FDA or TERRORISM
Which is More Dangerous?
What would you think if you knew that someone was contaminating your water supply with arsenic or lead? What would you do?
Well, mercury is far more neurotoxic than either arsenic or lead. Yet, the United States Food and Drug Administration (FDA) is stating that dental mercury is harmless, and so are mercury/silver amalgam dental fillings. This means that millions of Americans, including children and unborn babies will be exposed to the highly toxic mercury, because the FDA approves! A number of states are now considering legislation to BAN mercury fillings. It will not matter what the states want; they will be preempted by the FDA.
Let us quote from a recent FDA publication: "In the wake of the terrorist attacks on September 11, 2001, the FDA has also been entrusted with two critical functions in the Nation's war on terrorism: to prevent the willful contamination of all regulated products, including food, and improve the availability of medications to prevent or treat injuries caused by biological, chemical or nuclear agents." [Pub. No.FS 01-1]
WILLFUL CONTAMINATION!
CHEMICAL INJURIES!
The FDA proposes to act in direct contradiction to its own mission!
Terrorism is bad - this FDA action could be much worse!
So what are you going to do?

FDA Will Declare Mercury Safe!
The February 20, 2002 issue of the Federal Register (Vol. 67, No. 34) contained the Food and Drug Administration's (FDA) proposed rule "Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of

Table of Contents
FDA or Terrorism: Which is More Dangerous? .......................... 1
FDA Will Declare Mercury Safe! ........................................ 1
NAACP Endorses Amalgam Ban! ........................................ 4
U.S. Senate Bill on Mercury ............................................. 4
Norway Releases Amalgam Edict ....................................... 4
Legislation to Ban Mercury Amalgam: Federal and State ........ 5
So, What Are You Going To Do? ....................................... 5

SCIENCE
Mercury in Dental Restoration: Is There a Risk of Nephro-Toxicity. Mortada, WL et al ............................................. 5
Health and Neuropsychological Functioning of Dentists Exposed to Mercury. Ritchie, KA, et al .................................. 6
Maternal-to-Fetus Transfer of Mercury in Metallothionein-Null Pregnant Mice After Exposure to Mercury Vapor. Yoshida, M et al .................................................. 7

FORUM
IAOMT 2002 Annual Meeting............................................. 8
IAOMT 2003 Mid-Year Meeting.......................................... 8
National Dental Seminar in Homeopathy Seminar .................. 8
©2002 Bio-Probe, Inc. The Bio-Probe Newsletter is published bimonthly. Editorial office is at 5508 Edgewater Dr., Orlando, FL 32810. Subscription price in U.S. funds and Canada $75.00/year; other countries $90.00/year.
Special Controls for Amalgam Alloy." The comment period on this Proposed Rule ended on 21 May 2002. However, based on an electronic request for an extension of the comment period, the FDA has extended the comment period until 16 September 2002.

The intent of the proposed rule is to declare by the simple process of rule making that AMALGAM DENTAL FILLINGS ARE SAFE as well as incorporating language that effectively negates any state laws requiring full disclosure to patients of the potential health effects of amalgam/mercury dental fillings.

This action is being taken without regard to all the current studies published in peer reviewed medical and scientific journals demonstrating that there are unresolved serious health questions associated with the continued implantation of dental mercury in humans. It appears that any study concluding there was a problem with dental mercury was judged to have serious methodological flaws.

It is obvious from a review of the Proposed Rule that the only research studies considered to be "valid scientific evidence" are those studies that support the action being proposed. The simple fact remains that in all the U.S. Government, WHO, EU or other country studies cited not one anti-amalgam scientist, researcher, dentist, physician, academician was selected to be a part of the committees reviewing and evaluating the dangers of dental mercury. Consequently, it is imperative that we overcome this charade by letting the FDA and your Congressional Representatives know how you feel about this proposed rule.

While there are many problems with the Proposed Rule, the two primary problems are:

1. Permitting the FDA to classify encapsulated amalgam alloy and dental mercury as a class II device is a determination that mercury amalgam dental fillings are "SAFE." As an aside, this classification of dental mercury flies in the face of other FDA actions to eliminate mercury from all over the counter products. (Federal Register Vol. 63, No. 77, 22 April 1998) The only acceptable classification of dental mercury should be Class III, which requires the manufacturer to prove the safety of the product; and,

2. This Proposed Rule proposes "uniform disclosures" through labeling requirements. FDA's proposed guidance recommends that dental amalgam and dental mercury labeling list all ingredients. The clinician would be made aware of all materials he/she is placing in a patient's mouth, but this provision does not require anyone to inform the patient of the known toxicities of mercury.

In effect this Federal Rule if implemented as written would take precedence over all State Laws requiring dentists to inform patients of the hazards of dental mercury before placement in their mouths. The ADA is already publicly asserting this will preempt state disclosure laws.

***

ACTION ALERT: It is vital that everyone send e-mails and letters to the FDA regarding the proposed rule. PLEASE ask family, friends, and your mercury free dentist, your doctor (MD, ND, DO, DC) to write letters, too. We need everyone to help on this one. LET YOUR VOICE BE HEARD ON THIS CRITICAL HEALTH ISSUE.

1. Write a letter and send it to the FDA - e-mail address: fdadockets@oc.fda.gov
   Mailing Address: Dockets Management Branch (HFA -305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852

2. IMPORTANT: Write on subject line: "Docket No. 01N-0067 - Against FDA Rule"

2. Please send a copy of your FDA e-mails to Mary Ann Newell at bullelkman@aol.com as she will be maintaining a master file of responses for the Consumers for Dental Choice.

Here are some extra steps you can take.
Remember an e-mail/letter to the FDA is the important thing to do.
3. Use your FDA e-mail/letter to educate your elected officials, please send a copy of your FDA e-mail/letter to your U.S. Senators and your U.S. Representative - so they can learn about your issue with MERCURY dental fillings and your objection to FDA's Proposed Rule regarding MERCURY dental fillings.

HOW TO FIND your U.S. Representative and Senators: [www.Congress.org] When you get to the website, on the left side of the page see "elected officials." Select "U.S. Congress" and the next site will allow you to type in your zip code and will identify your member of congress. You can also find your two U.S. Senators the same way.

4. It would also be very helpful to send a copy of your FDA e-mail/letter to Congresswoman Diane Watson and Congressman Dan Burton (they have sponsored HR 4163, A Bill To Ban Amalgam). Let's let them know that we care about this IMPORTANT topic of mercury dental fillings and we are glad that they care, too. Send e-mails to diane.watson@mail.house.gov and Dan Burton at www.congress.org.

5. If you want, please post your e-mails to "Letters to the Leaders". It is located on the U.S. Government website - www.Congress.org. This step would help to educate other people about the important topic of MERCURY dental fillings.

***

KEY Talking Points from Charlie Brown and Sandy Duffy, who are attorneys for Consumers For Dental Choice and are actively involved in this issue:

*Tell the FDA your own personal story regarding MERCURY dental fillings.
*Tell the FDA why you care about this important topic - MERCURY in dental fillings.
*The Rule would undermine our state-by-state movement against the use of mercury dental填

fillings.
*The Rule would hide the risks of mercury fillings.
*The Rule states that the language will be uniform, leaving some to suspect the FDA wants to preempt (eliminate) state laws with stiff disclosures, such as those in California, Maine and New Hampshire.
*We want and demand public hearings around the country.
*The FDA is trying to write a rule that not only ignores the risks of mercury amalgam dental fillings, but assumes that they are safe.
*The FDA is using selected old data, ignoring all recent studies, even the most recent US Public Health Service Report.
*The FDA wants to classify mercury amalgams as a Class II dental device which does not require manufacturers to prove that mercury amalgam is safe; it must be classified as a Class III, so the manufacturer has to prove it is safe.
*Congresswoman Diane Watson (D-CA) and Congressman Dan Burton (R-IN) introduced a bill in the house on April 9, 2002, which will ban mercury amalgams. The FDA should extend its process to see what the congressional intent is regarding this matter.
*About 12 states have laws or bills before their legislatures on this issue. The FDA rule arguably preempts what the states are doing.
*Please ask FDA to use the most recent and most relevant research from peer reviewed scientific publications instead of old and out-of-date research.

Additional IMPORTANT POINTS to add:
*Request for public hearing and REBUTTAL and REPLY after new 60-day Comment period.
*Request for New Advisory Panel regarding mercury dental fillings as the old one was composed of individuals who were all pro-amalgam advocates.

************
NAACP ENDORSES AMALGAM BAN!
On 9 July 2002, the NAACP voted overwhelmingly to support the bill in the United States Congress (H.B. 4163, Diane Watson and Dan Burton) that would phase out the use of mercury amalgam dental fillings!
This is a huge step forward in eliminating mercury dental fillings, as the NAACP may well be one of the largest citizen representative groups in the United States (excepting, perhaps, AARP).
The NAACP resolution begins with ten "Whereas" points, most of which are contained in H.B. 4163, that emphasize the severe toxicity of mercury and the particular danger to unborn babies and children. The NAACP then calls for:
"1. disclosure be required to all dental patients
(a) that the main material in so-called silver fillings is mercury (not "silver"), (b) that mercury is highly toxic, and (c) that such fillings constitute a hazardous waste when removed;
2. a ban on mercury dental fillings being placed in young children, pregnant women, or nursing mothers;
3. all Americans, including families on Medicaid and/or dental insurance plans be given a choice of dental fillings, including the right to choose alternatives to mercury fillings;
4. The United States Congress give immediate consideration to the Watson-Burton Bill to phase out all mercury in dentistry within five years; and
5. State Legislatures to give immediate consideration to legislation comparable to the Watson-Burton Bill.
The NAACP is doing its part in fighting for the elimination of dental mercury - ARE YOU?

**********

U.S. SENATE BILL ON MERCURY
Status: Introduced, referred to Committee on environment and Public Works.

U.S. Senator Susan Collins (R-ME) has introduced a bill that would create a task force that would address the mercury problem nationally. The bill specifically addresses the sale of mercury thermometers, which are still for sale in many areas. Sale of mercury thermometers would be limited to prescription. The bill would also install very rigid requirements for the disposal of the mercury derived from thermometers.

**Key Language:** Section 2 Findings:
(2) according to recent studies, mercury deposition is a significant public health threat in many States throughout the United States;
(4) according to a report by the National Academy of Sciences, over 60,000 children are born each year in the United States at risk for adverse neurodevelopmental effects due to exposure to methyl mercury in utero;
(6) combustion of municipal and other solid waste is a major source of mercury emissions in the United States;
(8) the Governors of the New England States have endorsed a regional goal of the virtual elimination of the discharge of anthropogenic mercury into the environment;
10) according to the Environmental Protection Agency, the quantity of mercury in 1 mercury fever thermometer, approximately 1 gram, is enough to contaminate all fish in a lake with a surface area of 20 acres."

****************

NORWAY RELEASES AMALGAM EDICT
On 11 July 2002, the Norwegian Directorate of Health and Social Welfare released its "Draft for Public Comment" entitled "Directive for the Use of Dental Restorative Materials (in Norway)." The deadline for written comments is 1 October 2002. The Directive takes effect 1 January 2003. This Directive advises AGAINST the use of dental amalgam, based on "new" research revealing that mercury leaks out of the amalgam and can damage the kidneys and nervous system.
It states: "The use of amalgam shall be limited as much as possible due to possible health and environmental damage. Amalgam, if it is to be used, must not come in contact with other metals;" and, "New amalgam fillings should not be placed for persons with renal (kidney) ailments."

Under Informed Consent, the following is stated: "In the law on patients, rights, the right of the patient or next of kin to participate and to receive information is specified. The patient is to receive, in advance, and as the dentist receives additional knowledge, information that is necessary to understand their condition and the contents of the help to be given, including information about possible risks or adverse effects. In practice, this means that the patient or next of kin must be consulted when choosing restorative materials."

The Directive stops short of a full ban on the use of amalgam, thereby continuing the freedom of choice for those adult citizens choosing to accept amalgams.

*************

LEGISLATION TO BAN MERCURY AMALGAM: FEDERAL AND STATE

Watson-Burton H.R. 4163: This is a bill introduced into the United States House of Representatives by Diane Watson (D-CA) and Dan Burton (R-IN). It calls for 1) an immediate ban on the use of mercury/silver amalgam dental fillings in children, pregnant females, and nursing mothers; 2) the requirement for health warnings to all patients receiving mercury amalgam fillings; and 3) a total ban on mercury amalgam fillings by January of 2007.

The bill has been to the Health Subcommittee of the Committee on Energy and Commerce. No hearing has been scheduled as yet. The progress of this bill will depend entirely on public demand. **It is vitally important that everyone supporting this bill contact their U.S. Representative and two U.S. Senators urging them to support, or even co-sponsor, this bill!**

Names and contact information for your U.S. Representative and Senators can be obtained from the "Blue Pages" of your local telephone directory.

The following states have legislation introduced that mirrors the Watson-Burton Bill: **California A.B. 2270** (tabled in the Health Committee); **Alabama H.B. 378; Georgia H.B. 1715; Ohio H.B. 598**. Again, the progress of these bills will depend entirely on public demand.

*************

**SO, What Are You Going To Do?**

So, the United States Congress is considering a ban on mercury fillings; several states are considering bills to ban mercury fillings; the NAACP, and other groups endorse the ban of mercury fillings; more and more patients, health professionals, and scientists are urging a ban on mercury fillings; a number of foreign countries have already taken steps to limit, and eventually ban, mercury fillings.

Yet, the United States FDA, supported by organized dentistry, plans to certify their use as "safe and effective," thereby preempting the wishes and beliefs of everybody else!

**So what are you going to do about it?**

*************

**SCIENCE**

**Mercury in Dental Restoration: Is There a Risk of Nephrotoxicity?**

Mortada, WL; Sobh, MA; El-Defrawy, MM; Farhat, SE.

**ABSTRACT:** Background: Concern has been voiced about exposure to mercury (Hg) from dental amalgam fillings, and there is a need to assess whether this leads to signs of nephrotoxicity.

**Methods:** A total of 101 healthy adults (80 males and 21 females) were included in this study. The population as grouped into those having amalgam fillings (39 males and 10 females) and
those without (41 males and 11 females). Hg was determined in blood, urine, hair and nails to assess exposure. Urinary excretion of beta2-microglobulin (BETA2m), N-acetyl-beta-D-glucosaminidase (NAG), gamma-glutamyltransferase (gammaGT) and alkaline phosphatase (ALP) were determined as markers of tubular damage. Albuminuria was assayed as an early indicator of glomerular dysfunction. Serum creatinine, beta2M and blood urea nitrogen (BUN) were determined to assess glomerular filtration.

Results: Hg levels in blood and urine were significantly higher in persons with dental amalgam than those without; in the dental amalgam group, blood and urine levels of Hg significantly correlated with the number of amalgams. Urinary excretion of NAG, gammaGT and albumin was significantly higher in persons with dental amalgam than those without. In the amalgam group, urinary excretion of NAG and albumin significantly correlated with the number of fillings. Albuminuria significantly correlated with blood and urine Hg.

Conclusion: From the nephrotoxicity point of view, dental amalgam is an unsuitable filling material, as it may give rise to Hg toxicity. Hg levels in blood and urine are good markers of such toxicity. In these exposure conditions, renal damage is possible and may be assessed by urinary excretions of albumin, NAG and gamma-GT.

********************

Health and Neuropsychological Functioning of Dentists Exposed to Mercury

Ritchie, KA; Gilmour, Wh; Macdonald, EB; Burke, FJ; McGowan, DA; Dale, IM; Hammersley, R; Hamilton, RM; Binnie, V; Collington, D.


ABSTRACT: Objectives: A cross sectional survey of dentists in the west of Scotland and unmatched controls was conducted to find the effect of chronic exposure to mercury on health and cognitive functioning.

Methods: 180 dentists were asked to complete a questionnaire that included items on handling of amalgam, symptoms experienced, possible influences on psychomotor function, and the 12 item general health questionnaire. Dentists were asked to complete a dental chart of their own mouths and to give samples of urine, hair, and nails for mercury analysis. Environmental measurements of mercury in dentists’ surgeries were made and participants undertook a package of computerized psychomotor tests. 180 control subjects underwent a similar procedure, completing a questionnaire, having their amalgam surfaces counted, giving urine, hair, and nail samples and undergoing the psychomotor test package.

Results: Dentists had, on an average, urinary mercury concentrations over four times that of control subjects, but all but one dentist had urinary mercury below the Health and Safety Executive health guidance value. Dentists were significantly more likely than control subjects to have had disorders of the kidney and memory disturbance. These symptoms were not significantly associated with urinary mercury concentration. Differences were found between the psychomotor performance of dentists and controls after adjusting for age and sex, but there was no significant association between changes in psychomotor response and mercury concentrations in urine, hair, or nails.

Conclusions: Several differences in health and cognitive functioning between dentists and controls were found. These differences could not be directly attributed to their exposure to mercury. However, as similar health effects are known to be associated with mercury exposure, it would be appropriate to consider a system of health surveillance of dental staff with particular emphasis on symptoms associated with mercury toxicity where there is evidence of high levels of exposure to environmental mercury.
Bio-Probe Comment: As far back as the 1960's, mercury toxicologists clearly documented, and published, that measurements of mercury in blood, urine and hair did NOT correlated to the adverse effects of human exposure to elemental mercury. Too bad the contemporary scientific community ignores those findings. In any case, this is yet another study challenging the ADA position that dentists are healthier than the general population.

******

The Tagum Study I: Analysis and Clinical Correlates of Mercury in Maternal Blood, Breast Milk, Meconium, and Infants’ Hair
Ramirez, GB; Cruz, MCV; Pagulayan, O; Osteas, E; Dalisay, C.
[BP Note: Meconium is a material in the intestine of a full-term fetus.]

ABSTRACT: Objectives: To compare the indicators and levels of mercury (Hg) exposure in the mother with those in the fetal compartments, and determine its effects on the newborn.

Methods: Hg levels using atomic absorption spectrophotometry were determined in maternal blood, breast milk, cord blood, infants’ hair, and meconium of 78 consecutive mother-infant pairs in a community with high Hg pollution. The prevalence and levels of Hg both in meconium and in cord blood were correlated with maternal and infant risk factors.

Results: The prevalence of Hg in the fetal compartments was higher than in the maternal fluid compartments. Hg was present in 6.4% of maternal blood and 6.4% of breast milk, as compared with 16.7% of cord blood, 31.6% of infants’ hair, and 46.1% of meconium. Forty-six percent of infants with Hg in cord blood had none in meconium, whereas 80.6% with Hg in meconium had none in cord blood. Hg was not present in the maternal blood of all infants (n=36) with Hg in their meconium. Among those with detectable Hg, the mean levels were: mothers’ blood 24 ppb +/- 5.47, cord blood 53.3 ppb +/- 37.49, and meconium 48.6 ppb +/- 43.48. Quantitative measurement in hair was not done because of insufficient sample. Paired comparisons were all significant between Hg levels in the mothers’ blood and meconium, mothers’ blood and cord blood, and cord blood and meconium. Regression analysis showed Hg levels in meconium to be correlated with prevalence of Hg in infants’ hair, length of stay in Tagum, and meconium-stained amniotic fluid. Fischer’s Exact probability test showed that the prevalence of Hg in meconium was significantly related to the prevalence of Hg in the mothers’ blood and length of stay in Tagum. The prevalence of Hg in cord blood was significantly related to the prevalence in the mothers’ blood.

Regression analysis of levels of Hg in cord blood showed a significant relation to levels in mothers’ blood (.0001), prevalence in infants’ hair (.0126), gestational age (GA).0091, and head circumference (HC) (.0469). By quadrant analysis of weight against HC in 66 full-term infants all of 4 infants weighing an average of >3000 g at birth and with HCs lower than the fifth percentile had Hg in meconium.

Conclusion: The higher prevalence and levels of Hg in the fetal compartments reflect the ease of placental transfer with fetal trapping. Hg determinations in the mothers’ blood underestimate the degree and extent of fetal exposure. There is a significant difference in each compartment’s ability to reflect Hg exposure of the fetus. A small HC may be associated with the presence of Hg in meconium. Hg in meconium should be measured in addition to cord blood to determine the load of fetal Hg.

******

Maternal-to-Fetus Transfer of Mercury in Metallothionein-Null Pregnant Mice After Exposure to Mercury Vapor
Yoshida, M; Satoh, M; Shimada, A; Yamamoto, E; Yasutake, A, Tohyama, C.

ABSTRACT: This study examined the role of placenta metallothionein (MT) in maternal-to-fetal mercury transfer in MT-null and wild-type mice after exposure to elemental mercury (Hg(0)) vapor. Both strains were exposed to Hg(0) vapor at 5.5-6.7 mg/m(3) for 3 h during late gestation.
Twenty-four hours after exposure to Hg(0) vapor, accumulation of mercury in the major organs, except the brain, of MT-null maternal mice was significantly lower than that in organs of wild-type mice. In contrast to mercury levels in maternal organs, fetal mercury levels were significantly higher in MT-null mice than in wild-type mice. In placenta, mercury concentrations were not significantly different between the two strains.

Although MT levels in major organs, except the brain, of wild type mice were markedly elevated after the exposure to Hg(0) vapor, the placental MT levels were not elevated. However, endogenous MT level in the placenta is significantly higher than that in other organs, except the liver.

Gel filtration profile of the placenta cytosol in the wild-type mice revealed that a large amount of placental mercury was associated with MT. In MT-null mice, mercury in placental cytosol appeared miled in the high-molecular-weight protein fractions. Mercury in the placenta was localized mainly in the yolk sac and decidual cells in the deep layer of the decidua in both mouse strains. The similar localization of MT was found in the placenta of wild type mice.

These results suggest that MT in the placenta has a defensive role in preventing maternal-to-fetal mercury transfer.

**********

FORUM

IAOMT 2002 ANNUAL MEETING

Date: Fri.-Sat., 27-28 September 2002.
Site: Calgary, Alberta, Canada. [Note: Those not citizens of Canada must have a passport or certified birth certificate and picture identification, such as drivers license, for entry.]
Hotel: Hyatt Regency Calgary, 700 Centre Street South, Calgary, Alberta, T2G 5P6, Canada. T: 800-233-1234; F: 403-262-3490 for reservations. Specify IAOMT. Room rate/night (s/d): $65 (Sun-Thur); $125 (Fri-Sat); suites $165-$225. Deadline for IAOMT block: 26 August 2002!

Annual Awards Banquet: Saturday evening.

**********

IAOMT 2003 MID-YEAR MEETING

Date: Friday-Saturday, 27-29 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!

Meeting Registration: IAOMT, P.O. Box 608531, Orlando, FL. 32806-8531. T: 407-298-2450; F: 407-298-3075. Registration (U.S.): to be announced. Welcome Reception (Cash bar): Thursday, 4 April 2002, 7:30-10:00 pm.
Program: To be announced.

**********

National Dental Seminar in Homeopathy

25th Annual Seminar

Date: 11-13 October 2002. Site: Schaumberg, Ill.
Contact: NDS, P.O. Box 123, Marengo, IL 60152-0123. T: 815-568-5222.