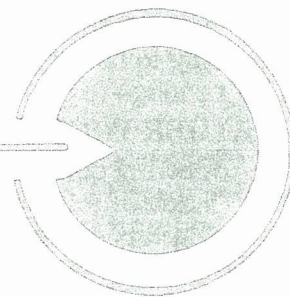


BIO-PROBE

NEWSLETTER



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**NIDR/NIH PANEL VIOLATES MANDATE!
NATIONAL INSTITUTES OF HEALTH
TECHNOLOGY ASSESSMENT CONFERENCE STATEMENT
EFFECTS AND SIDE EFFECTS OF DENTAL RESTORATIVE MATERIALS
26-28 AUGUST 1991**

THE PANEL'S STATEMENT

After announcing its "consensus opinion" at a press conference on 28 August 1991, the very first question a reporter asked of the NIDR/NIH Technology Assessment Panel on dental materials was: "How can you give dental amalgam a clean bill of health in one breath and in the very next breath admit that you have no scientific evidence to support that position?"

THE PANEL'S OWN CONTRADICTIONS

The Panel was unable to provide a satisfactory answer to that question- with good reason! At the opening session on the morning of 26 August the chairman of the panel, Dr. William D. McHugh of the Eastman Dental Center, instructed the Panel to base its findings solely on scientific evidence. The very same William D. McHugh, D.D.S. announced the Panel's conclusion at the press conference. It was: "Although mercury vapor is released from dental amalgam, the quantities released are very small and **DO NOT CAUSE VERIFIABLE ADVERSE EFFECTS ON HUMAN BEINGS.**" (pg 19, lines 12-14 of the NIH document distributed to the press and attenders.)

Dr. McHugh also read a statement added after that conclusion: "While current evidence supports the concept that existing dental restorative materials are safe, it must be recognized that the supporting data are incomplete." [BIO-PROBE NOTE: The qualifying statement was added to the conclusion after this writer pointed out the contradictions to the conclusion in the Panel's document.]

"Recognized" by whom- certainly not by the NIH Panel, since their second statement contradicts their conclusion! By specific direction, the conclusions were to be made on the basis of science, not unsubstantiated opinions.

Prior to announcing the conclusion, Dr. McHugh also made a number of other conflicting statements at the press conference (not placed in quotes as my notes do not contain the full, specific wording contained in the written document):

- * Dental amalgam releases very small amounts of mercury over many years.
- * Data on amalgam contribution to total body burden is still unclear. The relative importance of this is still not determined to their (the Panel's) satisfaction.

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* There is a paucity of data. This may be due to various factors, such as the inability of dentists to recognize the adverse effects of mercury.

* Under certain conditions, mercury exposure from dental amalgam fillings can cause systemic reactions.

* The risk/benefit ratio can not be calculated, due to the lack of data.

* Dr. Michael Kashgarian, a non-dentist member of the Panel, stated that we have assumed that dental

materials are safe, because of their long use. He also stated that dental materials should be subjected to the same scrutiny as are medical devices.

It is going to be very difficult for the Panel to reconcile their "conclusion" to these stated conditions. If that isn't enough to deal with, the following are statements in their own written document.

FURTHER WRITTEN CONTRADICTIONS FROM THE PANEL

The following quote is taken directly from the Panel's comments on risk/benefit ratios (page 16, lines 14-17): "Lack of reliable quantitative estimates of the risks and benefits of the various dental materials discussed at this conference preclude calculation of benefit/risk ratios. The paucity of data concerning predictable risks associated with restorative dental materials was striking."

The benefits of various dental restorative materials were clearly stated during the conference and in the Panel's document. As indicated in the second sentence of the above statement, the risks have not been fully investigated, which precludes conclusions on risk/benefit statements. The choice of the word "preclude" in this statement is interesting. By definition it means: "To make impossible by necessary consequence" (Webster's New Collegiate Dictionary). The Panel obviously violated their position by arriving at a conclusion that, in their own words, was unjustified.

If that isn't bad enough, the Panel provided further evidence of their misrepresentation. In presenting the future directions for research on materials for tooth restorations (page 18), the Panel made five recommendations:

1. "Carry out long-term epidemiological and multidisciplinary studies to determine whether there is a link between restorative materials and the incidence of local and/or systemic effects, and establish benefit/risk ratios of these materials."
2. "Determine the long-term effects of dental restorative materials on the developing organism."
3. "Develop new methods and materials for restoring teeth such as utilizing bonding agents with improved composites, amalgams, and new biocompatible materials that minimize removal of healthy tooth structure, release cariostatic agents, and reduce the risk of side effects."
4. "Determine the composition, degradation, release pattern, and pharmacokinetics of all restorative materials and their components under a variety of conditions. The effects of such materials and their components on cells, tissues, and organs should be established."
5. "Investigate the cellular and molecular mechanisms by which mercury at different concentrations damages different types of cells (e.g. CNS, kidney, oral epithelium, etc.)."

It is clearly obvious that these recommendations contradict a conclusion that the amounts of mercury vapor released from dental amalgam fillings "do not cause verifiable adverse effects on human beings", which is a concise statement indicating confirmation based on scientific evidence.

EXPERT TESTIMONY

The fourteen members (3 physicians, 3 Ph.D.'s, 2 with other degrees, and 6 dentists, including the chairman) of the National Institutes of Health Technology Assessment Panel on the Effects and Side Effects of Dental Restorative Materials heard expert testimony from twenty-two speakers. Of these, five speakers addressed side effects specifically related to dental amalgam.

One of these five addressed only oral mucosa and skin reactions related to dental amalgam, particularly from an allergic perspective. Another addressed only the potential teratogenic effect on unborn babies. A third speaker addressed only the mercury vapor release from dental amalgam.

Only two speakers addressed the potential toxic effects of mercury exposure from dental amalgam. One of these, Dr. John W. Reinhardt, presented the documented human autopsy studies demonstrating a correlation between the amount of amalgam fillings present and levels of mercury in human brain and kidney tissues. He also presented documented studies connecting mercury exposure to Alzheimer's Disease and Parkinson's Disease.

Dr. Michael F. Ziff presented nine studies demonstrating the pathologic effect of dental amalgam on periodontal structures, including the transfer of amalgam mercury into these tissues, as well as confirmation that such damage is a classic feature of mercury exposure. He also presented three studies connecting dental amalgam mercury to the occurrence of Oral Lichen Planus, including the transfer of amalgam mercury into these lesions, as well as three studies demonstrating the relation between the presence of amalgam fillings and an increased occurrence of allergic responses to mercury.