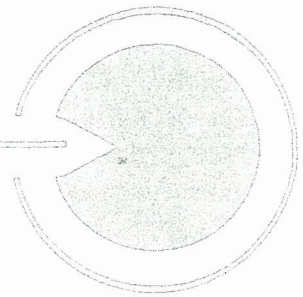


BIO-PROBE

NEWSLETTER



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FDA or TERRORISM

Which is More Dangerous?

What would you think if you know 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

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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
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.