

This file incorporates the covering letter to  
Professor Stephen Leeder, chair of NHAC,  
as well as the formal ASOMAT response to the  
NHMRC Amalgam Review Report  
from March 1999

31st May 1999

Professor Stephen Leeder,  
Chair, Health Advisory Committee,  
NHMRC,  
GPO Box 9848,  
Canberra ACT 2601

Dear Dr. Leeder:

I want to extend our support and appreciation to the NHMRC for finally focussing government attention on the lack of adequate data and information with which the Australian Dental Association, and the government, have continued to support the unlimited and uncontrolled use of dental amalgam. Contrary to claims that the Working Party report on amalgam exonerates dental amalgam and demonstrates its continued safety, the WP report concludes that health risk information is sorely needed on all dental materials, that restorative materials other than dental amalgam are required, and that there is inadequate risk-related information to defend the continued use of amalgam. The NHMRC's decision to accept the recommendation of the Working Party to undertake a risk assessment on dental amalgam is an effort particularly lauded by ASOMAT and its members. We only hope that the efforts of NHMRC in this regard parallel or exceed those of Canada and Sweden which have both taken an objective and scientifically defensible, albeit politically difficult, review of and position on this issue.

ASOMAT has a series of detailed comments on the content and tone of the Working Party report on amalgam. The report's pro-amalgam rhetoric is blatant, preventing any knowledgeable reader from considering the report as a serious, authoritative review, thereby reducing the report's value in the ongoing debate. However, we are pleased that this biased perspective has not pervaded your office, nor influenced your professional opinion that further risk-related information is required.

We have appended to this letter our detailed comments. We would be pleased to meet with your officials to discuss them further, but would ask that you read them personally before passing them on. We are particularly concerned with the Working Party's citation of older studies which purport to demonstrate the safety of amalgam, when those same older studies have been dismissed in the published literature as useless in the assessment of health risks presented by mercury vapour exposure. For example, the study by Smith et al. (1970) was emphasized by the Working Party (pg 42 of their report) as demonstrating a lack of effects of mercury exposure. However, this study is extremely dated, and Ratcliffe et al., (*Ratcliffe et al., 1996; Human exposure to mercury: a critical assessment of the evidence of adverse health effects, Journal of Toxicology and Environmental Health, vol 49, pp. 221-270*) in a review of all studies on mercury vapour exposure, published to 1995, concluded that the Smith et al. study was too deficient in design and statistical analysis to provide a suitable basis upon which to reach any valid conclusions as to the health impacts (or lack thereof) of mercury exposure.

We were also somewhat dumb-founded by the fact that the Working Party chose to totally ignore, nor even mention, the Toxicological Profile for Mercury prepared by the U.S. Public Health Service through its Agency for Toxic Substances and Disease Registry. This is perhaps the most thorough review available on the health hazards presented by mercury vapour exposure and any authoritative review of the dental amalgam and mercury issue can not ignore it.

Likewise, the recent research conducted by and for the government of Sweden was not considered, despite the ready availability of numerous papers prepared expressly for the Swedish initiative. The Working Party also all but ignored the very recent (post 1995) ground-breaking research conducted by Echeverria and co-workers on the sub-clinical impacts of mercury vapour exposure on cognitive function. These omissions challenge our confidence in the Working Party's efforts to be thorough and objective.

A number of issues arise as a consequence of the WP's report and ASOMAT requests the following from NHMRC.....

- a response to each point raised in our attached comments.
- that the original report, and the ASOMAT response, be reviewed by three independent, appropriately qualified, reviewers. ASOMAT believes this should include at least one risk assessment specialist, preferably someone with some familiarity with this area. This group would obviously exclude anyone who had made a submission to the WP or who had publicly aligned themselves with one side or the other. This would, for example, exclude Professor Michael Moore.
- that NHMRC advise the ADA of errors in their persistent and wilful misrepresentation of the WP's report. A precedent exists for this in the action of Health Canada which issued a correction of Canadian Dental Association comments in CDA publications.. ASOMAT, of course, would be more than happy to comply with similar scrutiny.
- that NHMRC write to all affected professional groups i.e. dentists, medical doctors, School Dental Services, Mother and Baby clinics and Renal Units to inform them of the WP's recommendations to not use amalgam for pregnant women, children and patients with kidney disease. This follows the example set in the UK by their Health Department.
- that NHMRC include patients with neurological problems in the at-risk group for whom materials other than amalgam are recommended..
- that NHMRC set up a reporting facility, similar to the drug reaction service, so that case reports of amalgam related problems can be collected and analysed as recommended by the 1992 US PHS report.
- that NHMRC consult with ASOMAT during the preparation of the proposed brochures which the WP recommended be prepared for dentists and patients.
- that NHMRC consider environmental monitoring of mercury waste from dental surgeries.
- that NHMRC consider a monitoring program for dentist and dental staff to assess health problems which could be related to mercury exposure. This should include facilities in each state to allow for a program of mercury vapour measurements in dental surgeries.
- that NHMRC advise the TGA of its findings and ask that appropriate warning information and labelling be included in all amalgam products

ASOMAT thanks you for your efforts to date and looks forward to the opportunity of presenting the findings of scientific research to the team nominated to undertake the coming risk assessment, a task which will no doubt be difficult, professionally taxing and politically challenging.

Yours sincerely,

Dr. Roman Lohyn  
President ASOMAT

# **Australasian Society of Oral Medicine and Toxicology**

**Response to the**  
**“Dental Amalgam And Mercury In Dentistry”**  
**Report of an NHMRC Working Party**  
**(February 1999)**

**Date: May 1999**

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*On behalf of ASOMAT*

**The point by point comments are made using the Working Party numbering format.**

***Page6 Para 1***

The working party state in the beginning of the summary that "At high doses mercury is recognized as a neurotoxin". High doses is not defined but is phrased in such a way that it gives the impression that mercury from dental amalgams is not a problem. This is an inappropriate slant as the extreme neurotoxicity of mercury has been demonstrated by several studies showing effects at low levels. (*Echeverria 1998, Echeverria 1995, Gonzalez-Ramirez 1995, Ngim 1992*)

The above studies are included in the references of the WP report but there is no discussion of their results nor any indication whether the WP accepts their validity or not. Some discussion of this should have been undertaken and the results of the research either accepted or rejected with an explanation. To not raise the issue in the body of the report is misleading and unacceptable.

Another study, The Faroe Islands study (*Grandjean, P. 1997*) is an example where effects were measured at levels previously thought to be safe, It is acknowledged that the Faroe Islands study looked a methyl mercury not mercury vapour but it is relevant because methyl mercury and mercury vapour are the two forms of mercury that readily penetrate cell membranes and accumulate in tissues of unborn babies. Methyl mercury is derived primarily from consumption of fish and seafood, whereas the primary contributor of mercury vapour to human body burdens comes from dental fillings. The mechanism of absorption into the brain is the same for both methyl and elemental (vapour) mercury. It is quite likely that mercury vapour will accumulate as easily in the brain.. This study is included as an example where effects were measured at levels previously thought to be safe but turned out not to be. Just as it was incorrect to assume certain levels of methyl; mercury were safe we cannot assume that certain levels of exposure to mercury from amalgam are 'safe', particularly since it is acknowledged that studies have not been performed for the appropriate end points (neurotox) on the appropriate at-risk population (people with amalgam)..

This research adds to the concern about effects of low levels of mercury on children's development raised some time ago by Marlowe (*1986*) Their research found that low mercury levels correlated significantly and negatively with full scale, verbal, and performance IQ and six subset scores of the intelligence test. They concluded that a continuing re-examination of mercury exposure was needed because mercury levels previously thought harmless and routinely encountered in the environment may be associated with intellectual decrements. Their concern about the adverse effects of low levels of mercury on the development process was influenced by several points.

***Neither of the above two studies were even mentioned in the WP report yet both had relevance in the area of low level exposure to mercury and its neurotoxic effects. Why were these studies not mentioned?***

## 1.2 paragraph 3

The nature of bonded composite resins is such that the criteria of minimising treatment and preserving tooth substance, put forward by the WP, are better served by composites than by amalgams. Dr. Harold Loe, Director of the National Institute of Dental Research, stated in September 1993.....

*“..With the first filling you should do something that can restore the tooth or retain more healthy tooth substance. Use new materials - composites or materials you can bond to the surface without undercuts. You can do this with little removal of the tooth substance so that the core of the tooth is still there.”*

Repairs to existing composites are also generally easier and require less removal of tooth and filling.

## 1.5.4

ASOMAT agrees that the usage of amalgam has declined but this does not preclude the danger of mercury for those who are still receiving it as a filling. The WP report acknowledges that people will still have large numbers of amalgams, will continue to do so for many years, and may well have even higher numbers as increased tooth retention increases in older people. It is likely that this group will be the main cohort experiencing health difficulties as a result of increased exposure and increased duration of exposure.

*This possibility does not appear to have been discussed.*

## 1.6.1

It is claimed that dental amalgam is still a desirable direct restorative material in certain clinical situations. Given that there are studies demonstrating that the combination of tooth and bonded composite resin makes a tooth stronger than the combination of tooth and amalgam, the WP's claim would be vigorously disputed by those dentists who no longer use amalgam. The current generation of alternatives are excellent materials with the major limitation, undoubtedly, being the technical skill of the dentist. This limitation is acknowledged by most dentists but this makes it an indication for better teaching in our dental schools, or the selection of more talented students, or both.

Cost / benefit cannot be discussed in the sole context of dental costs. If it is to be discussed it must take into account the medical costs incurred in trying to correct the effects of low level mercury exposure, a cost which can be substantial and exceeds by many orders of magnitude the additional cost of alternative materials, even if they would need to be replaced more frequently than amalgam.

*The WP needs to specifically identify those clinical situations where it believes amalgams are indicated in preference to any other material.*

### 3.8.1

The point of this section eludes us. ASOMAT stated what had been determined by research i.e. that no NOEL had been established, and then stated what that meant. The WP accepted the very same statement, seven pages later (pg 40) noting that US EPA, Richardson & Allan and ATSDR had all failed to establish a NOEL or LOAEL for mercury. ASOMAT is concerned at the way that the WP phrased their comment and the fact that the WP failed to mention that the above researchers had also come to the same conclusion. The WP statement implied that it was ASOMAT which had determined this, not the WHO from which this information was derived, and implied that ASOMAT was the only group which was saying this, and that ASOMAT had misunderstood the concept of NOEL. This was certainly implied by the opening sentence which immediately preceded 3.8.1 (3.8) This passage has since been used by the Australian Dental Association to attack ASOMAT and has been cited as evidence that NHMRC had criticised ASOMAT for its poor understanding of the issue.

ASOMAT's comments about NOEL were accurate and confirmed by the WP's own report (page 40). ASOMAT requests a clarification of this and an explanation for the manner in which this passage was written, particularly why it was not noted that the US EPA, Richardson & Allan, and the ATSDR all said the same thing.

***A reassurance by NHMRC that, on the basis of its comment about NOEL ( as referred to in 3.8.1) any criticism of ASOMAT, is unwarranted, would be welcomed.***

Of course it is true that failure to establish a clear NOEL does not mean that any level of exposure can cause harm. It is nevertheless also true that such failure means less assurance of safety at low levels. Neither does a failure to establish a NOEL preclude the estimation of a reasonable TDI. The WP's observation that virtually every activity has a finite risk and that the real issue is what level of risk is acceptable is self evident and does not advance our understanding of this issue. The whole point of this review was to try and make just such an assessment.

### 3.8.2

The issue is not whether a single molecule can kill a cell but whether enough cell deaths occur to create a measurable effect. This is the issue with mercury vapor exposure from dental amalgams. How much is needed for effects to occur? Incidentally, if the WP has evidence about the amount of mercury need to kill just one cell, the appropriate reference from the scientific literature would be appreciated. In the absence of such evidence the appropriate response should have been.....“No-one knows”

### 3.8.3

The WP was presented with evidence of that there have been hundred's of anecdotal reports of health improvement following amalgam replacement. It is virtually certain that not all of these cases were related to mercury toxicity. It is also unlikely, as the WP members admitted during the interview process, that ALL of them were placebo effects. Given that the extent of this problem is not known, something acknowledged by groups such as ASOMAT, it would have been more helpful if the WP had at least acknowledged the possibility that some of the case reports were genuine examples of amalgam

related problems ( particularly since at least two of the submission from medical practitioners related their own personal health improvement after amalgam removal). It would have demonstrated some open minded interest in the issue if the WP had proposed some mechanism to sort out the genuine cases from those unrelated to mercury exposure. The WP might have suggested some form of voluntary reporting by dentists similar to the drug reaction reports currently solicited from dentists and medical practitioners. Instead the WP listed all the reasons why the cases might not have been related to amalgams. All of their reasons were valid but it is disturbing that the WP could not even acknowledge the possibility of health effects from amalgams. It was also unable to suggest even some rudimentary reporting system as a preliminary screening device in developing a data base of possible symptoms for dentists and medical practitioners to consider. This one-sided view raises doubts about the WP's commitment to an objective assessment of the issues.

### **3.8.4**

Given the fact that this issue is not acknowledged as legitimate by the dental profession, and is basically unknown by the medical profession, it is not surprising that there is some inconsistency in testing and mis-diagnosing of the problem. This should not be used to attack those who believe this is a problem but should be recognised as an unavoidable problem until main-stream support or understanding of the issue develops, with the accompanying research which is needed to establish the full extent of the problem as well as the necessary measures needed to identify those affected and how best to help them.

### **3.8.5**

The WP says it is disturbed about the use of chelation as a treatment, but does not give details of its concern. It is our understanding that chelation is used commonly in other areas of medical treatment with no ill effects.

#### ***What are the WP's specific concerns about chelation?***

The WP's concern about DMSA may be justified but they have not included studies which demonstrate the value of this procedure. One example is a recent study (*Hibberd at al 1998*) which demonstrated increased urinary excretion of mercury when DMSA was used.

***ASOMAT supports the further critical assessment of relevant research in the use of DMSA. ASOMAT also suggests consultations with medical practitioners using DMSA so that consistent, reliable and safe procedures can be established.***

### **3.9.1**

The WP comments that this problem is seen by only a limited number of practitioners. The WP could have examined one of the reasons why this is so. The main reason for the "limited number of dentists" has been the extremely hostile atmosphere accompanying this issue within the dental profession. Dr.



Butler's (Executive director Australian Dental Association) submission to the WP (summarised on page 73 of the report) makes clear that dentists who oppose the use of amalgams are considered as promoting "bizarre theories", being guilty of "poor science" and "misquoting scientific literature". In a recent press release the ADA warned the public that anti-amalgam dentists were after patients wallets rather than their best interests. It is understandable that in such circumstances, many dentists feel it is better to keep a low profile on this issue. By failing to acknowledge that dentists have not been actively encouraged to report possible case of amalgam problems, indeed have been intimidated by the ADA as well as by some Dental Boards NOT to take an interest in this subject, the WP misrepresents the issue.

***The WP was not expected to take sides in the debate but if it raises the point of "limited numbers" it has an ethical responsibility to consider WHY the numbers were limited.***

**3.9.2** see 3.8.4

**3.9.3**

This statement is accurate but it should have included the comment that the WP could not exclude the possibility that at least some of the anecdotal cases could be amalgam related.

**4.1**

This section of the report has elicited the greatest level of concern regarding the WP's thoroughness and objectivity. The issue of the amount of mercury absorbed from dental amalgams has been debated for some time and it is therefore very disturbing that the WP has not even once mentioned the fact that autopsy studies have confirmed the accuracy of the Lorscheider and Vimy model (*Lorscheider & Vimy 1986, Lorscheider & Vimy 1990*) for determining tissue mercury accumulation from dental amalgams.

The calculations of Lorscheider and Vimy had been criticised by several dentists (Olsson & Bergmann as well as Mackert). Lorscheider and Vimy responded to criticisms of their vapour level estimates (*Letters to the editor, J.Dent Res July 1987 pg 1289*) In it they showed that their model, a 4 compartment model allowing for inorganic and elemental Hg distribution, which predicted brain Hg levels based on their mercury vapour level predictions, was vindicated by human autopsy studies which showed brain Hg concentrations in close agreement with their predictions. They made the point that if their mercury vapour levels calculations were so far out then there was no way that the human autopsy studies would have come so close to their predicted levels. This would appear to be a reasonable defence of their work. They later (*Lorscheider & Vimy 1990*) also showed close correlation with blood Hg studies. The autopsy studies (*Friberg et al 1986, Abraham et al 1984, Eggleston 1987, Nylander et al 1987*) confirmed Lorscheider & Vimy's revised calculations of 9.98 ug for 1-16 amalgams, 14.68 ug for  $\geq 12$  amalgams and 4.01 ug for  $\leq 4$  amalgams. It seems appropriate for the WP to explain why they did not consider this research, and, given that Lorscheider and Vimy's calculations were validated by marching tissue levels, exactly why they would not accept their figures as an accurate figure of mercury absorption from dental amalgams. Given that the WP estimates of 2-5 ug are purely unverified estimates opposed to Lorscheider and Vimy's validated tissue levels, it is inappropriate in ASOMAT's view to use the WP figures in preference to Lorscheider and Vimy's.

The WP's own citation of Halbach 1994 (para 3) who concluded a daily exposure of about 10ug/day, seems to confirm the Lorscheider & Vimy research. It seems unreasonable that the WP would also characterise the above as being within the range of estimates of 1-2 ug/day (Eley 1997c) Is it really the WP's contention that an error of magnitude of 5-10 times is "in the range". What would the WP consider totally "out of range", particularly in light of the fact that autopsy studies have confirmed the Lorscheider & Vimy figures. Surely it would be appropriate to conclude that Eley was wrong.

***Why are not even one of the autopsy and blood studies which support the Lorscheider and Vimy' model mentioned at all.***

Another matter of concern is the almost complete silence about the WHO 1991 study which reviewed the literature of the day regarding mercury exposure from ALL sources and concluded that mercury from dental amalgams could constitute up to 87% of daily exposure from all sources to all forms of mercury and at the very least represented almost 54% of daily exposure. This WHO review is barely mentioned in discussion, yet it was accepted by Health Canada as a valid assessment of exposure. The WHO report found that mercury from dental amalgam ranged from 3.0-17.0g/day for mercury vapour, 2.3 ug/day from seafood (methyl mercury). 0.3 ug/day from other food (inorganic mercury).

The WP was not unaware of this report. They criticised ASOMAT for its presentation of NOEL (3.8.1) and said that ASOMAT had cited a WHO report. It was the very same WHO 1991 report which the WP has ignored, which ASOMAT cited.

***Why was this so little credence given to the WHO report on the contributions of dental amalgam to total body burden?***

4.2 See 4.1 above, in addition to below.

#### **4.2 paragraph 1, sentence 3**

The WP figure of 2-5 ug/day is a purely arbitrary one, unsupported by any evidence, in contrast to the Lorscheider & Vimy figures which have been validated by several autopsy and blood Hg studies (not one of which has been mentioned in the WP report as previously noted).

Given that the WP figures are at least 50% understated, ASOMAT does not accept these figures as reasonable estimates of exposure particularly when figures, validated by autopsy studies already exist. It follows then that the subsequent calculations that the WP made using their invalid assumption have no basis in fact and should not be used for policy making.

It is also of concern that the WP focusses on averages in its attempt to paint a benign picture. It would have been more appropriate for the WP to consider the extremes of dental experiences and try to make some judgement about potential risk. Clearly not every person has the average number of fillings. It is the ones who large numbers of fillings, for long times, who are most at risk. The WP should have considered this aspect rather than ignoring it.

***ASOMAT believes that the validated Lorscheider & Vimy figures of approx 10ug/day, should have been used rather than the arbitrary and unsupported guesstimate of 2-5 ug/day, of the WP.***

#### 4.2, paragraph 1, sentence 5

Richardson's risk assessment is described as "simplistic" on the basis that it did not consider number and location of filling surfaces. I quote from the table of Contents in the Richardson Report, page iv, and draw your attention to headings 5.2.7 and 5.2.8

#### 5.2 Exposure Assessment I - after Olsson and Bergman (1992)

5.2.1 Selection of input variables	14
5.2.2 Release rate per filling	14
5.2.3 Stimulation magnification factor	19
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5.2.12 Oral breathing habits	27
5.2.13 Body weight	32
5.2.14 Factors not considered	32
5.2.15 Sensitivity analysis	32
5.2.16 Results	32

Also in this paragraph, estimates of the number of fillings in different age groups are presented. However, it is not clear if the statistics relate to the entire population (i.e., a survey that included people with no filled teeth), or just those with fillings. If it is for the entire population, then the average is 'diluted' by including zero for those with no fillings. The statistics presented in the Richardson Report were very specifically and explicitly for those with at least 1 filled tooth (i.e., those with no fillings were excluded, a reasonable step since they are not part of the identified 'risk' group).

#### 4.2 paragraph 2

The potential dose from amalgam is given very approximately (2 - 5 ug/day). (ASOMAT rejects this view as already pointed out above but will use it for illustrative purposes) Then the dose for food is given very precisely (5.8 ug/day). Finally, in the conclusion, 4.7.2, it is concluded that food constitutes 2 times the dose from amalgam.

This is a complete misrepresentation of the WP's own data. Given their incompatible levels of precision, the best that the WP could conclude is that exposure to total mercury from food and amalgam is about equal.

***Why does the WP misrepresent its own data?***

Also missing from this section is a discussion of the forms or species of mercury involved. Food contains a mixture of inorganic and methyl mercury, the latter from fish consumption. Dental amalgam exposes dental patients to mercury vapour and some inorganic mercury. If one compares mercury vapour exposure from amalgam to that from environmental sources (indoor and outdoor air), amalgam constitutes somewhere between 75% and 95% of exposure to vapour. Why was this not pointed out?

### 4.3

The WP's attitude here is very disappointing. They acknowledge that Richardson & Allan's work was comprehensive but appear to give credence to criticism of the work without evaluating the quality of the criticism. ASOMAT reminds the WP that NHMRC has already done an assessment of the Richardson report. Richardson's paper was reviewed by Dr. Maynard and by Departmental toxicologists in 1996 (HAMS Meeting, Melbourne 1996). They said... "It was found to be a sound paper and would seem to have important implications for the practice of dentistry".

It is disappointing that the WP fails to mention that the ONLY criticism is coming from the dental profession, specifically the so-called Jones report which was the result of a group convened by the Canadian Dental Association and charged with criticizing the Richardson report. The Richardson report has NOT been criticised by Health Canada nor by any risk assessment professional, ONLY by the dental profession. It must be said that the Richardson report was reviewed by 16 separate experts in the area of risk assessment and toxicology, including the head of the ATSDR in the USA (Agency of Toxic Substances and Disease Research). It was then further reviewed by another 3 reviewers before being published.

The Jones group was made up of the following members. Berglund. A, Eley. B.M, Fan P.L. Jones. D.W. Larrison. K.S., McCurdy. R, and Siew. C

Between them they have published a total of 44 articles on amalgams, of which 18 were review papers. Of the 44 amalgam articles only 11 had anything to do with biocompatibility, 9 related to oral symptoms and 2 to systemic symptoms. These 11 were written by just one individual, Eley. There was not ONE article from ANY of the other participants. This raises a critical question. What possible confidence could anyone have in recommendations put forth by this "expert panel", concerning the medical safety of mercury-containing dental fillings? In fact, Health Canada rejected a request that the review of the above group accompany the release of the Richardson report. Nor has it been published anywhere else.

I quote from a report by Dr. Murray Vimy, titled "Mercury Usage in Canadian dentistry part 2, the CDA's International Expert panel on Amalgam" ( included in the ASOMAT submission to the WP)

#### ***Begin Quote:***

*The C.D.A. specifically, highlighted the participation of Drs. Berglund and Larsson in their Panel.*

*Dr. Berglund recently graduated as a dentist in 1989 and then received his Dr. Odont. in dental materials engineering (equivalent to a Ph.D.) in 1992. Berglund trained under Dr. Maud Bergman, a well known Swedish dental materials engineer with very strong pro-amalgam opinions. Berglund has published 9 amalgam related articles since 1988, one being his thesis (customary in Europe). These articles have focused on the release of mercury from dental amalgam, attempting to develop a*

*predictive mathematical model to explain the phenomenon. Berglund's model theoretically estimates that only an average of 1.7 µg mercury are absorbed/day in humans with amalgam. However, the model is faulty, since it does not account for real measurable human urinary and faecal mercury excretion data attributable solely to amalgams. Nor does it adequately account for mercury loss due to wear and corrosion. Indeed, others have suggested that the model is in error by as much as 800%! In that case, the daily dose from mercury fillings would approximate 13.6 µg/day. Dr. Berglund has published no work investigating the medical consequences of mercury exposure from amalgam. Presently, he is affiliated with the Dental School at the University of Umea in Sweden.*

*Dr. K. Sune Larsson graduated as a dentist in 1955 and received a Dr. Odont. in 1963. His early research focussed on the affects of various chemicals (eg. salicylic acid and phenoxy herbicides) on fetal development. However, analysis of the Medline® data base, indicates that since 1982, he has not published any significant experimental research in any field. Instead, he has limited his publications to review articles and Letters to the Editor. In 1984, he was involved as an expert in the Royal Commission on the Use and Effects of Chemical Agents on Australian Personnel in Vietnam, Sydney Australia, 11 April 1984. As a result of his participation, he was later accused by a group of his academic colleagues of giving false statements to the Commission and of suggesting he collaborated in particular research investigations, which they claim he did not. Except for one recent publication, Larsson has never publish any experimental research on mercury or dental amalgam.*

*Dr. B.M. Eley, a British dental academic who's area of expertise involves oral soft tissue reaction to implanted amalgam and also periodontal inflammation, is the only member of the "expert panel" that warrants recognition. Dr. Eley has published 11 articles on the effects of amalgam implanted into the soft tissue of animals. His findings are consistent with previous investigators who showed a chronic localized giant cell granulomatous reaction to the implanted material. Eley has not examined systemic biologic effects extensively. Several studies he did report were inconclusive.*

*(His most recent review was a 7 part series published in the BDJ in 1997. While this has been greeted with enthusiasm by the dental profession, closer examination reveals many errors and lack of understanding. A rebuttal of Eley's BDJ review was presented in the ASOMAT submission to the WP....ASOMAT comment)*

*D.W. Jones' modest contributions to the amalgam debate have been reviewed in Part 1 of this report, previously disseminated.<sup>4</sup> The balance of the C.D.A. "expert panel" demonstrates no significant research expertise on the medical consequences of mercury exposure from dental amalgam.*

*Drs. Fan and Siew are employees of the American Dental Association. Fan is a dental materials engineer with publication expertise primarily in bonding. He is partly responsible for the generally held misinformed view of many dentists that mercury exposure from food is significantly greater than the mercury exposure from amalgam fillings (see Part 1, Appendix 2 for clarification). Dr. Siew has published medical and dental research papers, but none have had anything to do with amalgam bio-compatibility. Several of his papers dealt with blood mercury levels as a result of occupational exposure.*

*Significantly, none of the C.D.A.'s "experts" have published any articles employing risk assessment protocols similar to that used in the Health Canada Report.*

#### **CONCLUSIONS:**

*The data, presented herein, clearly demonstrates that this C.D.A. "expert panel" is not expert or qualified regarding the medical effects of mercury released from dental amalgam. Indeed, the*

*approach of convening "expert panels" is not new to the amalgam debate. The international dental community has regularly taken such an approach to mask their obvious lack of research expertise and to support their anecdotal position of amalgam safety.*

*Recently, other national dental associations have also attempted to influence public and governmental opinion by endorsing quasi academic symposia pervaded with amalgam advocates. These gatherings are non-consensus meetings often under government auspices, where the moderators responsible for drawing the conclusions are typically inclined toward the prevailing dental orthodoxy and the conclusions reached often blatantly disregard the experimental data presented. Most damning to the dental profession is that they have not advanced any reputable animal, cellular or molecular evidence of their own to support their belief in mercury filling safety.*

***End of Quote.***

A thorough review of the 'Jones report' was included in the ASOMAT submission. ASOMAT is puzzled as to why the WP would mention that there was criticism of the Richardson report but not mention that this criticism was rebutted very forcefully and that the critics' qualifications, as well as their report itself, were comprehensively reviewed and criticised. To give any credence to such a group by implying that there may be any substantial merit in their criticism of Richardson's risk assessment, after it has undergone such rigorous review, defies belief. The efforts of the Jones report was amateurish, ignorant and uninformed. If they believed in its worth, let them submit it for publication and let the world judge its merits. The fact that they haven't speaks for itself. It was inappropriate for the WP to dignify such a blatant attempt to muddy the waters and misrepresent the science of this issue.

***The WP should have mentioned who the critics were, i.e. the dental profession only, and that the critics' views had been rebutted. To not do so, especially when the WP had been made aware of them, raises the question of less than total objectivity.***

#### **4.4 paragraph 7**

The citation of Eley (*Eley 1997c*) is a strange one given the number of errors in the review article. Some of these were listed in the ASOMAT submission and it is disappointing that the WP did not at least acknowledge that Eley's accuracy had been questioned. Not only that but Eley has no standing as a risk assessment specialist. His calculations draw heavily from an unpublished, non peer reviewed, opinion paper by Mackert (ref 34 in the Eley 1997c paper). Mackert himself is well known as a pro-amalgam advocate. As far as the accuracy of Mackert's work is involved ASOMAT repeats that published autopsy studies (*Friberg et al 1986, Abraham et al 1984, Eggleston 1987, Nylander et al 1987*) confirmed Lorscheider & Vimy's revised calculations. By so doing they automatically, by definition, totally discredited Mackert's calculations which calculated mercury levels from dental amalgams as only 1/8 the levels of Vimy & Lorscheider.

*What more needs to be said?*

It should also be pointed out that there are serious flaws in Eley's work which were documented in the ASOMAT submission. It is disappointing that the WP did not take note of this information before citing Eley as having proposed a credible alternative TDI.

#### **4.4 paragraph 7**

The WP laments the fact that the Smith et al (1970) study has not received attention. This study looked at large numbers of chloralkali plant workers in the US and Canada. The WP failed to consider the documented research (*Viola 1968*) demonstrating that when mercury vapors are mixed with chlorine gas, as it is in the chloralkali industry, the relatively insoluble mercurous chloride is formed. This results in a vastly altered toxicity pattern with gastrointestinal effects superceding neurologic effects, and with much higher tolerable levels of mercury vapor exposure before the appearance of clinically observable adverse effects.

Perhaps this was why the Smith et al. (1970) study referred to by the WP has been rated as "inconclusive" due to "deficiencies in the study design or methodology" (see Ratcliffe et al., 1996; Human exposure to mercury: a critical assessment of the evidence of adverse health effects, Journal of Toxicology and Environmental Health, vol 49, pp. 221-270).

It is regrettable that the WP report contains numerous references to deficiencies in studies which indicate that mercury exposure is associated with effects, but then there is no equal or balance mention of the deficiencies associated with those studies which have found no association between mercury exposure and effects.

*A balance in this regard would add greatly to the WP's credibility.*

#### **4.4 paragraph 20**

The point which the WP is trying to make here is unclear. There seems to be some confusion of exposure assessment with derivation of TDI's. Exposure assessment has nothing to do with the LOAEL. Clarification of this point would be appreciated.

#### **4.4 paragraph 21**

This statement, as written, is false. Repeated studies demonstrating similar results is what "weight of evidence" is all about and is a very important component of a toxicological evaluation of any chemical. Perhaps the point the WP intended to make is that different studies will contribute in varying degrees to that "weight of evidence" depending on each study's limitations. This is certainly true.

#### **4.4 paragraph 22 (second last paragraph of section)**

An explanation is required for the statement..... "An extensive search should be made for unpublished negative studies". Was this a mis-statement or are we to believe that the WP is interested only in those studies which support a particular (perhaps predetermined) point of view?

*If so, then an explanation is required to show how such an approach is consistent with an objective and open minded appraisal of ALL the evidence.*

## **Table 8 footnote, pg 44**

The reference to Richardson's work in the footnote to Table 8 is incorrectly and misleadingly labeled. This work was undertaken for the Swedish government and is an integral part of their recent evaluation of amalgam, and as such it should be titled as follows....

Richardson, G.M. 1999. Mercury Exposure from Dental Amalgam: Re-evaluation of the Richardson Model, Standardisation by body surface area, and consideration of recent occupational studies. In: Amalgam and Health, Swedish Council for the Planning and Coordination of Research, Stockholm, Sweden. In press.

Alternately, it can be listed as:

Richardson, G.M. 1998. Mercury Exposure From Dental Amalgam: Re-evaluation of the Richardson Model, Standardization by Body Surface Area, and Consideration of Recent Occupational Studies. In: Amalgam Frågan, FORSKNINGSRÅDSNÄMNDEN (FRN - Swedish Council for the Planning and Coordination of Research), Stockholm, Sweden, February, 1998.

By citing it as O'Connor Associates Environmental Inc., Ottawa, the WP makes it appear much less credible than it is, and draws attention away from the fact that it was commissioned by the Swedish government and was peer reviewed by Mats Berlin ( one of the world's leading authorities on mercury) and others prior to finalization.

Interestingly, despite the long list for studies presented in Table 8, the WP make absolutely no comment on them or on the health effects issue in general other than to imply that positive studies are somehow invalid due to "deficiencies" and that the problem would be solved by finding all those "unpublished" studies that demonstrate no impact of mercury on occupational health.

## **4.5 paragraph 1**

This paragraph implies that the uncertainty factor of 100 is too conservative (compared to U.S.EPA). However, they fail to include any mention of the ATSDR which also relied on the Fawer et al. study and applied a total uncertainty factor of about 450. With ATSDR included, Richardson's UF of 100 is very reasonable. The WP had already previously acknowledged that Richardson had used a standard toxicological method in 4.4, last paragraph, page 40, so why does it raise the issue again without clarification or explanation of the differences?

***Why did the WP NOT discuss the ATSDR and its application of UF's but imply that Richardson's was too conservative?***

ASOMAT points out that there are documented principles for establishing risk standards for general population exposure. The US-ATSDR rules for risk assessment are found in the US Federal Register [FR Vol. 61(125):335 11-15, 27 June 1996. An UF of 10 is generally used to account for intra-human variation. However, a UF of 3 or 1 may be applied when a large epidemiologic study or a study of the sensitive population was used. As occupational studies are not large enough nor conducted on sensitive populations (children, pregnant females, etc.), the UF of 10 is required. Finally, the ATSDR addresses "LOAEL to NOAEL Extrapolation stating [pg. 33 514]: MRLs are derived , from NOAEL's. In the



absence of a NOAEL, the lowest LOAEL that causes less serious adverse health effects is used, and a UF of 10 is generally applied. When the less serious LOAEL approaches the threshold level, that is only minimal effects are observed representing an early indication of toxicity, the effect level is considered to be a minimal LOAEL and a UF of 3 may be used. " The Working Party itself admitted that researchers have never been able to find a NOAEL for mercury, and neurologic damage can hardly be considered a minimal effect. So, in doing a risk assessment for mercury, a UF of 10 for conversion to the NOAEL. Is appropriate. Even if UF of 3 is applied the WP would still find that patient exposure to amalgam mercury falls within the risk range, as did US-EPA, US-ATSDR, and Health Canada.

#### 4.5 paragraph 2

The 2nd paragraph is patently false. Safety factors (preferably termed uncertainty factors) are based largely on rules developed by regulatory agencies to assist risk assessors in developing valid and consistent uncertainty factors. (See above section) Subjectivity has been largely removed from the process.

#### 4.5 paragraph 3

The WP have presented no data to support the last sentence. What is the evidence indicating that "there is a substantial margin between the intakes of mercury associated with the effects observed and the intake of mercury from a limited number of amalgam restorations"? Richardson's calculations of limits on fillings suggest just the opposite. Even if the WP relied on the USEPA TDI, then an adult could have 11 or 12 fillings and not exceed that reference dose. The difference between "a limited number of amalgam restorations" and 11 or 12 restorations is not substantial either.

***What evidence exists for the WP's belief that there is a very large safety margin?***

#### 4.7.2

ASOMAT disagrees strongly with the WP figures. The WP estimate is unsubstantiated by published research, in contrast to the figures of Lorscheider and Vimy, (*Lorscheider & Vimy 1990*) whose figures have been validated by autopsy studies. (*Friberg et al 1986, Abraham et al 1984, Eggleston 1987, Nylander et al 1987* )

Even if the WP figures are accepted as valid, the WP misrepresents its own data here. At best, given the level of precision in their earlier estimates of exposure from amalgam and foods, (see 4.2 in their report) the best they could say is that exposure from food and amalgam is about equal, when averaged over the entire Australian population, not that amalgam is only half that of food.

### 4.7.3

The WP stated that a proper review of the various issues is beyond their terms of reference, but then they enter into an incomplete and unbalanced criticism. If they have serious reservations they should specifically identify them otherwise they should not say anything.

### 4.7.4

This should read “...no study was identified which reported clear-cut *clinical* illness...”

### 4.7.5

This section is false. There have been several papers by Robert Siblingud (*Siblingud 1990-1994*) which have looked at health effects from dental amalgams, including a comparison of patients with amalgams with patients without amalgams. In addition to the papers listed there are at least three which are as yet unpublished. Perhaps Siblingud’s papers fit the WP’s criteria on page 43 of its report where it calls for a search for unpublished negative studies.(except Siblingud’s papers are published and unpublished positive studies) The WP certainly has the option of concluding that Siblingud’s papers were flawed, giving its reasons for so believing, but it cannot pretend that nothing at all has been published. This is simply untrue.

In any case, even ignoring the existence of the Siblingud papers, the statement should have read...

*“..No studies have been completed which have compared the health outcomes among dental patients with and without dental amalgams to determine whether there may be any differences in symptoms..”*

It is incorrect to specify mercury neurotoxicity as the symptom because it misleads by inferring that other symptoms have been looked at. This is a false inference. ASOMAT challenges the WP to produce even ONE study where there is a comparison of patients with NO amalgams (not few amalgams, but NO amalgams) with patients who have amalgams.

### 4.8.2

Why did the WP conclude that “it is desirable to move toward alternative direct restorative materials to dental amalgam”? The whole gist of their report was to cast doubt on any connection. What about the WP’s comment that dental amalgam is still a desirable direct restorative material in certain clinical situations? ASOMAT does not disagree with the WP conclusion, but finds it difficult to reconcile this conclusion with previous comments.

### 4.8.3 Refer to 4.4 paragraph 21

### 4.8.4

The WP refers to a "safety margin for the lowest-observed-adverse-effect level". However, a 'lowest' observed effect level indicates that the threshold has not been reached or identified. How then, can a level of exposure, that is knowingly associated with effects, offer any safety margin? By definition it can not.

### *General comments on section 4 as a whole:*

Throughout Section 4.4, the committee repeatedly states or implies that a proper review of the various issues is beyond their terms of reference, but then they enter into an incomplete and unbalanced criticism of studies which demonstrate or suggest a positive association between mercury and exposure, or mercury and effects and ignore the numerous deficiencies, weaknesses and other problems with the 'negative' studies which they cite or suggest exist. This leads to an unfortunate impression of lack of balance and bias. Acknowledging the deficiencies in these other negative studies would have alleviated such impressions.

The other thing missing from this section is any mention whatsoever of the fact that mercury levels in urine, liver, kidney, brain, fetuses, etc. increase as the number of amalgam-filled teeth increase and the length of time they are in place. This deserves at least some mention as it is one of ASOMAT's main concerns. i.e. it is the chronic long term accumulation of mercury from dental amalgams which is the problem.

## 5.1

The WP cites several “International Reports”, one of which is the so-called WHO Consensus statement released in 1997. ASOMAT would like to bring to the WP’s attention that .....

**This report is NOT an official WHO report, is not endorsed by WHO, and is only an opinion paper presented to WHO as advice.**

I quote from a letter from *Ewa Carlsson Hopperger, Legal Officer WHO Geneva* in a response to a query from Ms Kaupi, editor of the Heavy Metal Bulletin, a small magazine which writes about the amalgam issue....

*28 October 1997*

*Dear Mrs Kaupi,*

*Reference is made to your telefax of 12 September 1997 to the WHO Regional Office for Europe, which was forwarded to this Office for a reply to your query concerning the status of statements and recommendations made by expert groups.*

*As you indicate in your telefax, WHO calls for the advice of a large number of experts in order to obtain technical guidance and support on a particular subject. The experts can be invited in many forms, eg as Expert Committees, Study Groups, Scientific Groups, and other less formal expert groups. It could even be that individual experts are called, if this is in the interest of the Organisation.*

*Expert groups, whatever the form, are usually set up as ad hoc groups, and what they have in common is that they are only set up in order to provide advice to WHO. This means that any statements or recommendations made by the group or individual experts are not in any way binding for WHO, or for any other body for that matter, they are only made as advice to WHO. Also WHO is on no way responsible for the advice provided to it by the experts.*

*We hope that the above explanation clarifies the situation.*

*Ewa Carlsson Hopperger, Legal Officer, WHO Geneva*

The majority of the WHO group are dentists and many, e.g. Dr.Reich, Dr. Widström, Dr. Berglund and Dr. Zeilig are well known as pro-amalgam advocates. As revealed by a Medline search, few of the delegates have published scientific articles in the field of medicine and amalgam..Others, Dr Meyer and Dr Mjor were from the American Dental Association and the FDI respectively.

The main papers, relevant to this review, was titled “Mercury Exposure from Dental Amalgam Fillings: Potential for Adverse Health Effects”. The authors were J.Mackert and A. Berglund. Both are prominent pro-amalgam advocates and both critics of Richardson’s work, and of Vimy & Lorscheiders work (which was validated by the autopsy studies mentioned earlier in 4.1)

Why would anyone think that anything other than complete endorsement of amalgam would result from such a gathering?

*Why did the WP not point out the above facts?*

## **5.2 paragraph 7**

The working party state “No evidence exists to justify the removal of dental amalgam restorations to relieve certain symptoms or treat particular conditions (other than hypersensitivity).”

This is untrue. The evidence is, admittedly, primarily anecdotal, as represented by hundreds of case reports mentioned in the submissions to the WP, as well as a very small number of published reports (*Siblerud 1990-1994*) It is true that full studies in mainstream journals do not exist but it is not true to say that NO evidence exists.

Even if the statement was true the WP acknowledged in 4.7.5 that no studies exist comparing health outcomes of amalgam bearing patients and non-amalgam bearing patients. This leads to the obvious question..

*Is there no evidence because studies have been done and the results showed no evidence ( in which case, cite the studies) or is there no evidence because no studies at all have been done, (therefore there can be no evidence, one way or another). Given the WP’s own finding that no such studies have ever been conducted, it is clear that all evidence of safety is itself anecdotal.*

## **Section 5.3, paragraph 2**

Again, the WP fails to mention the Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service. That agency has also established a reference exposure level, called a minimum risk level (MRL). The currently published value is 0.014 ug/m<sup>3</sup> of air, although it is being revised. The revised value of 0.2 ug/m<sup>3</sup> is draft only, and not official yet. It appears that ATSDR may be forced into a major review given the extent of comments received on the revised MRL

## **5.4.2**

The WP accepts the notion of the application of public health principle of risk avoidance but then inexplicably excludes people with neurological problems as an at risk group. Given that the WP has stated that their recommendations about pregnant women, children and kidney patients were based on risk avoidance and not on any evidence of harm, on what basis did the WP exclude people with neurological problems in the at risk group? The WP will be aware that the current guidelines of the Canadian Dental Association, developed as a result of Health Canada recommendations, includes

people with neurological problems.

There is also no mention of Sweden's policy that their social dental health program will no longer pay for the placement of dental amalgam. ASOMAT sees this as a very significant government policy that should be included in Section 5.

#### **5.4.6**

The WP comments that there is a “remote possibility of allergic hypersensitivity to mercury from amalgam restorations”, but it does not quantify this.

Peer reviewed, published studies have shown a wide range of allergy levels. These include the following.... 5%-8% (*Rudner*) 27% (*Djerrasi & Berova*), 2%-10.8 % (*White & Brandt*), 31%, 27%, 32%, 39% (*Miller et al*), 11.3% (*Brun*), 9.6 % (*Nebenfuher et al*), 13% (*Sato et al*)

***Could the WP please explain the apparent contradiction between their assertion of “remote possibility” of allergic hypersensitivity and the published literature.***

#### **Table 9,**

An entry should be included for the Health Canada policy, under "Other" (last row of table) regarding their recommendation not to use amalgam when there are other metals (such as braces) in the mouth.

It is also regrettable that no attention was given to the health of dentists and dental staff, or to the issue of environmental contamination caused by the continuing use of dental amalgams.

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