Is the FDA
[Dental Devices Division]
Confused On Dental Amalgam?
*Is Dental Amalgam an approved Class II device?
*Is Dental Amalgam, by rule, a Class III device?
 ***
Who knows? The FDA doesn’t seem to know!
If you were to call the Dental Division of the FDA (and please do: 301-827-5283), they will
tell you that FDA has approved Dental Amalgam
as a Class II device. However, and this is a BIG
however, they cannot provide any documentation
to support that position. There is no notification
of approval, no 510K, no classification of dental
amalgam in the Federal Register, no placement in
the FDA listing of approved dental devices.

Others say that, because dental amalgam is a
widely used dental device that a previous FDA
Commissioner refused to exempt from its
definition of ‘implant’, it automatically becomes
a Class III device until it can be reclassified by
evaluation according to FDA Rules.

The time has come for everyone to demand
explanations from FDA for their conduct! Only
public demand and pressure from the United
States Congress will oblige FDA to publicly
stand responsible for their actions on dental
amalgam.

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The documented facts: FDA on Amalgam

- In 1976, the President and the Congress of the
  United States directed FDA to evaluate all
  medical (including dental) devices intended for
  human use and to classify them according to
  their safety and effectiveness. [FR
  41(157):34099, 12 Aug 1976] To this day,
  "Dental Amalgam" is not listed as an accepted
and classified dental device, even though it been the most widely utilized of all dental devices. **WHY?**

- FDA has ruled that mercury is not GRAS (Generally Recognized to be Safe). [FR 63(77): 19799-19802, 22 Apr 1998] Yet, the FDA Dental Device Division accepted and classified "Dental Mercury" as a Class I safe and effective dental device. [FR 52(155):30082-30108, 12 Aug 1987] **WHY?**

- FDA accepted and classified "Amalgam Alloy" as a Class II safe and effective dental device [FR 52(155):30082-30108, 12 Aug 1987], knowing full well that amalgam alloy is a powder that will immediately wash out of a dental cavity. **WHY?**

- In 1978, the FDA Dental Device Panel requested that dental amalgam be exempted from the FDA Rule definition for "implant" ("a device that is placed into surgically or naturally formed cavities of the human body." [FR 42(177):46035, 13 Sep 1977]) The FDA Commissioner denied that request [FR 43(146):32988, 28 Jul 1978] Yet, the FDA Dental Device Panel ruled that dental amalgam was not an implant, in direct contradiction to the ruling of the FDA Commissioner. [FR 45(251):85964, 30 Dec 1980] **WHY?**

- FDA Rules clearly define acceptable evidence in determining safety and effectiveness of devices [FR 43(146):32988-32999, 28 Jul 1978], expressly excluding "random experience, reports lacking the details to permit scientific evaluation, or unsubstantiated opinion" as acceptable. [Pg. 32995] Further, FDA Rules define the "valid scientific evidence" required to accept devices. [Pg. 32990-32996] Yet the Dental Division of FDA violated FDA Rules in accepting "Dental Mercury" and "Amalgam Alloy" as safe and effective dental devices, without providing valid scientific documentation as required by FDA Rules. **WHY?**

- FDA Rules further state: "Although no device can be regulated adequately in Class I or Class II unless there are adequate data and information establishing its safety and effectiveness, a device for which there are such data and information may nevertheless require regulation in Class III because of the public health concerns posed by its use." [FR 42(177):46030, 13 Sep 1977] The Dental Device Division clearly violated this requirement in their final ruling in 1987. [FR 52(155):30082-30108, 12 Aug 1987] **WHY?**

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This brings us to current activities of the FDA on mercury, specifically dental amalgam mercury.

FDA, on 20 February 2002, announced a proposed rule entitled: "Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy." With this, FDA's only intention is to reclassify Dental Mercury into Class II and accept a "capsule" containing dental mercury on one side and amalgam alloy on the other as a "safe and effective" dental device.

**Questions:** Are any of these three devices actually inserted into the patient? Are any of the three, by themselves, "effective" as dental devices? The answer is obviously NO! Therefore, FDA acceptance of the three is a patent violation of their own rules.

**Questions:** Why does FDA recall products, such as shark and swordfish, for containing "excessive amounts of mercury" while deeming a daily exposure to mercury from amalgam dental fillings to be "safe" for humans? Does FDA really expect the public, and the United States Congress, to accept their position that an extremely rare exposure to shark or swordfish mercury is more
dangerous to humans than a continuous daily exposure to amalgam mercury? How can a device consisting of 100% pure mercury be ruled to be "safe" to humans?

**Question:** Why has FDA still refused to address the actual dental device used in humans - Mixed Dental Amalgam? FDA admits in their new proposed rule that mercury is released from mixed dental amalgam! Having done so, they now formally and publicly acknowledge a potential public health concern! With this, FDA is obliged to acknowledge that "Dental Amalgam" is indeed a dental device, is indeed an implant and, therefore, must place the device into Class III immediately!

Obviously, there are many serious questions about dental mercury that have not been answered by FDA. FDA has had over 25 years to address them, but has failed miserably in their responsibility. In consideration that millions of Americans have this mercury-containing and releasing dental device implanted into their teeth, it is imperative that the United States Congress immediately investigate this issue. **Call your United States Representative now to demand this investigation! Only the United States Congress has the authority to correct the position of the FDA on dental amalgam!**

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**Two Major Legal Victories Against Dental Amalgam!**

Perhaps the primary obstacle preventing action, professional or regulatory, against dental amalgam mercury has been the issue of credibility. Very few professionals or government authorities actually read documents or full research studies. Instead, they rely on "credible sources" to substantiate their positions. The promoters of dental mercury have established a number of "committees" to provide consensus opinions that dental amalgam mercury is harmless to humans. This "alphabet soup" of committee opinions and organizations is impressive to those not familiar with the actual published research on the subject. When faced with a decision, very few authorities will accept a minority position in opposition, even with the presentation of the documented science.

This has been particularly noticeable in the courts of the United States. All previous law suits have been dismissed in pretrial motions before the issue can be brought to a jury. These pretrial doctrines of evidence (Daubert in some states, Frye in others) fundamentally hold that no scientific testimony can be placed before a jury unless it has general acceptance in the relevant scientific community. Obviously, this is where credibility has its greatest impact.

Now, for the first time, two United States courts have ruled that the scientific evidence challenging the safety of dental amalgam mercury does have credibility, do satisfy the evidence requirements, and can be introduced into trial.

These two rulings have enormous impact! For the first time, there is a legal precedent and ruling that scientific testimony challenging the safety of dental amalgam mercury has credibility and cannot be dismissed. These rulings allow this evidence to now be placed before regulatory authorities and government representatives with credibility that cannot be denied.

To attorneys James M. Love and Robert E. Reeves - thank you!

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**Daubert Ruling**


I am pleased to report the following news. As you know, Robert Reeves and I represent Dr. David Barnes in a law suit filed against Kerr Corporation, one of the largest manufacturers of dental amalgam in the world. Dr. Barnes is a dentist who claims he suffered severe injuries resulting from his occupational exposure to mercury derived from
Kerr's dental amalgam products. In January, Kerr filed its long-awaited "Daubert" motion, claiming the expert testimony proffered by Dr. Barnes' designated expert witnesses constituted "junk science," was not scientifically valid and reliable, and should not be admitted into the evidence at the trial of this matter.

As you know, Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 595, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), held that, in order to be admissible, an expert witness's opinions must be based on scientifically valid and reliable methodologies. The scrutiny applied to scientific testimony has become so rigorous that some are questioning the continued viability of toxic tort lawsuits.

The Daubert Court suggested that there were at least four questions that should be considered by courts presented with Daubert challenges:
1. Is the scientific evidence testable and has it been tested;
2. Has the scientific evidence been subjected to peer review;
3. What is the potential rate of error;
4. Is the technique widely accepted in the relevant scientific community;
5. Does the scientific evidence grow naturally and directly out of research that has concluded independently of litigation.

In Barnes, the opinions of the plaintiff's designated expert witnesses were based almost exclusively on the peer-reviewed scientific literature, the first consideration enumerated by the Daubert Court.

I should mention that Kerr's expert witnesses are undeniably well-qualified in their respective fields. Kerr's team included the following designated experts:
1. James R. Albers, M.D., a board-certified neurologist and expert in mercury neurotoxicity;
2. Rodway Mackert, D.M.D., Ph.D., a dentist and expert in dental materials;
3. Thomas W. Clarkson, Ph.D., a biochemist and expert in mercury toxicology;
4. Michael S. Werley, Ph.D., DABT, a toxicologist specializing in aerosols;
5. Joel Cohen Ph.D., CIH, a certified industrial hygienist.
6. Stanley Berent, Ph.D., a psychologist.

Dr. Barnes designated the following expert witnesses:
1. Mark Richardson, Ph.D., a specialist in risk and exposure assessment;
2. Gary Ordog, M.D., a board-certified toxicologist;
3. F.L. Lorscheider, Ph.D., a psychologist and author of many important papers concerning dental amalgam;
4. Gregory Bothe, MS, CIH, CSP, a certified industrial hygienist;
5. Robert Granacher, MD, a psychiatrist board-certified in Psychiatry and Neurology;
6. Pam Floener, PT, RMA, CNC, CT, a physician's technician and an expert in mercury chelators.

I know that the expert witnesses on both teams are familiar to many IAOMT members. The Court's 54-page opinion found that each of the Plaintiffs experts were "clearly" qualified in their respective fields and further found that each of the opinions proffered by these experts were valid and reliable and therefore admissible. Following are my observations concerning the Court's opinion.

1. I am not aware of another case involving injuries allegedly caused by dental amalgam that has been subjected to-- and survived-- Daubert (or Frye) scrutiny. The Federal Court's order in this case is unprecedented and certainly opens doors for future amalgam litigation.
2. Courts prefer to be clothed in the affirmation of "general acceptance." Even in the post-Daubert era, courts look for institutional guidance on questions of scientific controversy. The Barnes Court proved to be no different. Although Barnes did not make a genuine attempt to demonstrate "general
acceptance", the Court's order engaged in a sua
sponte discussion of the amalgam controversy
with references to the stated positions of various
governments and governmental agencies.
3. Dr. Barnes's proffered expert testimony
emphasized strict adherence to the published
science and an emphasis on the IAOMT byline
"show me your evidence." The Court approved as
valid and reliable the scientific methodologies
employed by Dr. Barnes's designated expert
witnesses. However, the Court also emphasized
the following legal and regulatory developments
in support of its order:
a. Dan Burton (R-Ind.) stated on April 25, 2001,
that he would ask the National Institutes of
Health to study the safety of low level medical
and dental uses of mercury, including amalgam.
b. The organization called "Americans Against
Mercury Coalition" recently announced a "first
round" of legal actions against individual
dentists, dental and vaccine manufacturers, and a
dental service corporation alleging various
misrepresentations and product defects in the use
and manufacture of dental amalgam and
childhood vaccines. ADA was also named as a
defendant in a lawsuit by an individual against
her dentist for alleged malpractice.
c. Two lawsuits filed in California alleged that
the ADA and its California counterpart had been
lying to the public for decades about the health
risks of dental amalgam containing the poisonous
heavy metal mercury and have been engaging
dentists who oppose use of mercury in dental
fillings. Kids Against Pollution v. The American
Dental Association, Case No. BC 22125,
California Superior Court, Los Angeles County,
(June 12, 2001); Tibau v. American Dental
Association, Case No. 322110, California
Superior Court, San Francisco County (June 12,
2001).
d. According to Pharmaceutical and Medical
Device Law Bulletin for February 2002, the FDA
and other organizations of the U.S. Public Health
Service continue to investigate the safety of
amalgams used in dental restorations, but point out
that no valid scientific evidence has ever shown
that amalgam causes harm to patients with dental
restorations. The FDA is aware that some
manufacturers have advised in their labeling
against using amalgams in very young children and
pregnant or nursing women. The FDA plans to
uniformly regulate dental mercury, amalgam alloy,
encapsulated dental mercury and amalgam alloy.
e. Mercury amalgam treatment has been regulated
in Sweden, Germany, and Austria. The Swedish
Dental Association has publicly admitted that
mercury amalgam is an unsafe substance based on
a 1987 report commissioned by the Swedish
government to examine the effects of mercury
exposure from dental amalgams. As of July 1,
1995, Sweden has eliminated the use of mercury
amalgam on children and adolescents, and a
complete ban of mercury amalgam fillings for adult
was projected in 1997. Austria has initiated a
similar ban, effective by the year 2000. The article
further reports that the German Ministry of Health
has issued similar advice, and in 1992, informed
local mercury amalgam manufacturers of its
intention to ban amalgam production.
f. In April 1994, the U.S. Public Health Service
released an evaluation of mercury containing
dental amalgam. It found that amalgam has
continuing value in maintaining oral health.
Although the Public Health Service reported that
there had been only 50 confirmed cases of allergic
reactions since 1900, the Public Health Service did
acknowledge that their is no conclusive evidence
that mercury vapors are harmless.
g. The U.S. Occupational Health and Safety
Administration found that approximately 10% of
all dental offices are severely contaminated by
mercury since most have inadequate mercury
decontamination systems.
h. In the case of Mikel v. Kerr Manufacturing
Company, (1999), Plaintiff allegedly received mercury amalgam fillings from her dentist in 1984 and began to experience significant health problems within one month. While these symptoms continued, the Plaintiff received additional mercury fillings from her dentist in 1990. In that year Plaintiff saw a segment of 60 Minutes which described the potential side effects of mercury amalgam.

4. Clearly, these legal and regulatory developments played a role in the Court's decision to find in Barnes's favor. In this regard, the recent efforts of the IAOMT quite clearly played an invaluable role.

5. The Court found "it is clear that the majority view in the United States is that the dental amalgam containing mercury is not unreasonably dangerous or unduly hazardous to human health. At the same time, there is a strong minority view that dental amalgam containing mercury is both unreasonably dangerous and hazardous to human health. It is not for the Court to decide which view is correct or incorrect. The strong minority view referred to by the Court is quite clearly the voice of the IAOMT. The IAOMT's recent efforts undoubtedly influenced the congressional and other regulatory activities referenced by the Court. In my view, the Court's Order constitutes a clear and unequivocal breakthrough in both the scientific and legal realms. We have demonstrated to the satisfaction of a disinterested jurist that the rigorous Daubert standard may be satisfied by the existing and developing state of scientific, legal, and regulatory affairs surrounding the amalgam issue.

Clearly, the efforts of the IAOMT in the scientific and regulatory arenas are bearing well-deserved fruit in our country's courtrooms. James M. Love, Gassaway & Love, PLLC

Frye Ruling
Re: A lawsuit filed by a dental patient against a dentist alleged that the patient believed she was allergic to mercury and requested that the dentist remove her amalgam fillings and replace them with composite fillings. Ignoring her instructions, the dentist allegedly removed her amalgam fillings, took no precautions to protect the allergic patient from mercury vapor and amalgam particulate generated during the removal procedure, and replaced the old amalgam fillings with new amalgam fillings. The dental patient claimed she suffered adverse health effects following this dental appointment that she attributed to her exposure to mercury.

The defendant dentist filed a pretrial Frye motion, challenging the conclusions of the dental patient's expert witnesses based upon the position of organized dentistry and a number of "Consensus Committees" that dental amalgam is safe when used as a restorative material. The trial judge granted the defendant's Frye motion and precluded all of the plaintiff's expert witness from testifying at trial on the basis that dental amalgam is safe and that any opinion to the contrary was inadmissible at trial.

The patient appealed the ruling to the Missouri Court of Appeals. On 1 October 2002, the appellate tribunal vacated the lower court's judgement and remanded the case for reconsideration. The appellate court did not address all of the alleged errors raised by the appellant but identified enough errors to conclude that the lower court's ruling on the Frye issue constituted error and should be vacated and reconsidered by the trial court.

James M. Love, Gassaway & Love, PLLC

BP Comment: These dramatic rulings by courts of the United States, one of them a Federal Court, provide a clear legal precedent that the scientific evidence challenging the safety of dental amalgam mercury is valid and cannot be dismissed. This information has already been provided to FDA, and is now available to the United States Congress.
Belgium Bans Fluoride Supplements

On 1 August 2002, Belgium banned the sale of fluoride supplements! Belgium’s ban resulted from a report by the High Council for Health, the health minister’s advisory body. The Council had reviewed all scientific studies on fluoride supplementation and concluded that excessive use of fluoride increases the risk of osteoporosis, and could also lead to damage of the nervous system.

A health ministry spokesman stated: "We base our opposition to fluoride on the fact that there is no positive impact from the supplements - brushing teeth with fluoride toothpaste is sufficient and there is no reason to do anything else. Fluoride should be applied topically to prevent caries, but should not be swallowed, especially by children who are more vulnerable to it."

Although no decision has been made on fluoride in toothpaste, the health ministry stated that it would ask manufacturers to make toothpaste fluoride-free.

[International Fluoride Information Network Bulletin #651, 3 September 2002]

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SCIENCE

Effects of Continuous Low-Dose Exposure to Organic and Inorganic Mercury During Development on Epileptogenicity in Rats.

Szasz, A; Barna, B; Gajda, Z; Balbacs, G; Kirsch-Volders, M; Szente, M.

ABSTRACT: The effects of chronic, low-dose fetal and lactational organic (MeHgCl) and inorganic (HgCl2) mercury intoxication on epileptogenicity were investigated and compared in rats.

The main observations after both mercury treatments were a facilitated seizure expression and propagation evoked by 4-aminopyidine (4-AP). The seizure susceptibility of the offspring seemed to be in a parallel relation to the mercury concentration in cortical tissue, which was significantly higher in treated animals as compared to controls.

While MeHgCl enhanced the number of ictal periods, HgCl2 facilitated the duration of seizure discharges in younger animals. HgCl2 intoxication seemed to be more permanent than MeHgCl. Changes in the summed ictal activity - which is an indication of epileptogenicity - were observed in the opposite directions in the two treated groups with increasing age. The amplitudes of seizure discharges were smaller in both mercury-treated groups than in the controls, which could be a consequence of a depressed proliferation of neurons or enhanced cell death in the neocortex.

In summary, we observed that adult rats exposed to organic or inorganic mercury chemicals during their embryonic life, are more prone to epilepsy than control rats given only 4-AP.

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Effects of Metals on the Nervous System of Humans and Animals.

Carpenter, DO.

ABSTRACT: Several metals have toxic actions on nerve cells and neurobehavioral functioning. These toxic actions can be expressed either as developmental effects or as an increased risk of neurodegenerative diseases in old age.

The major metals causing neurobehavioral effects after developmental exposure are lead and methylmercury. Lead exposure in young children results in a permanent loss of IQ of approximately 5 to 7 IQ points, and also results in a shortened attention span and expression of anti-social behaviors. Thee is a critical time period (<2 years of age) for development of these effects, after which the effects do not appear to be reversible even if blood lead levels are lowered with chelation. Methylmercury has also been found to have effects on cognition at low doses, and prenatal
exposure at higher levels can disrupt brain development. Metals have also been implicated in neurodegenerative diseases, although it is unlikely that they are the sole cause for any of them. Elevated aluminum levels in blood, usually resulting from kidney dialysis at home with well water containing high aluminum, result in dementia that is similar to but probably different from that of Alzheimer’s disease. However, there is some epidemiological evidence for elevated risk of Alzheimer’s in areas where there is high concentration of aluminum in drinking water. Other metals, especially lead, mercury, manganese and copper, have been implicated in amyotrophic lateral sclerosis and Parkinson’s Disease.

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Disposition of Inhaled Mercury Vapor in Pregnant Rats: Maternal Toxicity and Effects on Developmental Outcome.
Morgan, DL; Chanda, SM; Price, HC; Fernando, R; Liu, J; Brambila, E; O’Connor, RW; Beliles, RP; Barone, S, Jr.
ABSTRACT: The disposition and toxicity of inhaled elemental mercury (Hg0) vapor for pregnant Long-Evans rats, potential adverse effects on reproductive outcome were investigated. Rats were exposed to 0, 1, 2, 4, or 8 mg Hg0/m3 for 2 h/day from gestation day (GD) 6 through GD 15. Maternal toxicity occurred primarily in rats exposed to 4 and 8 mg/m3 and was manifested as a concentration-related decrease in body weight gain and mild nephrotoxicity. Total Hg concentrations in maternal tissues increased with increasing number of exposure days and concentration. Total Hg concentrations in fetal tissues increased with increasing number of exposure days and concentration, demonstrating that a significant amount of Hg crossed the placenta. One week after the last exposure, significant amounts of Hg were still present in brain, liver, and kidney of PND 1 neonates. The total amount of Hg in neonatal brain (ng/brain) continued to increase after termination of inhalation exposure, suggesting a redistribution of Hg from the dam to neonatal brain. These data demonstrate that inhaled Hg0 vapor is distributed to all maternal and fetal tissues in a dose-dependent manner. Adverse effects of Hg on developmental outcome occurred only at a concentration that caused maternal toxicity.

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FORUM

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IAOMT 2003 MID-YEAR MEETING
Date: Friday-Saturday, 28-29 March 2003.
Site: Las Vegas, Nevada.
Hotel: Tropicana, 3801 Las Vegas Blvd., South, Las Vegas, Nevada 89109-4317. T: 702-739-2222. Specify IAOMT. Room rate/night (s/d): $65 (Sun-Thur); $125 (Fri-Sat); suites $165-$225. Deadline for IAOMT block: 27 Feb 2003 @ 5:00 p.m. Pacific Time!
Welcome Reception (Cash bar): Thursday, 27 March 2002, 7:30-10:00 pm.