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Executive Secretary Dental Products Panel DHHS/FDA/CDRH/ODE

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To: FDADockets@oc.fda.gov Docket Number 2006N-0352

Dear FDA Advisory Committee,

Mercury filling materials are toxic before they are placed in the mouth and after they are removed. The human mouth does not make them safe.

- A. Manufacturer IFU and Warnings: The FDA should at least follow the manufacturer's previous or current warnings regarding mercury dental fillings.

Caulk formerly had warnings/IFU:

- Do not have amalgams in contact to dissimilar metal restorations
- Do not have amalgams in patients with severe renal deficiency
- Do not have amalgams in patients with known allergies to amalgam
- Do not have amalgams under a cast crown
- Do not have amalgams in children 6 and under
- Do not have amalgams in women who are or may become pregnant

The new warnings are even more strict. "Ingestion: Do not swallow or take internally." When asked whether implanting in the teeth was considered "internal", Caulk failed to respond. The IFU also warns, "Inhalation: Do not breathe vapor". We know mercury vapor is coming off mercury fillings all the time. When asked whether the amount of mercury vapor coming off after the fillings had set was enough to fit in this warning. Again Caulk failed to respond.

The vast majority of patients we see have amalgams in violation of manufacturer's warnings. The FDA should at least support the manufacturer's warnings and not permit the swallowing, inhaling or internal placement of mercury fillings.

- B. Total Intake and Individual Exposure to Mercury. The FDA has been asleep at the switch on the total dosage of mercury from all sources: vaccinations, mercury dental fillings, foods, environment, industrial hydrofluorosilicic acid, etc.

C. Mercury sensitivity and allergy. The FDA does not appear to take into consideration the level of sensitivity subsets of the Public have to mercury. The ADA has suggested up to 5% of the population are allergic to amalgams. We have tested individual patients find 100% to have some allergic reactions to mercury. How do we tell who has allergies to amalgams and who does not? What are the reactions to look for and the testing to use? The FDA must take a lead in protecting the Health of the Public.

D. Mercury dental fillings are not needed. Like many other dentists, we have not used mercury for the last 18 years (Drs Bowden and Lawson since Dental School). When informed, none of our patients want mercury fillings and most want serviceable mercury fillings removed. So while

some Dentists place amalgams, other Dentists (after the patient is informed) are removing all Amalgams regardless of decay.

- D. The ADA is unreliable and biased. The ADA web site still suggests it is unethical for a dentist to recommend the removal of an amalgam on the advice of the Dentist. Dentists have and do threaten to report and censure their colleagues who remove amalgams.

The Superior Court of the State of California Case No. 718228, Demurrer (October 22, 1992).

“The American Dental Association (ADA) owes no legal duty of care to protect the public from allegedly dangerous products used by dentists. The ADA did not manufacture, design, supply or install the mercury-containing amalgams. The ADA does not control those who do. The ADA's only alleged involvement in the product was to provide information regarding its use. Dissemination of information relating to the practice of dentistry does not create a duty of care to protect the public from potential injury.”

E. Our State Departments of Environmental Quality are concerned with the toxic effects of parts per trillion of mercury in rivers. Dentists are putting in trillions of times that amount in people's mouths without patient consent and the human body is mostly water.

F. Mercury does come off mercury fillings. See www.IAOMT.org.

See also <http://atsdr1.atsdr.cdc.gov/tfacts46.html> and

Svare, C.W. Dental Amalgam Related Mercury Vapor Exposure. Cal. Dent. Ass J. pp 55-60, Oct. 1984.

Vimy, et al. Intra-Oral Air Mercury Released From Dental Amalgam. J. Dent. Res. Vol 64, 1069-1071, August 1985

Vimy, et al. Intra-oral Air Mercury. Estimation of Daily Dose from Dental Amalgam J. Dent. Res. Vol. 65:1072-1075. Aug 1986.

Emler et al. An assessment of mercury in mouth air. J. Dent. Res. Vol 64:247, IADR Abstract No. 652, 1985

Patterson et al, Mercury in Human Breath from Dental Amalgams, Bul Environ. Contam. Toxicol. 34:459-468, 1985

The amount of mercury vapor in people's mouths with several fillings is higher than permitted for 40 hours in the work place by OSHA. WHO and the EPA also consider the levels of mercury vapor in many mouths unsafe when exposed 24/7.

Consider also

P. Kaub et al, Universitat Tubingen, Institut fur Organische Chemie 1997

I. Bernhard, et al, Tubingen Univ. Gynecological Clinic, Heidelberg, 1996

B. Windham, Annotated Bib. Of Exposure and Health Effects from Amalgam Fillings, 1997

If a half gram of mercury is dropped in a 10 acre lake, warnings should be placed not to eat the fish. Our bodies are mostly water and 2 fillings can have half a gram of mercury. True, it comes off slowly, but it comes off and some are harmed.

WD Kuntz "Maternal and chord blood mercury background levels: Longitudinal dsurveillance:, Am J. Obstet and Gy. 1982

E. Lutz et al, "Concentrations of mercury in brain and kidney of fetuses and infants, J. of Trace Elements in Medicine and Biology, 1996

H. Cardiovascular system

The relationship between mercury from dental amalgam and the cardiovascular system

Compared to the control group, amalgam-bearing subjects had significantly higher blood pressure, lower heart rate, lower hemoglobin, and lower hematocrit.

The amalgam subjects had a greater incidence of chest pains, tachycardia, anemia, fatigue, tiring easily, and being tired in the morning.

Dept. of Physiology, College of Vet. Med. And Bio. Sci., Colorado State U. Fort Collins, Sci Total Environ, 1990

I. Mercury's harmful effects that may be passed from the mother to the fetus include brain damage, mental retardation, incoordination, blindness, seizures, and inability to speak. Children poisoned by mercury may develop problems of their nervous and digestive systems, and kidney damage.
<http://atsdr1.atsdr.cdc.gov/tfacts46.html>

Thank you for considering this information and moving away from the use of a material totally unnecessary and harmful to the Health of the Public.

In brief, Mercury filling material is toxic before it goes in the mouth and is toxic after it is removed. There is nothing about the human mouth which makes the material safe.

Our recommendation is for the FDA to require signed informed consent from each patient prior to amalgam placement and a date set when no more amalgams maybe placed.

Sincerely,

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