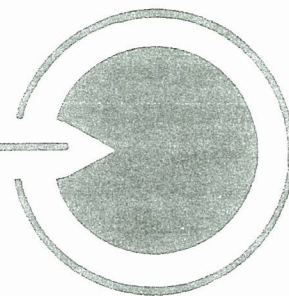


BIO-PROBE

NEWSLETTER



Volume 8

November 1992

Issue 6

FDA WRIT OF MANDAMUS PETITION

On 25 September 1992, a Petition for a Writ of Mandamus was filed in the United States Court of Appeals in Washington, D.C. (A Writ of Mandamus is an order from a superior court commanding that a specific thing be done.) The petition asks the Court to require the Commissioner of the Food and Drug Administration to: (a) require the manufacturers of dental mercury to provide a warning as to its tendency to cause hypersensitivity to the dentists using it, (b) require proper warnings to patients of the danger of hypersensitivity to dental mercury, and means of reducing the risk and (c) require mercury fillings to be listed as a device and give it an appropriate category under the Act.

In 1976, Congress and the President directed the Food and Drug Administration (FDA) to "evaluate all medical (including dental) devices intended for human use" and to classify them according to their

"safety and effectiveness".

The FDA established Device Panels (including a Dental Device Panel) and Rules and Regulations for evaluation and classification. The FDA also accepted the following definition: "'Implant' means a device that is placed into a surgically created or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health." The FDA also noted that Sections of the act clearly state that an implant need not be classified into class III if such classification is not necessary to provide reasonable assurance of safety and effectiveness. Because of the latitude in this provision of the act the Commissioner denied any consideration of the request to specifically exempt dental fillings from the definition. (Page 32988, FR 43, 146-Friday 28 July 1978)

The following information provides background regarding the history of not considering dental amalgam as a dental device. A report entitled "Medical Devices: A Legislative Plan," which was released in September 1970 established the entire framework for the classification of all medical and dental devices according to their safety and effectiveness. Based on Congressional action in 1973 to incorporate all the provisions of the 1970 report into legislation, the Commissioner of the FDA appointed 14 classification panels to begin the task of identifying and grouping devices that would have to be classified. It is interesting to note that the first Dental Device Panel appointed in 1973 was chaired by John W. Stanford, Ph.D. Dr. Stanford was then and still is Chairman of the American Dental Association's Council on Dental Materials,

Table of Contents

FDA Writ of Mandamus Petition	1
FDA Citizens Petition	2
A possible answer to why some people do not improve after amalgam removal. Malmstrom C, Malmstrom I	3
Toxicity assessment of mercury vapor from dental amalgams	4
Is amalgam in dental fillings a health risk? Berlin M.	5
In vitro effect of mercury on enzyme activities and its accumulation in the first-trimester human placenta. Boadi et al	6
Impaired cortisol stress response in fish from environments polluted by PAHs, PCBs, and Mercury. Hontela et al	7
Mercuric chloride-treated Brown Norway rats develop widespread tissue injury including necrotizing vasculitis	7
Autoantibodies to myeloperoxidase in Brown Norway rats treated with mercuric chloride. Esnault et al	8
FORUM	
IAOMT 1993 Orlando Winter Meeting	8

© 1992 by Bio-Probe, Inc. The Bio-Probe Newsletter is published bi-monthly. Editorial office is at 4401 Real Ct., Orlando, FL 32808. Subscription price \$65.00 per year. Postage paid at Orlando.

Instruments and Equipment (CDMIE).

The minutes of some of the initial meetings of the Dental Device Panel held in 1973 clearly indicate that dental amalgam was not going to be considered as a dental device, even though it was the most widely used device in the history of dentistry. Instead, the panel in 1973 decided to only consider dental mercury and amalgam alloy, the components of dental amalgam, as dental devices. This resulted in the decision to classify (without evaluation) dental mercury and amalgam alloy as being "safe and effective" dental devices. Both "devices" were recommended for automatic acceptance in Class II, based solely on the ANS classifications. ANS (American National Standards) are developed by a private company called The American National Standards Institute (ANSI) under contract to the American Dental Association. In the Final Rule for dental devices in 1987, the Dental Device Panel switched dental mercury to Class I, deciding that mercury presents no health risk to humans and is effective as a dental device.

The FDA has refused to approve mixed amalgam as a dental device and both the FDA and the ADA have formally declared that responsibility for its use rests with the individual dentist that uses it!

The position of the Food and Drug Administration, and the actions of its Dental Device Panel are clearly in violation of the 1967 Congressional and Presidential directive. Dental amalgam is obviously a dental device "intended for human use". Dental mercury and amalgam alloy are obviously not "effective" as dental devices, let alone "safe". In addition, there is no legal status for the use of dental amalgam. This means that there is no legal basis for denying patient rights for the removal of the device or for punishing dentists for its removal!

For years, many attempts have been made to encourage the FDA to honor its responsibility on dental amalgam, to no avail. These attempts are well documented. These, along with the voluminous scientific documentation questioning the safety of dental amalgam, provide the background for the Petition for the Writ of Mandamus. The Petition has been initiated by a number of individuals and seven organizations: The Foundation for Toxic Free Dentistry; The International Academy of Oral Medicine and Toxicology; The American Academy of Biological Dentistry; The Association of Health

Practitioners; The Environmental Health Network; The Environmental Dental Association; and The Foundation for Advancement of Innovative Medicine.

The petition for mandamus represents months of intensive preparation by attorneys Robert Reeves (Kentucky) and Jim Turner (Washington, D.C.). Up to the present time, the financial burden for this entire effort has been borne by a small number of dedicated dentists and individuals. However, it is now necessary for all dentists and physicians who do believe that mercury dental fillings pose a serious health threat, to accept some financial responsibility in support of that belief. The extensive and expensive process of developing legal briefs for presentation to the court has begun and your help is needed. Consider contributing at least \$100.00 per month to the Legal Action Fund of the Foundation For Toxic Free Dentistry. The Foundation is a 501(c)(3) nonprofit tax-exempt organization and your contribution is tax deductible to the full extent the law allows. Just consider that you are buying an insurance policy for \$100.00 per month that will protect you from future harassment from the mercury zealots of the dental establishment and eliminate forever the bizarre dental practice of implanting a poison in patients. Make your contribution to the Foundation for Toxic Free Dentistry, Legal Action Fund. P.O. Box 608010, Orlando, FL 32860-8010.

FDA CITIZENS PETITION

In a further effort to force the consideration of valid information on the dental amalgam issue, the FTFD Legal Fund has also initiated a Citizens' Petition to the FDA itself. This Petition asks the FDA to withdraw its approval of dental mercury as a "safe and effective" dental device.

Mercury is neither harmless to human health nor effective in itself as a dental device. The FTFD Legal Fund attorneys have also prepared the documentation to support this petition.

The effort to generate signatories for this petition is being directed by the FTFD and the leadership of the Dental Amalgam Mercury Syndrome (DAMS) support groups and the ADAMS support group in the state of Washington. If enough signatures are obtained, along with the considerable documentation of the health risk of mercury