensive studies of the potential risks and adverse health effects associated with dental amalgam products. ADA agrees with the Agency's determination that, upon review of the scientific evidence, there are no major health risks associated with the use of encapsulated amalgams, amalgam alloy, and dental mercury. ADA also agrees that the proposed special controls will adequately address the risks associated with

improper handling of dental amalgam products and the risks to the small subpopulation of individuals who are allergic to the ingredients of these products.

II. The FDA Process Supporting the Proposed Rule

A. The Agency's Scientific Review Related to Dental Amalgam Products Has Been Complete and Appropriate

The proposed rule and Draft Guidance at issue are the result of many years of study and evaluation of the safety of dental amalgam products. The Agency has carefully examined extensive information about the safety of dental restorative materials that contain mercury. Public concern about the safety of dental amalgam engendered several national and international comprehensive reviews of scientific information about the risks and benefits of these products. FDA has carefully studied the reports prepared by the Public Health Service on the topic, as well as information submitted in support of citizen petitions and numerous reports by international health organizations. FDA undertook this review in an effort to promulgate the appropriate classification regulation for these three categories of devices. ADA agrees that the results of this scientific literature review support the uniform classification of these dental amalgam products as class II devices with special controls.

From 1991 to 1992, the U.S. Public Health Service ("PHS") performed a comprehensive risk assessment of dental amalgam. In 1993, the PHS issued a

report on its findings ("1993 PHS Report") 1/ and concluded that historic experience with dental amalgams did not offer persuasive evidence of adverse health effects related to amalgam treatments other than a few reported cases of hypersensitivity. Specifically, a Risk Assessment Subcommittee of the PHS, comprised of 34 senior level experts from the fields of health promotion and disease prevention, dentistry, dental materials, toxicology, and biostatistics, reviewed nearly 120 publications that reported the results of studies on levels of exposure to mercury and its salts. The Risk Assessment Subcommittee found that available data were not sufficient to indicate that health hazards could be identified in non-occupationally exposed persons.

A companion PHS subcommittee, the Benefits Assessment Subcommittee, reviewed the benefits of dental amalgam products. It concluded that dental amalgam, which had been used successfully to treat millions of individuals for over 100 years, was an effective restorative material. The subcommittee also stated that dental amalgam products had reasonable clinical serviceability, wide potential applications, ease of manipulation, and relatively low cost.

The conclusions reached in the 1993 PHS Report were reaffirmed by

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1/ "Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education, and Regulation," Public Health Service, U.S. Department of Health and Human Services, January 1993.

the PHS in 1995 2/ and 1997 3/. The 1997 PHS Report included information from two PHS-sponsored workshops on mercury and amalgam safety. Both workshops concluded that there was insufficient scientific evidence to link mercury vapor exposure, at typical levels associated with dental amalgam restorations, with an unacceptable health risk to the general population.

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

2/ "Update Statement by the U.S. Public Health Service on the Safety of Dental Amalgam," September 1, 1995.

3/ "State of the Science on the Safety of Amalgam and other Restorative Materials," Public Health Service, U.S. Department of Health and Human Services, 1997.

4/ Citizen Petition Docket No. 93P-0424, Citizen Petition Docket No. 94P-0354/CP1, and Citizen Petition from Dr. Baylin et al.

Ultimately, none of the experts who reviewed the petitioners' data concluded that dental amalgam restorations caused adverse health effects to patients. The experts' analyses, like the 1993, 1995, and 1997 PHS Reports, acknowledged that mercury is a well-known toxicant, that its toxicity is dependent on dose, that mercury from amalgam fillings can accumulate in tissues, and that mercury is an allergen sensitizer in some humans. However, significantly, the experts' analyses concluded that there is no evidence in the scientific literature to suggest that individuals with dental amalgam restorations will experience adverse health effects.

Furthermore, The National Institute of Dental and Craniofacial Research initiated a two-pronged study 5/ to examine: (1) the establishment of mercury levels from amalgam fillings and the occurrence of various reported health symptoms; and (2) a longitudinal cohort assessment in which the number of amalgam restorations were analyzed retrospectively and comparisons made of reported health effects between groups with high and low exposure levels and those with no exposure. To date, no discernable causal or correlational connection has been observed between study subjects with amalgam fillings and adverse health effects.

In addition, FDA has evaluated a number of reports from international authorities that both assessed the available body of scientific literature as well as

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5/ "Casa Pia Study of Dental Amalgams in Children; Children's Amalgam Trial," National Institute of Dental and Craniofacial Research.

reviewed the opinions of leading researchers and renowned experts in the fields of oral health, toxicology, medicine, and other related disciplines. Expert groups from Sweden 6/, New Zealand 7/, Canada 8/, and the European Commission all concluded that mercury exposure from dental amalgams does not have an adverse effect on health, with the exception of isolated cases of allergic reactions. Likewise, a report generated from a nine-country information exchange 9/ concluded that no systemic dose-dependent toxic effects have been shown to be related to dental amalgams. Also, several studies included in a comprehensive report published by the World Health Organization 10/ concluded that, while it is well documented that individuals with dental amalgam fillings have higher concentrations of mercury in tissues than those without amalgam fillings, there is no direct evidence of an adverse effect of mercury from amalgam tooth fillings on general health.

6/ "Possible Health Effects and Dental Amalgam," Swedish National Board of Health and Welfare, 1994.

7/ "Dental Amalgam and Human Health (A Current Consensus)," WHO Collaborating Centre in Oral Health, Wellington School of Medicine, University of Otego, Wellington, New Zealand, June 1996.

8/ "The Safety of Dental Amalgam," Health Canada, 1995; "The Safety of Dental Amalgam: A State of the Art Review," Conseil d'Evaluation des Technologies de la Sante de Quebec, April 1997.

9/ Dental Amalgam – A Report with Reference to the Medical Devices Directive 93/42/EEC from and Ad Hoc Working Group Mandated by the European Commission, June 1998.

10/ "Consensus Statement on Dental Amalgam," World Health Organization Consultation on Assessing the Risks and Benefit to Oral Health, Oral Care, and Environment Using Dental Amalgam and its Replacement, and FDI World Dental Federation, 1997. See also "Dental Amalgam and Alternative Direct Restorative Materials," World Health Organization, 1997.

Finally, FDA requested in 1993 that its Dental Products Advisory Panel ("Panel") make a classification recommendation for the encapsulated amalgams product 11/. After reviewing updated literature and hearing testimony from representatives of FDA, ADA, and the PHS, the Panel unanimously recommended to classify encapsulated amalgams into class II with special controls. The panel concluded there were no major health risks associated with encapsulated amalgams when used as directed, but the Panel also recognized that there was a small population of patients that could experience allergic reactions to the materials in amalgam.

It is clear that FDA has not ignored the scientific evidence on this issue, nor has the Agency rushed to judgment in its determination that uniformly classifying the three dental amalgam products as class II devices with special controls will provide a reasonable assurance of the safety and effectiveness of these devices. Indeed, just the opposite is true. The Agency has taken its time to gather and evaluate all relevant studies in order to determine the proper classification regulation of dental amalgam products. The scientific literature supports the Agency's conclusion that the benefits of encapsulated amalgam, amalgam alloy, and dental mercury far outweigh any potential adverse health effects. In fact, as discussed below, the labeling requirements in the special control documents adequately protect the small population of patients who could experience allergic

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11/ Transcript from 1993 meeting of the Food and Drug Administration Dental Products Advisory Panel, December 1-3, 1993; Transcript from 1994 meeting of the Food and Drug Administration Dental Products Advisory Panel, June 29, 1994.

reactions from dental amalgams as well as occupationally exposed health care workers.

B. Class II with Special Controls Is the Appropriate Level of Regulation for Dental Amalgam Products

The FDC Act promulgated a classification scheme for the regulation of medical devices intended for human use depending on the regulatory controls needed to provide a reasonable assurance of their safety and effectiveness. Under the Medical Device Amendments of 1976, a device was classified into class II if there was insufficient information to show that general controls alone would assure safety and effectiveness, but there was adequate information to establish performance standards that would provide this assurance. The passage of the Safe Medical Devices Act of 1990 ("SMDA") amended the FDC Act to allow FDA to require special controls for class II devices as well as specific performance standards. FDC Act § 513 (a)(1)(B) currently permits the classification of devices into class II with special controls if the Agency concludes that the special controls provide a reasonable assurance of safety and effectiveness. Pursuant to FDC Act § 513(a)(2)(C), this determination of safety and effectiveness through the use of special controls is made primarily through a balancing of the probable benefits to health from the use of the device with the probable risks of injury or illness from such use.

ADA agrees with the Agency's determination that under FDC Act § 513(a)(2)(C) the probable benefits associated with the use of encapsulated amalgams, amalgam alloy, and dental mercury outweigh the probable risks of using

these products. The potential risks of amalgam are generally applicable only to a small population of patients who may experience allergic reactions to the materials in amalgam, as well as to health care workers who may have occupational exposure due to the mishandling of dental amalgam products. The known benefits of dental amalgam products include a broad range of applicability in clinical situations, reasonable serviceability, durability, ease of use, relatively low cost, and relative insensitivity to variations in handling technique and oral conditions. ADA fully concurs with FDA's conclusion that valid scientific evidence exists to determine the safety and effectiveness of dental amalgam products with the use of special controls. Moreover, the extensive scientific evidence submitted by ADA in these comments also supports the Agency's conclusion that dental amalgam products are safe and effective with the use of special controls.

ADA also agrees that the potential benefits and potential risks of the dental amalgam products are sufficiently characterized such that the appropriate level of regulation for these products is class II with special controls. The potential risks of allergic reactions to dental amalgam products and the risks associated with the mishandling of these three categories of devices are fully addressed in the proposed rule. The ADA agrees that the special controls proposed by the FDA will address those risks presented by dental amalgam products, both to the hypersensitive individuals and health care workers. Reasonable protection against these adverse health effects is precisely what the special controls are intended to achieve. The recommendations set forth in the Draft Guidance, ISO Specifications,

and ANSI/ADA Specifications provide a reasonable assurance that those with allergies to the materials in amalgam will be made aware of the products' contents prior to use. Likewise, the special controls provide health care workers who handle the products with explicit instructions as to proper handling procedures.

1. **Draft Guidance**

The purpose of a guidance document is to provide assistance to the regulated industry by clarifying requirements that have been issued in regulations by FDA. In the proposed rule on dental amalgam products, the Draft Guidance is proposed as a special control applicable to encapsulated amalgams, amalgam alloy, and dental mercury, and represents the Agency's current thinking on the content and format of labeling of these products. The Draft Guidance describes a means by which manufacturers of the three dental amalgam products addressed in the document may comply with the requirements of class II special controls. ADA supports FDA's proposal of the Draft Guidance as a special control as it provides a reasonable assurance of safety and effectiveness for all three dental amalgam products.

The Draft Guidance clearly addresses the potential risks for those individuals who are allergic to ingredients in the dental amalgam products, as well as the risks related to improper handling of these devices. The Draft Guidance recommends that all encapsulated amalgams, amalgam alloy, and dental mercury products bear conspicuous labels that list all ingredients based upon the descending order of the weight percentage, including all component elements. This information

will enable the clinician to avoid using the product if it contains ingredients to which the patient is known to be allergic. The Draft Guidance also recommends labeling that instructs clinicians not to use the product in hypersensitive persons and includes instructions to follow in the event of an allergic reaction. This guidance also recommends instructions for storage, handling, and use to addresses the potential toxicity risks related to improper storage, trituration, and handling by health care workers. The Draft Guidance also includes recommendations that manufacturers of these dental amalgam products adhere to additional standards set forth in the ISO Specifications and the ANSI/ADA Specifications.

2. ISO Specifications

The ISO Specifications contain several recommendations that also address the potential risks associated with encapsulated amalgams and amalgam alloy. These specifications were developed by the International Standards Organization in conjunction with international governmental and non-governmental committees. The ISO Specifications focus on the consistency of chemical composition and the important physical properties of the restorative material.

Specifically, the ISO Specifications address the appropriate provisions and test methods for alloys used in amalgam. They set forth the minimum silver content, and the maximum content of tin, copper, indium, palladium, platinum, zinc, and mercury. They also recommend proper physical properties of the alloy, i.e. the maximum percent creep, percent dimensional change, and compressive strength

after one hour and after 24 hours. The ISO Specifications recommend test methods for determining these physical properties. These recommendations serve to inform clinicians about what substances are in the dental amalgam products so that potential allergic reactions can be avoided. They also specify minimum performance characteristics necessary for clinical use. Furthermore, the ISO Specifications address the potential risks to health care workers by providing recommendations, specifications, and instructions as to storage, proper handling, and trituration. Finally, they contain packaging and labeling instructions that are generally consistent with those proposed in the Draft Guidance. 12/

3. ANSI/ADA Specifications

The ANSI/ADA Specifications also contain several recommendations to address the potential risks associated with encapsulated amalgams and dental mercury. These specifications address specific mercury-related issues to inform the dentist of the physical properties of the mercury to be used in restorations. Such awareness will, again, allow the dentist to avoid potential allergic reactions to the dental amalgam products.

The ANSI/ADA Specifications articulate the specifications and test methods for mercury suitable for the preparation of dental amalgam. They also recommend packaging in air-tight containers and providing hazard warnings regarding mercury hygiene. The occupational risks associated with these products,

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12/ The ISO Specifications do not suggest the listing of an ingredient present in the alloy in concentrations less than 0.1% mass/mass. In contrast, FDA's Draft Guidance recommends the listing of all ingredients.

such as toxicity from improper handling and storage, are covered in the ANSI/ADA Specifications through detailed recommendations for mercury manipulation and its packaging information, transport, and handling procedures.

In sum, ADA supports the class II level of regulation of the dental amalgam products with the special controls addressed above, because such classification provides a reasonable assurance of the safety and effectiveness of these products. The scientific evidence points to two main groups of individuals who could potentially experience adverse health effects from dental amalgam: hypersensitive patients who may experience allergic reactions to the ingredients in amalgam and health care workers occupationally exposed to mercury. The special controls described in the Draft Guidance, ISO Specifications, and ANSI/ADA Specifications provide adequate and reasonable protections against the remote potential risks of the use of these products. Therefore, a uniform class II classification with special controls for encapsulated amalgams, amalgam alloy, and dental mercury is entirely proper.

C. Administrative Hearing on Proposed Rule Not Necessary

The ADA supports FDA's decision not to hold a formal administrative hearing with respect to this proposed rule. An administrative hearing on the proposed classification level of encapsulated amalgams, amalgam alloy, and dental mercury is not required, nor is such a hearing necessary. The regulations governing hearings on proposed rules are codified in 21 C.F.R. § 10.40(f) and state:

> In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a

> proposed or final regulation, before or after publication in the Federal Register, to the following additional procedures:
>
> (1) Conferences, meetings, discussions, and correspondence under § 10.65.
>
> (2) A hearing under Parts 12, 13, 14, or 15.
>
> (3) A notice published in the Federal Register requesting information and views before the Commissioner determines whether to propose a regulation.

(emphasis added). Part 12 of the Code of Federal Regulations, referenced above, is entitled "Formal Evidentiary Public Hearing," and states as to its scope:

> The procedures in this part apply when—
>
> (a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or
>
> (b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA. 13/

Simply put, FDA *may* hold a formal evidentiary hearing on the proposed rule on dental amalgam products if the Agency concludes that it is in the public interest to do so. There is no specific statutory requirement mandating such a hearing.

There is no "public interest" need to hold an evidentiary hearing on the proposed rule on the dental amalgam products. As described above, in formulating the proposed classifications, the Agency considered several reports on this issue from the U.S. Public Health Service; studies and reports reviewed by international health organizations and foreign governments; other U.S. government sponsored

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13/ 21 C.F.R. § 12.1. It is important to note that 21 C.F.R. § 10.50, referenced above, does not apply to the proposed rule on dental amalgam products.

studies; voluminous information submitted in support of citizen petitions requests; recommendations from the Dental Products Advisory Panel; and the significant human experience with amalgam for over 100 years. For years, the Agency has been evaluating the scientific evidence as to the safety of the dental amalgam products, and those opposed to the use of such products have had ample time to submit information in favor of their position both before the publication of the proposed rule and during the notice and comment period. In fact, FDA has reviewed numerous reports and studies calling for the outright ban of dental amalgam products in the United States. A hearing on the proposed rule would be inefficient for no new facts would likely come to bear. In addition, holding a public hearing would only slow down the reclassification of these dental amalgam products, which (as described above) imposes more rigorous regulatory requirements on these products than currently exist.

III. ADA's Scientific Review Related to Dental Mercury and Amalgam

Based on currently available scientific evidence, ADA has concluded that dental amalgam is a safe, affordable and durable material for all but a handful of individuals who are allergic to one of its components. This section first summarizes several of the more recently published studies analyzed by ADA that, together with the exhaustive survey of the scientific literature published by the FDA in the preamble to the proposed rule, confirm the lack of adverse health effects from the use of dental amalgam products. This is followed by ADA's refutation of

the validity of other studies often cited by those opposed to the continued use of amalgam restoration products in dentistry. The ADA believes it is important to address the limitations and misunderstandings surrounding these studies in order to understand why they are not, and should not be, relied on by FDA.

A. Recent Studies that Support the Use of Dental Amalgam Products

Issued in late 1997, the FDI World Dental Federation and the World Health Organization consensus statement on dental amalgam stated, "No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations." The document also concluded that, aside from rare instances of local side effects of allergic reactions, "the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any . . . adverse health effects." 14/

The ADA's Council on Scientific Affairs' 1998 report on its review of recent scientific literature on amalgam similarly states: "The Council concludes that, based on available scientific information, amalgam continues to be a safe and effective restorative material." The Council's report also states, "There currently appears to be no justification for discontinuing the use of dental amalgam." 15/

14/ World Health Organization, FDI World Dental Federation, *supra* note 10 at 9.

15/ "Dental amalgam: update on safety concerns," Journal of the American Dental Association, ADA Council on Scientific Affairs, 1998;129:494-503.

Additionally, there have been several, more recent, peer-reviewed scientific studies concerning the safety of dental amalgam. These studies, abstracted below, refute allegations of a causal link between dental amalgam and various medical conditions:

- Saxe S.R., Wekstein M.W. et al., "Alzheimer's disease, dental amalgam and mercury," JADA 1999;130(2):191-99.

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

- Saxe, S.R., Snowdon, D.A. et al., "Dental amalgam and cognitive function in older women: findings from the Nun Study," JADA 1995;126:495-501.

This article reported on a study that focused on the relationship of dental amalgams with the onset of Alzheimer's disease. Conclusions: Researchers reported finding "no significant association of Alzheimer's disease with the number, surface area, or history of having dental amalgam restorations" and "no statistically

significant differences in brain mercury levels between subjects with Alzheimer's disease and control subjects."

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

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

- Clarkson, T.W., "The Three Faces of Mercury," Environment Health Perspectives 2002;110 (Supp. 1).

This review article describes the perception of risk from the exposure of billions of people to methyl mercury in fish, mercy vapor from amalgam tooth fillings, and ethyl mercury in the form of thimerosal added as an antiseptic to widely used childhood vaccines. Key gaps in current knowledge are identified from the points of view both of risk assessment and of mechanisms of action. Conclusions: The levels of inorganic mercury in tissue caused by release of vapor from amalgam are well below those associated with overt toxic effects or even with subtler neurobehavioral and renal effects. Furthermore, this review summarizes

the relationship between mercury level in different tissues and Alzeimer's disease and concludes that overall studies in the literature have not produced a convincing picture of any kind of correlation between mercury level and this disease.

- Wahl, M.J., "Amalgam - Resurrection and redemption. Part 1: The clinical mythology of anti-amalgam," Quintessence International 2001; 32(7):525-35.

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

- Dahl JE, Sundby J, et al., "Dental workplace exposure and effect on fertility," Scand J Work Environ Health 1999;25(3):285-90.

This study cohort consisted of 558 female dental surgeons (1/3 of whom placed more than 50 fillings a week) and 450 high school teachers (control) that had given birth in Norway to at least one living child. The study comprised data from a total of 1,408 pregnancies. The effects of practicing dentistry and of the given workplace exposure on fertility were analyzed using the discrete proportional hazard regression method. Conclusions: Occupational exposure to mercury had no clear adverse effects on fertility for the female dental surgeons studied.

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

This paper analyzed the potential reproductive effects of handling dental silver amalgam. Experimental studies on animals, case reports, and epidemiological studies were reviewed. Conclusions: Negative reproductive effects from exposure to mercury in the dental office are unproven. Consequently, given the low amount of mercury derived from dental amalgam fillings, the population at large is at even less risk of mercury exposure than dental office staff.

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

A review of the literature indicated that amalgam restorations release small quantities of mercury but apparently not enough to cause systemic health problems. Mercury from dental amalgam restorations cannot be linked to kidney damage, Alzheimer's disease, multiple sclerosis, other central nervous system diseases including "amalgam disease," mental disorders, damage to the immune system, increases in antibiotic resistance, or harmful reproductive effects. Conclusions: This review of the latest literature concluded that dental amalgam remains a safe and effective restorative material.

The National Institute of Dental and Craniofacial Research is currently supporting two large clinical trials on the health effects of dental amalgam. Studies under way for several years in Portugal and the northeastern United States involve not only direct neurophysiological measures but also

behavioral and cognitive functional assessments. In addition, the trials are monitoring the impact of amalgam on immune function, antibiotic resistance, and renal function. Conclusions: Preliminary findings from these studies show a lack of a causal relationship between dental amalgams and adverse health effects and are consistent with any number of small and large epidemiological studies published over the years concerning the health effects of dental amalgam.

B. ADA's Refutation of Scientific Evidence that Dental Amalgam Products Are Unsafe

There does exist certain scientific literature that is frequently cited by those who call into question the safety of dental amalgam products. The FDA has already comprehensively addressed the body of available scientific literature often cited by the opponents of amalgam, and the Agency has concluded that there are no major health risks associated with the use of dental amalgam products. Below is ADA's refutation of several of the most frequently cited articles of this nature and others published more recently.

1. Release of Mercury Vapor from Dental Amalgam

Vimy and Lorscheider were the first to perform systematic intra-oral mercury vapor measurements in the mid-1980s to estimate the daily intake of mercury from amalgam fillings. Two of their major publications remain controversial even today.

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

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

Conclusions: Vimy and Lorscheider estimated that the daily exposure to mercury from dental amalgam is 48 ug, which approaches the limit established by OSHA for inhalation of mercury vapor in a working environment.

ADA Response: Olsson and Bergman have evaluated this study using a comprehensive inspiratory-expiratory air-volume analysis, and concluded that the mercury release was 16 times less than that claimed by Vimy and Lorscheider. Olsson S., Bergman M.J., "Factors affecting estimation of dental amalgam mercury exposure from measurements of mercury vapor levels in intra-oral and expired air." J Dent Res 1987;66:1775-1780. Other investigators have since confirmed this discrepancy (Berglund A., "Estimation by a 24-hour study of the daily dose of intra-oral mercury vapor inhaled after release from dental amalgam," J Dent Res 1990; 69:1646-51; Bjorman L., Lind B., "Factors influencing mercury evaporation rate from dental amalgam fillings," Scad J. Dent Res 1992 Dec;100(6):354-60; Skare L., Engqvist A., "Human exposure to mercury and silver released from dental amalgam restorations," Arch Environ Health 1994;49(5):384-94; Mackert J.R., Jr., Berglund A., " Mercury exposure from dental amalgam fillings: absorbed dose and the potential for adverse health effects," Crit Rev Oral Biol Med 1997;8(4):410-36). The major error committed by Vimy and Lorscheider is their methodology. The use of intra-oral mercury vapor measurements to estimate daily uptake must take into account the differences between the collection volume and flow rate of the

measuring instrument, and the inspiratory volume and the flow rate of air through the mouth during inhalation of a single breath. Their failure to account for these differences resulted in a substantial overestimation of the absorbed dose.

- "Toxicological Profile for Mercury," Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, 1999.

This updated mercury profile ("1999 ATSDR Report"), which broadly addresses the effects of mercury from all sources, has been cited in various documents by opponents of dental amalgam as support for the alleged adverse health effects associated with these products. Conclusions: The opponents to amalgam claim the 1999 ATSDR Report concludes that mercury vapors released from amalgam pose a major health risk for the developing brains of children.

ADA Response: The opponents selectively cite those studies that were reviewed in the 1999 ATSDR Report that supposedly support their position and ignore those that do not. The fact that a study is included in a literature review does not mean that the reviewers agree with the study's conclusions. The broad scope of the 1999 ATSDR Report includes a subsection entitled "More on Health Effects and Dental Amalgam" to specifically address the state of the science with regard to dental amalgam. This section states that "[a] number of government sponsored scientific reviews of the literature on the health effects associated with the use of dental amalgam have concluded that the data do not demonstrate a health hazard for the large majority of individuals exposed to mercury vapor at levels commonly encountered from dental amalgam." 1999 ATSDR Report at 293.

The 1999 ATSDR Report then mentions that certain European countries have placed restrictions on the use of amalgam for environmental reasons, stating "[t]he restrictive actions, however are prospective, and none of the government reports recommend removing existing fillings in people who have no indication of adverse effects attributable to mercury exposure." Id. This 1999 ATSDR Report does not conclude that dental amalgams pose a major health risk for the developing brains of children. Rather, the report states that "[t]o prevent misleading or unduly alarming the public, the layperson should be informed that the presence of metallic mercury in dental amalgams is, in itself, not sufficient to produce an adverse health effect." Id. at 294.

2. Biotransformation of Inorganic Mercury into Toxic Organic Mercury

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

In this study, investigators took paraffin-stimulated saliva from 187 human subjects and measured both the organic as well as inorganic mercury with a cold-vapor atomic absorption spectrometry. They divided the subjects into amalgam (A), no lifetime exposure to amalgam (NA), and amalgams removed (NAR) groups. The percentages of the study subjects, whose fish eating frequency was <1 per week, were 2.3, 4.7 and 7.1%, respectively. Conclusions: The amount of organic and inorganic mercury concentrations in saliva were significantly higher in subjects with amalgams than in NA and NAR individuals. Therefore, the authors concluded

that amalgam fillings may be a continuous source of organic mercury, and because organic mercury is known to be more toxic than inorganic mercury, inorganic mercury derived from dental amalgam was biotransformed into organic mercury in vivo.

ADA Response: First, there is a major discrepancy in the age of the subjects included in this study:

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

Amalgams placed 40-50 years ago are not the same as those placed more recently. The number of amalgam fillings in Group A is large, and the mean number of amalgam surfaces is 22; range 2-51. Second, saliva sampling time varied. Diurnal variation and diet may influence the composition of saliva. Third, study methodology details were sketchy and the authors left many questions unanswered. The authors did not explain the "zero" values in the Hg range, and the investigators used stimulated whole saliva, which is a mixture of secretion from three pairs of different glands; all of them are richly perfused by blood. The authors provide little information on the method and its reliability or reproducibility, e.g., standard curve, percentage of recovery, etc. These deficiencies cast significant doubt as to the conclusions reached by Leistevuo et al.

3. Central Nervous System

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

In this study, a cross-study design was used to evaluate the sensitivities of five psychomotor tasks previously used to assess preclinical (subclinical) effects of low-level mercury (urinary> or=55 ug/L). This study pooled dental professional subject populations from six studies (including the one previously reported in 1995) over the preceding six years. The five psychomotor tests were: (1) Intentional Hand Steadiness Test (IHST); (2) finger tapping; (3) the one-hole test; (4) NES Simple Reaction Time (SRT); and (5) hand tremor. Multivariate analyses were conducted following the hierarchical analysis of multiple response (HAMR) approach. Conclusions: The Intentional Hand Steadiness Test (IHST) factor summary score is very highly related (B =0.42, p > ten to the six) to the long-transformed urinary mercury at low levels (>55 ug/L) and holds occupational relevance for dental professionals.

ADA Response: The subjects involved in this study were highly selective (urinary mercury greater than 55 ug/L), and the study subjects' past history of mercury exposure was unknown to the investigators. Peak exposure in the past may play an important role in the neuropsychological deficits observed in these subjects. Albers et al. (Albers JW, Kallenbach LR et al., "Neurological abnormalities associated with remote occupational elemental mercury exposure,"

Ann Neurol 24:651-659) in 1988 demonstrated that the number of peak exposure events may be actually responsible for the neurological damage that is revealed by neurobehavioral tests (i.e., the number of peak exposure events have been shown to be a better predictor of neurological effects associated with exposure to mercury than mean or cumulative Hg exposure levels).

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

- Pendergrass J.C., Haley B.E., Vimy M.J., Winfield S.A. and Lorscheider F.L., "Mercury vapor inhalation inhibits binding of

GTP to tubulin to rat brain: similarity to a molecular lesion in Alzheimer diseased brain." Neurotoxicology 1997;18(2):315-24.

Since it is well known that Hg vapor is continuously released from "silver" amalgam tooth fillings and absorbed into the brain, in this study rats were exposed to mercury vapor 4 hours/day for 0, 2, 7, 14 and 28 days at 250 or 300 micrograms Hg/cubic meter air, concentrations present in the mouth air of some humans with many amalgam fillings. Conclusions: The average rat brain mercury concentrations measured in this study increased significantly (11-47 fold) with duration of mercury vapor exposure. The identical neurochemical lesion of similar or greater magnitude is evident in Alzheimer brain homogenates from 80% of patients, when compared to human age-matched neurological controls. Since the rate of tubulin polymerization is dependent upon binding of GTP to tubulin dimmers, chronic inhalation of low-level mercury vapor can inhibit polymerization of brain tubulin essential for formation of microtubules.

ADA Response: The concentration of mercury vapor (250-300 ug/m^3 air) used by the investigators was 5-6 times higher than the OSHA and NIOSH threshold limit values of 50 ug/m^3. This is not a realistic or simulated level of mercury exposure for patients with dental amalgams.

The Pendergrass conclusions are refuted by other studies. In a series of studies published by Fung et al. (Fung Y.K., Meade A.G., Rack E.P., Blotchy A.J. et al. "Determination of blood mercury concentrations in Alzheimer's patients." J Toxicol Clin Toxicol 1995;33(3):243-7; Fung Y.K., Meade A.G., Rack E.P. et al. "Mercury determination in nursing home patients with Alzheimer's disease." Gen

Dent 1996;44(1):74-8 and Fund Y.K., Meade A.G., Rack E.P. and Blotcky A.J., "Brain mercury in neurodegenerative disorders." J Toxicol Clin Toxicol 1997;35(1):49-54.), investigators attempted to determine the concentrations of mercury in seven different brain regions from patients histologically confirmed with Alzheimer's disease, as compared to control subjects without known central nervous system and renal disorders. Brain mercury concentrations in all deceased subjects can be derived from amalgam restorations, diet, and the working environment. Based on their studies, the investigators concluded that there is no significant difference in blood and brain mercury concentrations between Alzheimer patients and aged-matched control patients, thus demonstrating that mercury derived from dental amalgam is not considered a significant factor in the pathogenesis of Alzheimer neurologic disorder.

A similar study conducted by Saxe S.R. et al. (Saxe S.R., Wekstein M.W. et al. Alzheimer's disease, dental amalgam and mercury. JADA 1999,;130(2):191-9), also refutes Pendergrass. Then Saxe study consisted of 68 human subjects with diagnosed Alzheimer's disease and 33 control subjects without Alzheimer's to determine mercury levels in multiple brain regions at autopsy and to ascertain the subjects' dental amalgam status and history. The investigators concluded that mercury in dental amalgam restorations does not appear to be a neurotoxic factor in the pathogenesis of this disease. Furthermore, the authors found that brain mercury levels are not associated with dental amalgam, either from existing amalgam restorations or according to the subjects' dental amalgam

restoration histories. Moreover, dental amalgam restorations, regardless of number, occlusal surface area or time, do not relate to brain mercury level.

- Leong, CC, Syed, NI, and Lorschedier, FL., "Retrograde degeneration of neurite membrane structural integrity and formation of neurofibillary tangles at nerve growth cones following in vitro exposure to mercury," NeuroReports 2001; 12(4)233-737.

This study involved the exposure of snail neuron cells, in the culture system of the laboratory, to mercury chloride salt, which the authors claimed caused the formation of neurofibillary tangles (NFTs) -- one of the hallmark pathological findings in the autopsy brain samples of patients who died from Alzheimer's disease. In addition to NFTs, such abnormalities as amyloid plaques and the hyperphosphorylation of Tau protein have also been found in post-mortem brain tissues obtained from Alzheimer patients. Conclusions: These morphological changes are direct evidence that mercury is an etiological factor for Alzheimer's disease in humans.

ADA Response: The major criticism with this paper is that the study only provides morphological data. Also, the mercury chloride concentration (20.1 ug/L) used in the study is at least five times higher than data reported by other investigators on patients with amalgam restorations. This contradicts the claim made by the authors that the mercury dose employed in the study has clinical relevance in humans. It is well documented and commonly known that manganese (Mn), lead (Pb) and cadmium (Cd) are neurotoxins. Yet, in the Leong study, these authors showed no adverse effects. Also, the purity of $HgCl_2$ salt, as well as other metal salts, were not known or provided in their study. Furthermore, the Leong

study lacked a cause-and-effect relationship establishing the sprouting assay of the neurite outgrowth study. A dose-response is needed to establish this relationship. This study has not been independently verified in other laboratories.

Finally, this study simply showed that the treatment of mercury chloride caused disruption of the membrane structure and reduction of linear growth rate of neuritis of cultured snail neurons. The authors' finding that mercury from amalgam restorations was linked "as a potential etiological factor for Alzheimer's disease" is not supported by this study.

4. **Renal System**

- Boyd ND, Benediktsson H, Vimy MJ, Hooper DE, Lorscheider FL 1992, "Mercury from dental 'silver' tooth fillings impairs sheep kidney function." Am J Physio. 1991;261(4Pt2):R1010-4.

In this study, twelve occlusal fillings were placed in each of six adult female sheep under general anesthesia, using standard dental procedures, and glass ionomer occlusal fillings (12) were inserted in two control sheep. Several days before dental surgery and at 30 and 60 days after placement of fillings, renal function was evaluated by plasma clearance of inulin and by plasma and urine electrolytes, urea, and proteins. Conclusions: When 12 fillings are placed in sheep teeth, the kidneys will concentrate amalgam mercury at levels ranging from 5 to 10 micrograms Hg renal tissue 4-20 weeks after placement. The authors concluded that sheep kidney function is impaired by the placement of dental amalgams.

ADA Response: In 1992, Boyd's study was severely criticized by Malvin et al. ("Mercury from dental 'silver' tooth fillings – letter. Am J Physiol 262

R 716-717). Malvin, a well-known renal physiologist from the University of Michigan School of Medicine, indicated that the evidence provided by Boyd et al. did not demonstrate nephrotoxicity as a result of the placement of dental amalgam. Furthermore, the data presented in the paper is incompatible with the conclusion. The only result in the paper that appears to support the conclusion is the 60% decrease in the glomerular filtration rate (GFR) of sheep that received 12 amalgam fillings. Malvin et al. questioned the validity of the GFR data. Malvin pointed out errors in the inulin clearance technique used to measure the GFR, noting that "the clearance methods are so poorly described that they are not possible to understand."

Furthermore, critical data necessary to interpret the results are not presented. The data are not self-consistent, and the evidence for a reduced GFR was based on faulty and poorly described inulin clearance methods and were contradicted by the urea data. Also, data in the paper are inconsistent with mercury nephrotoxicity, and there was a lack of appropriate controls.

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

cause kidney dysfunction in humans.

The second study was reported by Sandborgh-Englund et al. in 1996 ("No evidence of renal toxicity from amalgam fillings." Am J Physiol 271:R941-945). The aim of this study was to determine whether signs of renal toxicity could be observed in humans exposed to inorganic mercury from amalgam fillings in conjunctions with dental treatment. In ten patients, all amalgam restorations were removed during one single treatment session. One week before and 60 days after removal, the glomerular filtration rate (GFR) was determined by the Cr(51)-EDTA clearance techniques. No detectable effects occurred on excretion of NAG, Beta(2)-microglobulin, or albumin. The authors concluded that no signs of renal toxicity could be found in conjunction with mercury released from amalgam fillings.

One additional study was conducted at the Health Screening Program, held annually at the American Dental Association's Annual Meeting (Naleway C, Chou, FIN, Muller I, Dabney J, Roxe D, and Siddiqui F. "On-site screening for urinary Hg concentrations and correlation with glomerular and renal tubular function." J Public Health Dentistry 51(1),12-17, 1991). At the ADA 1985-1986 Annual Sessions, an on-site screening for mercury was conducted to identify dentists having elevated urinary mercury concentrations. The data generated from this study were used to examine the relationship between elevated urinary mercury exposure and kidney dysfunction. An analysis for the clinical markers indicated no clear relationship between elevated urinary mercury concentrations and kidney dysfunction.

5. Immune System

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

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

ADA Response: Hultman's study was later challenged by Langworth in a human study. Langworth's paper, "Minor effects of low exposure to inorganic mercury on the human immune system," was published in Scand J Work Environ Health 1993;19(6):405-13. In this study, the influence of exposure to inorganic mercury on the immune system was examined in 36 workers, who were occupationally exposed to mercury vapor, and a control group without known mercury exposure. The authors concluded that virtually all of the immunologic

parameters were within normal ranges and did not differ significantly between the two groups. Only a few individuals known to be sensitive to amalgam demonstrated minor reduction of the in vitro production of both tumor necrosis factor alpha and IL-1. No significant correlations were noted between different mercury exposure estimates and the immunologic parameters.

C. Conclusion of ADA Scientific Review

ADA believes that there is no valid or persuasive scientific evidence to suggest that those with dental amalgam restorations will experience adverse health effects except in the rare case of an allergic reaction. ADA supports ongoing research in the development of new materials that it hopes will someday prove to be as safe and effective as dental amalgam. However, the ADA continues to believe that amalgam is a valuable, viable and safe choice for dental patients and concurs with the findings of the U.S. Public Health Service that amalgam has "continuing value in maintaining oral health." 16/

IV. The Proposed Rule Should Preempt State Laws Regarding Dental Amalgam Products

ADA submits that the proposed rule should operate to preempt state laws that conflict with the requirements encompassed by the proposed rule. State laws regarding disclosure requirements for products that contain dental mercury or calling for the abolishment of dental amalgam products are directly at odds and

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16/ HHS News, January 21, 1993.

incompatible with the federal requirements set forth by FDA. Consequently, such state laws should be considered preempted by the proposed rule on dental amalgam products. It is not in the public interest to have competing state requirements that conflict with the special controls proposed by the Agency, nor is it appropriate under the FDC Act to permit states to ban the sale of dental amalgam products, which are cleared to market by FDA. In sum, as explained more fully in the following paragraphs, ADA maintains that the Agency should consider such conflicting state laws unacceptable and preempt them with the proposed rule under consideration.

A federal agency issuing an order or regulation within the scope of its delegated authority also may preempt state law, as long as the agency clearly communicates its intent to do so. See Hillsborough County, Florida v. Automated Medical Laboratories, 471 U.S. 707, 718 (1985); see also City of New York v. FCC, 486 U.S. 57, 63-64 (1988); Brookhaven Cable TV v. Kelly, 573 F.2d 765, 768 (2d Cir. 1978). Congress, through the Medical Device Amendments of 1976 ("MDA") to the FDC Act, clearly communicated its intent to allow FDA to preempt state laws that conflict with federal requirements for medical devices.

The MDA contains an express preemption provision regarding FDA's regulation of medical devices. Section 521 provides for preemption of state requirements applicable to a medical device that are "different from, or in addition to, any requirement applicable under this chapter to the device, . . . and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." FDC Act § 521.

FDA has promulgated a regulation interpreting section 521, which states:

> State . . . requirements are preempted only when . . . there are . . . specific [federal] requirements applicable to a particular device . . . thereby making any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements. 17/

21 C.F.R. § 808.1(d). Furthermore, the Supreme Court has interpreted FDA's preemption regulation to mean that:

> [I]n most cases a state law will be pre-empted only to the extent that FDA has promulgated a relevant federal "requirement." Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [FDC] Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Medtronic v. Lohr, 116 S.Ct. 2240, 2255 (1996). The Court found that when Congress enacted section 521, it "was primarily concerned with the problem of specific, conflicting State statutes and regulations rather than the general duties enforced by common-law actions." Id. at 2252. The Court understood the "overarching concern" of section 521 to be "that pre-emption occur only where a

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17/ It is acknowledged that FDA's regulation provides that section 521 does *not* preempt state requirements that: (1) are generally applicable to products other than devices; (2) are equal to, or substantially identical to, federal requirements; (3) impose occupational licensure (*e.g.*, physicians, device distributors); or (4) involve general enforcement for all devices (*e.g.*, state registration and licensing of device manufacturers). 21 C.F.R. § 808.1(d)(1), (2), (3) & 6(i). The state laws regarding dental amalgam products do not fall within these four categories of exemptions.

particular state requirement threatens to interfere with a specific federal interest." Id. at 2257.

Federal courts have applied the principles set forth in Medtronic to deny claims based on state laws that conflict with FDA's regulations, concluding that the federal regulations preempt the contrasting state law. For example, in Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997), the plaintiff brought an inadequate warning claim under state law for an approved investigational pacemaker. The plaintiff claimed that the warnings for the pacemaker, which was subject to an investigational device exemption ("IDE") under the FDC Act, did not comply with state laws requiring more detailed warnings as compared to those under the FDC Act. In denying the claim because the state law was preempted by the federal regulations regarding warnings for IDE medical devices, the Court stated "the state requirement would impede the implementation and enforcement of specific federal requirements. To allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations." Id. at 1100.

The Martin Court similarly rejected plaintiff's state law products liability claims by way of preemption. The plaintiff asserted manufacturing and design defect claims based on state law that, again, conflicted with the federal requirements for manufacture and design of an investigational device. Holding that plaintiff's state law claims were preempted, the Court reiterated that the state

products liability laws constituted "the kind of requirement that would impede the implementation and enforcement of specific federal requirements." Id. at 1099.

Likewise, in Enlow v. St. Jude Medical, Inc., 171 F. Supp.2d 684 (W.D. Ky 2001), the Court preempted certain state strict liability laws with respect to medical devices because such laws were at odds with the MDA. The plaintiff's claims were thus denied because there was no longer a basis on which to seek relief as a result of preemption. The plaintiff in Enlow brought design, manufacturing, and failure to warn claims regarding a PMA-approved heart valve based on state law. Much like the Court in Martin, the Enlow Court decided that conflicting state and federal regulations detailing such manufacture, design, and warning requirements for a medical device could not co-exist, stating:

> Therefore, under the state requirement, the fact finder could determine the FDA approved product design renders the mechanical heart valve unreasonably dangerous. Since the state requirement differs from the federal requirement, plaintiff's claims for defective design must be preempted. . . . To the extent plaintiff's manufacturing defect claim alleges that St. Jude Medical's mechanical heart valve was defective despite its adherence to the FDA approved manufacturing processes, it imposes a requirement different from the federal requirements and is accordingly preempted.

Enlow, 171 F. Supp.2d at 690. See Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) (holding that negligence per se, fraud, and failure to warn claims were preempted by MDA because of conflicting state and federal requirements).

These cases make clear that through the MDA, the FDC Act should preempt any state laws banning dental amalgams or requiring labeling significantly contradicting that required by FDA. Such state laws are clearly "specific,

conflicting State statutes and regulations" that "stand[s] as an obstacle" to a "relevant federal 'requirement.'" Competing labeling standards between a state and federal requirement will lead to confusion, and an outright ban on dental amalgam products plainly conflicts with the classification scheme proposed by the Agency. Congress expressly provided for federal preemption of state laws regarding medical devices for just this type of situation, and ADA strongly believes that the proposed rule should be construed as preempting all state regulations regarding dental amalgam products which are in significant contravention of the FDA imposed federal requirements.

V. Conclusion

FDA has spent decades analyzing scientific literature on the safety of dental amalgam products. Studies, reports, and opinions from nearly every viable source on the topic have been reviewed by the Agency prior to its issuance of the proposed rule. ADA agrees with FDA that there exists no meritorious scientific evidence to indicate that the use of dental amalgam products will result in adverse health effects. The benefits of these products clearly outweigh their potential risks, and as such a uniform class II classification regulation with special controls is appropriate for encapsulated amalgam, amalgam alloy, and dental mercury. The special controls specifically address the risks associated with these products for those with allergies to the ingredients in dental amalgam and for those occupationally exposed persons who may mishandle dental amalgam products. These special controls do adequately provide a reasonable assurance of the safety

and effectiveness of the dental amalgam products. In addition, a formal evidentiary hearing on the proposed rule is not required or necessary, for such a hearing would not be in the public interest. Finally, the proposed rule should operate to preempt conflicting state laws and regulations regarding dental amalgam products.