



DENTAL TRUTH



A publication of **DAMS, Intl.**
Dental Amalgam Mercury Syndrome .

© 2006 Summer 2006

The Children Amalgam Trials

Luring 8 year-olds into mercury

In 1998, 1000 children were recruited into two similar dental amalgam mercury experiments. In these bold experiments, about half of the children were given dental amalgam fillings in order to determine whether such exposures are harmful. To this day, the lead experimenters insist that their mercury experiments were ethically sound and did not violate international ethical standards. Their defense of experimentation on human children would tend to be vindicated by their claimed results. The studies' data and published conclusions claim that there are no adverse health effects to children from amalgam fillings, which are half mercury. There was a professional and personal pressure, no doubt, on the researchers to reach such a conclusion of safety; any other conclusion would have invited lawsuits by the children or their families and a shower of criticism for the researchers having experimented on unsuspecting vulnerable children. DAMS' look at the details of these studies reveal just how these researchers may have cut corners, in their eagerness to reach their conclusion of amalgam safety; we have also learned just how unsuspecting and vulnerable the children were.

DAMS has found is that the analysis of data from the children studied is far from complete, even today. Researchers involved in the studies have revealed to DAMS that important data involving the toxicology of the mercury exposures and effects of the mercury on immune function have not yet even been analyzed.

continued on page 4

The Children Amalgam Trials

continued from page 1

• **The Media Message** On April 19, 2006 the mass media reported widely that two large scientific studies had shown that dental amalgam fillings are safe for children. "Children aren't harmed by fillings that have mercury, 2 new studies say," headlined the Chicago Tribune. "Silver Fillings Found Kid-Safe," blared the Baltimore Sun, despite its mention, in the fine print, of a dissenting editorial by Dr. Herbert L. Needleman. Needleman's dissent appeared in the same issue of the *Journal of American Medical Association (JAMA)* that published the two headlined studies. The *ADA News*, always pro-amalgam, further exaggerated the findings to imply that amalgams had been proven safe for *everyone*: "*JAMA* studies support safety of dental amalgam," *ADA News* proclaimed.

Did the authors of the JAMA reports have a factual basis for concluding that amalgams had been found safe for children? They knew, or should have known, that a near-consensus exists among leading mercury scientists that amalgams are hazardous to health and should be banned!

• **A Biased Funder, the National Institute of Dental and Craniofacial Research (NIDCR)**

NIDCR, the source of the \$11 million in grants that funded the two studies, is *an agency that has been noted for its pro-amalgam bias*. It has collaborated, hand-in-glove, with the ADA Health Foundation and the ADA itself. The dental research arm of the

National Institutes of Health, it is headed by Lawrence Tabak, DDS, PhD. His top assistant is **Norman Braveman, PhD**. It was Braveman who set up and was "Project Coordinator" for the Children Amalgam Trials.

• **Braveman and the LSRO flap**

Norman Braveman set up an earlier project that has been regarded by critics as a whitewash of amalgam's hazards. In 2004, Braveman sought a contractor to provide to NIDCR an assessment of the existing literature regarding amalgam's safety. According to his critics, Braveman set up a secret committee to find the contractor in a no-bid fashion, a contractor who would be willing to declare that amalgams are safe, ignoring all studies to the contrary. A small and secretive committee consisting of Braveman, FDA's Susan Runner, DDS, and a few others, picked out Life Sciences Research Office (LSRO) as the contractor. LSRO had already shown its use to the tobacco industry by producing a study down playing the hazards of cigarettes. To avoid the need to seek bids for the research contract, Braveman apparently awarded the contract to a middleman, Beutah, with whom it had existing contracts.

Ironically, LSRO's panel itself lacked the expertise to evaluate the mercury amalgam literature, so it needed to subcontract with a scientist with that expertise. It chose Thomas Clarkson, a pro-amalgam mercury scientist. For decades Clarkson had been a reputable mercury researcher but, late in his career, he morphed into a defender of amalgams,



authoring studies of dubious merit and becoming a paid consultant to Kerr, the world's largest manufacturer of amalgams. Needless to say, the NICDR's LSRO report found no reason to be concerned about amalgam's safety.

As to questions about his involvement as Project Coordinator for the Children Amalgam Trials, Norm Braveman was unreachable. "Norm Braveman does not generally talk to reporters," DAMS was told.

The Children Amalgam Trial in Lisbon, Portugal

• **Biased Investigators**

Norman Braveman picked Timothy A. DeRouen, PhD, School of Dentistry, University of Washington, to lead the Portuguese study. His colleague, Michael Martin, DMD, PhD, was also on the team. Their pro-amalgam bias was on display in a 2002 public forum in Seattle where they sat on a pro-amalgam speaker panel. They were staunch in their defense of their firm conclusion that amalgams would be found to be safe for their experimental subjects - Portuguese children - even though their study was only half-way completed at the time. Other signs of bias on DeRouen's team show up in the disclosure section (fine print) of DeRouen's report

- DAMS, International. Newsletter

in JAMA. There, it was disclosed that two of the investigators from Lisbon, Leitao and Bernardo, had received funds from amalgam manufacturers.

- **Children in The Portuguese Study.**

507 disadvantaged, at-risk children in the Casa Pia school system in Lisbon, Portugal were recruited. They had never before received a dental filling. Aged 8 to 10, many were blind, deaf, or had other disabilities; a hundred of them were orphans. There was a mean IQ of 85. They asked to sign a consent form disclosing that he/she will get dental fillings that are needed. Some children would get “shiny ones” and others will get “white ones” and “right now, we don’t know which ones you will get. It will be a surprise.” *The child is not even told that the “shiny ones,” amalgams, are toxic or even that they contain*

mercury. The consent form’s only mention of mercury was oblique: a description of the study said “...we want to know if there is mercury or lead in your body in normal quantities.” In addition to the dental visits, the child would have “special visits” when he/she will be tested mentally, give urine samples – and receive a present.

Half of the recruits were randomly chosen to receive Dispersalloy, a mercury amalgam filling made by Dentsply for rear cavities; for the other children a composite filling, Z-100, made by 3M was used.

- **Unfinished Work, Odd Results**

The investigators measured memory, attention/concentration, motor visuomotor performance, nerve conduction velocities, mercury in urine, glutathione transferases and porphyrins in urine. They found “no statistically significant difference in

behavioral assessments or in nerve conduction velocities between the amalgam group and the composite group.” Urine mercury measures showed that the amalgam group had significantly higher levels of mercury in the urine, but urine mercury excretion dropped off markedly after the second year. The urine porphyrin results, regarded by mercury experts as giving the most accurate indication of mercury toxicity problems, were absent from the April report.

Oddly, starting five years after treatment, the children in the composite group had more caries and needed 50% more treatment than the amalgam group. DeRouen concluded that this showed that composites fail sooner than amalgams, adding to his argument for continuing the use of amalgams. But another explanation for greater decay

Children Amalgam Trials (continued from page 5)

with the composites suggests itself: perhaps the composites placed in Casa Pia children were not prepared or cured properly, causing them to fail sooner.

In spite of all the limitations and questions, DeRouen's conclusion in *JAMA* was that "Amalgam should remain a viable dental restorative option for children."

Ongoing Issues For the Portuguese Study

• **DeRouen's own April 19th JAMA report included a possible indicator of mercury toxicity in the amalgam group of children: their urine mercury levels, dropping off after year two, suggest a lessened ability to detoxify mercury.**

The meaning of urine mercury levels was pointed out by Professor Haley. *Urine mercury is a poor indicator of body burden, since at higher levels of mercury accumulation, people lose their ability to get rid of mercury through their kidneys. In fact, urine mercury is more an indicator of the person's ability to excrete mercury.* Figure 2 in DeRouen's report suggests that *the amalgam group is losing its ability to excrete mercury in the urine after the second year of the experiment.* This suggests that many, perhaps most, of the children are developing a "mercury retention" problem. "Were these children also becoming less able to excrete mercury through the liver/ bile flow route and into the feces?" Haley asks. The liver's bile flow



is by far the major route of heavy metal elimination from the body, but fecal mercury tests were not taken.

• **James S. Woods, PhD, one of DeRouen's co-authors, reveals that the Toxicology part of the study is far from complete.**

Woods told DAMS that his role in the Portuguese study is the toxicology assessment. The urine mercury and urine porphyrin data, he said, was finally completely gathered only as of July 31 2006, and is just beginning to be analyzed in August, 2006. Woods said that analysis of the urine

porphyrin data is key to understanding toxicity issues in the children and he expected that it will be sometime in 2007 before a toxicity report would finally be completed. DAMS asked "Weren't the announcements of amalgams as being safe for children

therefore premature?" He did not directly answer, but he observed that the results in the April 19th *JAMA* articles did not actually make any claim as to toxicity results.

But in his *JAMA* report, chief author Tim DeRouen portrayed porphyrin readings as merely giving a measure of kidney function. He failed to acknowledge the important role of porphyrin testing and evaluation in evaluating mercury toxicity.

• **Major Medical Data Not Accessible to the Study.**

Two of the children in DeRouen's amalgam group died during the course of the study. Responding to DAMS' questions,

DeRouen indicated that he did not even know if there had been autopsies performed. Even if autopsies had been performed, he said, he would not have had access to the autopsy findings.

• **Child Abuse Scandal at Casa Pia School.** In November of 2002, news media revealed a child abuse scandal at the Casa Pia school system that had gone on for several decades and had involved large numbers of the students. Many of the children at Casa Pia had been sexually abused by school employees who also provided sexual access to the children for politicians, media personalities, academics, and others. In December 2003, international media disclosed criminal indictments of ten high profile people for the sexual abuse of an estimated 100 Casa Pia children.

The Children Amalgam Trial in America

The chief author was David Bellinger, PhD, Dept. of Neurology, Children's Hospital, Boston, and Harvard Medical School and Dept. of Environmental Health, Harvard School of Public Health. His team recruited 534 children found at community health dental clinics in Boston, Massachusetts and Farmington, Maine. Using gifts and cash incentives, children aged six to ten at baseline were recruited. Recruits were required to have had no prior amalgam fillings and needed to have two or more caries filled. Half were randomly picked to receive Dispersalloy mercury amalgams and the others received Z-100 composites.

• **The Consent Form**

The consent form implied that the amalgam fillings contain some mercury, but *did not disclose that amalgams are half mercury*. The form mentions that “mercury in large amounts can cause health problems” such as tremors, memory loss, insomnia, fatigue, headaches, irritability,...” But the form wrongly adds there “is no evidence that any of these health effects happen with the small amounts of mercury from dental fillings.”

The consent form required parents to *waive claims for damages due to injury* to their children from the study, other than for immediate emergency care.

• **Methods, Findings.**

The investigators measured the following every year: IQ scores, memory, visuomotor ability, mercury in urine, and albumin in urine. They found no statistically significant difference in IQ test, memory index, visuomotor scores or urinary albumin. It down played their finding that urine mercury was significantly higher in the amalgam group. Its over-reaching conclusion was “health effects of amalgams in children need not be the basis of treatment decisions when choosing dental materials.”

• **Failure to Properly Assess the Mercury Toxicology Issue.** Urine mercury and hair mercury levels do not reliably correlate with body burden of mercury. The American study had no valid measure of mercury body burden. Porphyrin testing would have been helpful, but the American study did not include urine porphyrin testing.

• **Immune Function Analysis Still Far From Complete.**

Bruce Shenker, PhD, had been slated to investigate immune function, but tests of immune function were not even mentioned in the April 19th report by Bellinger; and Shenker was not even listed then as an investigator on the American team. Yet Shenker’s analysis of immune function would likely yield significant results. Indeed, based on Shenker’s own earlier research, there is reason to suspect that adverse effects for immune function would show up, in blood tests, for the amalgam group. In 2002, for example, a Shenker study concluded “there is growing evidence that heavy metals in general and mercurial compounds in particular, *are toxic to the human immune system.*”

DAMS asked Shenker if he were still working on the children’s study. “Yes,” he told DAMS, he intends to analyze immune function data from the study. “That code (for immune function data) is being broken by the statisticians and it is then being analyzed.” We asked Shenker, if his findings on the immune function of the children will be published. “I don’t know, but I assume so,” he replied.

• **Thomas Clarkson’s Role Suppressed?**

Thomas Clarkson, PhD, was undoubtedly the most experienced of the American team of investigators. His credentials on mercury research far exceed those of lead author, Bellinger. Undeniably, Clarkson has been involved: he was listed as a co-author in a report done some years ago, describing the design of the American study. But, *Clarkson was dropped from the list of*

authors of the April 19th JAMA report. Did Clarkson design and guide this study along for years and *then disappear as a listed author?* Was Clarkson dropped as an author to *avoid the need to disclose, in the JAMA report, that he has been a paid consultant to Kerr, the world’s largest amalgam manufacturer?*

• **Apparent Failure to Assess the Health Status of the Children and Failure to Stop the Study to Protect Sickened Children.**

There appeared to be no in depth medical assessments for adverse events beyond superficial testing - urinary mercury and urinary albumin. Rather, Bellinger relied on adverse reports by the primary caregiver; there *were numerous disorders* reported, including sensory disorders (36 in the amalgam group), psychological disorders (24 in the amalgam group), asthma (19 cases in the amalgam group), and neurological disorders (4 in the amalgam group). Why were none of these sick children pulled, even as a precautionary step? Mercury exposure is linked to such disorders and the fact that many children were reported as having these disorders suggests a lack of child protection measures.

Weaknesses in Both Studies.

• **Reliance on Averages:** By focusing on statistical averages, DeRouen and Bellinger may have obscured or missed the *damage that individual children* were having.

• **No Mercury Free Control Group** The mercury history of the control group and the amalgam groups was poorly investigated. Many of the American children, for example, would surely

Children's Amalgam Trials (from from page 7)

have been exposed to mercury through the mother – dental amalgams, flu shots, rho-gam shots, etc. – and the children themselves would be exposed to *substantial amounts of thimerosal, the toxic mercury compound*, if fully vaccinated. *But by excluding from the study all the children who have already been mercury injured* due to the unwise childhood vaccination mania of the 1990s, the selected experimental group became *non-representative of the larger population*

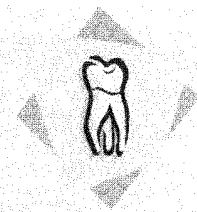
• **Many Types of Possible Mercury Damage Were Not Tested For.** Consider the past work of Lars Barregard, PhD, a Swedish researcher listed on the American study. In 1995, Barregard authored a kidney biopsy study that showed that the subjects with dental amalgams had *three times higher levels of mercury in the kidneys* than did controls! In 1995, Barregard published noteworthy findings that some people with amalgams... “have daily uptake of mercury as high as 100 micrograms.” In 1994, Barregard published an occupational study which showed that mercury is able to interfere with the conversion of the thyroid

hormone, T4, to T3, the more active form of the hormone. These prior Barregard findings point to two conclusions: (1) These experiments - placing amalgam in these young children - unnecessarily put them in harm's way and (2) The conclusions announced on April 19th were at misleading, having glossed over mercury health concerns that had not been addressed. The authors *failed to acknowledge what they well knew*: the recognized toxicity, immune and hormonal issues had not yet been addressed.

• **Many Major Problems Are Seen Mostly with Adult Onset.** Rheumatoid arthritis, lupus, MS, depression, ALS, Parkinson's, Alzheimer's, cardiovascular disease and other chronic illness linked to mercury show up primarily as *adult-onset diseases*. Other recognized dangers linked to mercury include infertility and birth defects. Obviously, these important and well known risks cannot be assessed in the time frame of the Children Amalgam Trials.

• **Unsafe Amalgam Removal Looms Ahead as a Threat.** Because of the false assurances that the amalgams are “kid-safe,” these children are *not* apt to seek out *safe* amalgam removal when the amalgams are to be replaced. Amalgams simply do not last forever and unsafe amalgam removal likely awaits these vulnerable children. Ideally, the children in the amalgam group children should be fully informed of this looming trouble and should be offered safe amalgam removal at government expense.

• **In summary:** The limited data published with these studies do not support the conclusion that amalgam poses no significant health effects for children. Further, vulnerable children were put at risk due to these studies and the children were recruited using methods that were deceptive.



Daniel Vinograd, D.D.S., N.M.D.
Mercury free dentist, U.S.D. 1978, Member of
Intl Academy of Oral Medicine and Toxicology

1260 15th St, Suite 805
Santa Monica, CA 90404

(310)-804-0252