

A look at the 2006 FDA hearing on the safety of dental amalgams and possible toxicological concerns

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Abstract

In early September 2006 the FDA staff of the Dental Devices Branch released a 'white paper' on their evaluation of the research in the past 10 years that provided data that could be used to evaluate the safety of dental amalgams. This white paper was to be used to convince the FDA appointed 20 member external advisory committee of the safety of amalgams. It failed badly as the advisory committee voted 13 to 7 to not accept the conclusions of the white paper. The advisory committee asked for further research into the issue and expressed the opinion that the white paper did not present all of the relevant research. It is my opinion that the bulk of the research showing toxic effects from mercury were dismissed by the FDA staff using an invalid assumption that mercury toxicity can be determined by simply measuring urine or blood mercury levels. The FDA staff also took the position of questionable expertise in dismissing research done at major research universities and published in highly regarded journals. They also overlooked many important research papers by only using one search engine to identify the literature they would address, and only considered research done in the last ten years. This paper presents a few of the relevant articles overlooked by the FDA and gives a different evaluation of the research articles that were somewhat dismissed by the FDA staff using the outdated concept that urinary mercury levels can be used to determine if a toxic exposure has occurred.

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