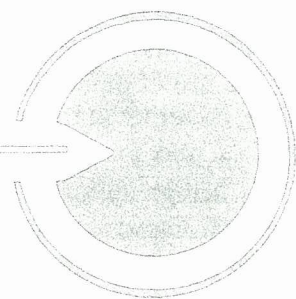


# BIO-PROBE

# NEWSLETTER



Volume 7

March 1991

Issue 2

## FDA DOES NOT APPROVE THE USE OF AMALGAM!

The Dental Products Panel of the Medical Devices Advisory Committee met at the Food and Drug Administration building in Rockville, Maryland on 15 March 1991. After a full day of testimony from numerous speakers, the Panel voted unanimously on two resolutions:

1. There was not sufficient evidence presented to warrant a position that dental amalgam is unsafe, but unanswered questions were raised that warrant further investigation.
2. A committee should be formed to define the required areas of investigation and the appropriate research to resolve the question of amalgam safety.

### WHAT THE FDA PANEL DIDN'T DO!

This panel will be remembered more for what it didn't do than for what it did do. Although it was only an advisory committee with no authority to determine policy or actions, it did have an obligation to recommend a classification for dental amalgam to the Food and Drug Administration.

The law is clear on medical and dental devices. The Medical Device Amendment to the Federal Food, Drug, and Cosmetic Act was signed into law on 28 May 1976. This Amendment (Sections 513 through 521) requires the Food and Drug Administration to classify all medical (including dental) devices accepted for use in the United States. If a material is not classified under the law, it cannot be considered a device approved for dental use.

Having personally witnessed the testimony presented at the meeting, it is easy for this writer to understand why the Panel did not make a recommendation to classify dental amalgam. There was no

scientific documentation presented that demonstrated amalgam to be harmless. Claims of safety are still based on the strictly anecdotal position that over 150 years of use demonstrates the safety of dental amalgam.

In view of the lack of scientific data demonstrating the safety of dental amalgam, the Panel could not recommend acceptance of the device under FDA rules. Recommended acceptance into Class II or Class III of the FDA mandate would have placed amalgam manufacturers, as well as amalgam-using practicing dentists, in an untenable position. These categories require valid scientific documentation demonstrating the safety and effectiveness of devices containing materials of potential health risk. Class I is reserved for those devices determined to not contain materials of potential health risk.

### REMOVAL OF AMALGAM FILLINGS IS NOT A PUNISHABLE OFFENSE!

The significance of the actions (or rather the lack

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there-of) of the FDA Advisory Panel is truly astounding. The FDA is the only body with legal authority over the use of dental devices. Since the FDA does not consider dental amalgam to be an accepted dental device, its removal from patients cannot possibly be considered illegal! Dentists who have been previously punished may yet have recourse in this matter.

This brings us to the question of public statements that the FDA "grandfathered" approval of dental amalgam. These statements are absolutely false!

### **DENTAL DEVICE PANEL VIOLATES FDA MANDATE!**

The Final Rule of the FDA on Classification of Dental Devices is found in the Federal Register, Volume 52, Number 155, 12 August 1987. There is no mention in this document of dental amalgam as a dental device. Rather the FDA accepted and classified the following: "Dental mercury" (Section 872.3700) as a Class I device. "Amalgam Alloy" (Section 872.3050) as a Class II device.

The same is found in the 1980 Proposed Rules (with the exception that dental mercury was recommended to be in Class II) and all previous actions of the Dental Device Panel as documented in the Federal Register. Dental amalgam was never addressed or considered as a dental device.

The acceptance and classification of these two materials was a clear violation of FDA rules, which mandate that classified medical devices must be both "safe" and "effective".

Neither "dental mercury" nor "amalgam alloy" can be used alone as a dental device. Either of these "devices" would rapidly wash out of a dental cavity preparation. Both materials fail the clear, and often repeated, FDA rule requirement for "effectiveness". The Dental Device Panel erred in classifying them in the first place, and the FDA is obligated to correct that error by immediately withdrawing their classification.

### **CONSIDERATION OF UNITED STATES TORT LAW**

Should the FDA consider future classification of dental amalgam as an accepted dental device, the effectiveness of this device would not be challenged. However, one extremely important factor concerning the "safety" of the device has been totally overlooked. United States Tort Law [Restatement of Torts] defines "harm" as: "Any change in the structure or function of the body." It is further stated that nothing beyond that definition need be proven to establish tort.

Titled disease states are nothing more than names given to eventual body responses to pre-existing harm. The scientific literature is clear. Mercury causes damage within the body long before clinically observable signs and symptoms appear. Recognized authorities on mercury toxicology have publicly declared that no amount of exposure to mercury vapor can be considered totally harmless.

Currently, defenders of amalgam rely on the position that patient exposure to mercury from dental amalgam fillings has not been conclusively connected to any disease state. This position ignores U.S. Tort Law and places the amalgam-using practicing dentist in an absolutely indefensible position.

**BIO-PROBE NOTE:** We should all be grateful to dentist/attorney Joel Berger for discovering the two preceding issues. Unfortunately, Joel came down with the flu and could not get to the FDA meeting. They were presented in his stead by Michael F. Ziff, D.D.S.

### **WORLD HEALTH ORGANIZATION CONTRADICTS DENTISTS!**

Two renowned speakers at the FDA meeting were Dr. Lars Friberg and Dr. Thomas W. Clarkson. They are the world's foremost authorities on mercury toxicology and members of the World Health Organization's committee on mercury. They stated that W.H.O.'S new document on mercury would soon be available and that they had permission to release data from that document.

The most significant information they presented was the W.H.O. conclusion on estimated intake of mercury subjects receive from dental amalgam fillings. The major contributions to human intake of mercury were: Dental amalgam fillings = 3.0-17.5 micrograms/ day (mercury vapor); fish = 2.4 micrograms/day (methylmercury); non-fish food = 0.3 micrograms/day (inorganic mercury). Other sources (air and water) were found to be negligible.

It was pointed out that these data contrast sharply with estimates derived by dental authorities (Mackert, Olson, Bergman, et al) who have decided that patient intake of mercury from dental amalgam fillings is