

Final Report
of the
Stakeholder Review Committee
on the Safety of Dental Amalgam

Submitted to Health Canada

Dr. D. Wayne Taylor
Chairman

March 1, 1996

The Medical Devices Bureau of Health Canada is completing a review of the scientific data relating to the safety of dental amalgam. This study will be used to develop a Departmental position statement on the safety of amalgam.

As part of the Health Canada study, Dr. Mark Richardson, formerly of the Health Protection Branch, prepared a report entitled, *Assessment of Mercury Exposure and Risks from Dental Amalgam*. This report (hereafter referred to as the Richardson report) underwent scientific peer-review and was made public November 27, 1995. Dr. Richardson's report:

- reviewed the scientific and medical literature on the health effects of mercury;
- estimated the exposure of the Canadian population to mercury from amalgam, food and the environment, and;
- proposed a tolerable daily intake (TDI) level for mercury vapour, the principal form of mercury to which people with amalgam fillings are exposed.

The Richardson report did not include a risk-benefit analysis of amalgam, or an analysis of the risks of alternative restorative materials. The executive summary of Dr. Richardson's report is attached as Appendix I.

Health Canada convened a committee of stakeholders to:

- 1) review and comment on the methodology and conclusions of the Richardson report and,
- 2) provide Health Canada with advice in developing a position statement on the safety of amalgam.

A list of the members of this committee appears in Appendix II.

An initial meeting of the committee was held November 27, 1995 to familiarize the committee with the review process and the committee's terms of reference. Dr. Richardson made a presentation of his report and answered questions about it.

A second meeting of the committee was held February 16-17, 1996 under the chairmanship of a mediator, Dr. D. Wayne Taylor of McMaster University.

Committee members were given an opportunity to make presentations and submissions on the first day of the meeting. Two members were allowed to be assisted by legal counsel. Dr. Richardson responded at the conclusion of the first day. On the second day the committee discussed the Richardson report, discussed policy options for Health Canada and reached conclusions on several points. There remained at the end of day two, some dissenting views on some parts of the committee's overall position.

Below is a brief summary of the main issues discussed and general views expressed. Also included is the Committee's positions regarding the Richardson report and policy recommendations to Health Canada. Although formal dissensions have been noted herein, members also were requested individually to submit their dissenting views directly to the Medical Devices Bureau of Health Canada. Alternatively, if all of the dissenters agreed, they were invited to submit a minority report directly to the Medical Devices Bureau of Health Canada.

Issues and Viewpoints

General

Debate on the issue of the safety of amalgam was strongly polarized within the Committee as it is in society. At one extreme were those who argued that amalgam is safe, that the known benefits far outweigh any potential risks, and that we were wasting time and money in discussing the issue. At the other extreme were those who argued that mercury is a poison, amalgam contains mercury, the risks of amalgam far outweigh the benefits, and that zero is the only acceptable level of exposure to the mercury in amalgam.

However, most members of the Committee were somewhere in the middle. For them, a practical response to the issue of amalgam safety was to attempt to draw a line somewhere along the continuum of risk inherent in exposure to amalgam.

In essence, there were three schools of thought about the study of amalgam: the pro-amalgam school which saw nothing wrong with the status quo; the anti-amalgam school which called for its outright ban; and the Paracelsian "dose makes the poison" school which preferred a very judicious use of amalgam.

The Richardson Report and Other Research

There was general agreement amongst the members of the Committee that the Richardson Report provided a good model to investigate the safety of amalgam. Although the methodology was valid, the input data were not reliable thus not allowing the distinction to be made between health and disease.. Specifically the following issues were raised:

- there were too many layers of assumptions;
- a safety factor of 1000 could be argued as easily as the factor of 100 used;
- no new epidemiological evidence was generated;
- the relationship between somatic symptomatology and amalgam exposure was not critically appraised;
- the previous studies which were reviewed were poorly designed and their results were skewed; and,
- mercury concentration in urine is a poor proxy for measuring mercury contamination in humans.

Many members of the Committee also reviewed the original studies used by Richardson as well as other human research. Generally, the Committee believed this small body of work was not reliable. Specifically:

- sample sizes were small;
- females were under-represented;
- no age-weighted control groups were used;
- no strong, direct, positive correlations (let alone causation) were shown between amalgam and disease.

For the most part, the Richardson Report and the existing body of human research are helpful in hypothesis-building but not in hypothesis-testing.

Animal research on the safety of amalgam was felt to be important by several members of the Committee. It showed the uptake of mercury in animal tissue, not urine, from exposure to low doses of amalgam. The empirical evidence seemed to show that amalgam can bring about cell or organ pathophysiology in animals.

Overall, the research was deemed to be inconclusive.

The Need for Research

The Committee strongly felt that there is a need for further research into the potential health effects of mercury absorption from dental amalgam. The Committee believed the following studies should be conducted:

- (i) A comprehensive, critical meta-analysis of all the human and animal research literature on amalgam toxicity by a panel of experts with representation from biology, toxicology, epidemiology, medicine, dentistry, risk assessment, dental materials and policy/economic analysis;
- (ii) A comprehensive, well-designed, large, epidemiological study to investigate amalgam, and its effects on human health;
- iii) Using Statistics Canada's all cause mortality database, a computerized, record-linkage study to identify excess deaths among dentists who have a high-risk exposure to dental amalgam;
- (iv) A risk-benefit analysis of amalgam;
- (v) Animal research on the toxicity of amalgam to identify a threshold dose; and,
- (vi) The same studies (i, ii, iii, iv and v) for all alternative, restorative materials.

The Committee believed that the dental materials industry, the dental associations, and the federal government should fund this research through government, peer-reviewed funding agencies.

The Committee also believed that the dental materials industry should actively research and develop a biocompatible, cost-effective, alternative, restorative material with superior performance characteristics equal to or exceeding those of amalgam, as a replacement for amalgam. Such a product should be required to demonstrate safety to Health Canada before being allowed to enter the market place.

Choice of End Point

There was general disagreement over specific, suggested endpoints, where to draw the line on a mercury concentration-adverse effect graph, and even the whole attempt to determine an endpoint. The Committee finally agreed

that **any** quantifiable, irreversible effect of mercury, whether demonstrable impairment or chronic disease, would be acceptable as an endpoint.

Choice of a TDI

The Committee generally did not like the calculation of the TDI because the available scientific evidence could not support a reliable estimate. Although TDI is the standard terminology used by risk analysts, some members of the Committee felt that it could be misleading and misinterpreted, and therefore cautioned against its use.

Relationship Between Number of Amalgam Fillings and TDI

Survey data of Ontario children showed that the average number of fillings per child was well below the limit recommended in the Richardson Report. This was directly related to the fewer caries found in children today as a result of fluoridation, fissure sealants and better dental hygiene. The relationship between number of amalgam fillings and TDI was not discussed further by the Committee given its earlier rejection of the TDI.

Replacement of Amalgam Fillings

The Committee unanimously felt that the wholesale replacement of amalgam fillings across the population was totally inappropriate. Evidence did not exist to warrant it. Some evidence, in fact, indicates such a radical move could do more harm than good if amalgam is not removed according to established safe removal protocol.

Discontinuing The Use of Dental Amalgam

The majority of the Committee did not support discontinuing the use of amalgam given the lack of scientific evidence to support such a move. Some members of the Committee favoured a gradual phase-out of the use of amalgam. Industry sales of amalgam have been declining 5% per year for several years. Differences in opinion existed whether this represented a fast enough phase-out.

Others believed that a TDI would be an "effective ban" and rejected it earlier for that reason.

In addition, insufficient evidence existed to either support or dispute the safety of alternative restorative materials. Some dentists may not have sufficient expertise to use alternative restorative materials without additional training.

Restricting The Use of Dental Amalgam

Again, the majority of the Committee believed that the research evidence did not support excluding children, pregnant or lactating women, or patients with kidney disease from receiving amalgam fillings. Common sense dictated that pregnant women should avoid any unnecessary medical or dental intervention until after delivery. Similarly, individuals with diagnosed allergic, or other systemic, reaction to mercury should avoid amalgam fillings.

The Committee agreed that the dental profession should place a priority on the preservation of healthy tooth structure through preventive measures and the judicious use of any and all restorative materials.

Informed Consent/Education

The Committee supported the use of informed consent in the practice of dentistry. However, to make it effective in this case, it was felt by some members that dentists, as well as general medical practitioners, required additional training in heavy metal poisoning symptomatology. Others believed that the *Journal of the Canadian Dental Association* should contain more science-based articles, abstracts of relevant articles from scientific journals not usually accessed by dental practitioners, and articles both for and against the use of amalgam.

* * * * *

The Committee agreed that votes be taken and recorded, as positions were developed and adopted.

Committee Position Statement Regarding the Richardson Report:

The committee believes that the ***Assessment of Mercury Exposure and Risks from Dental Amalgam*** was done in a careful and conscientious manner with methods generally appropriate for this type of risk assessment. However, given the poor quantifications of exposure in key toxicological studies used, it is inappropriate to conclude that a TDI set using this approach represents a distinction between health and disease.

In any further risk assessments (when sufficient data become available), the committee believes that significant adverse effects on the central nervous system (or other body systems) would be the appropriate end points **[passed unanimously]**

Committee Position Statement Regarding Policy Recommendations to Health Canada:

- 1) The evidence does not exist to warrant the wholesale removal of amalgam fillings **[passed unanimously]**
- 2) The medical and dental practitioners should be alert to the fact that some individuals have sensitivities to amalgam and to the needs of these individuals. All individuals have the right to participate in the selection of the materials that will be placed in their mouth **[passed 18-1 with Laporte abstaining]**
- 3) Some patients may have concerns that they have adverse systemic effects due to amalgam fillings. Although removal of existing amalgam fillings may, in some individuals, have positive effects, at this time substantial experimental evidence does not exist to confirm those positive effects. Individuals considering such an action should thoroughly discuss the issue with their physician and dentist **[passed 17-2 with Laporte in the negative and Jones abstaining]**
- 4) Although there is no evidence that dental amalgams contribute to immunological, neurological, or kidney disease in human populations, there is some evidence that mercury exposure from all sources is of more significance to individuals with those problems than to the general population. Dentists and physicians should be aware of these concerns in their choice of dental materials for these patients **[passed 12-4 with Babiuk, Pressey, Sang, Saville, and Vimy in the negative, Des Marais abstaining and Wilson absent]. ***

- 5) It is recommended that a public and professional information package be prepared to make the public more capable, in collaboration with their health care providers, of making informed dental health choices [**passed unanimously**].
- 6) The public should be aware that it is the responsibility of the dentist to obtain and update a patient's health history. It is also the responsibility of patients to notify their dentist of any changes in their health status [**passed unanimously**].
- 7) Dentists are to be encouraged to decrease the use of amalgam and other restorative materials through the use of diagnostic and preventive treatment strategies based on tooth structure preservation [**passed 15-3 with Babiuk, Sang and Saville in the negative**].
- 8) The committee strongly recommends that funding be made available to support research on the use of dental amalgam or alternatives in order that any concerns and questions surrounding their safety be addressed. This funding should be a joint effort of industry, the dental profession and government [**passed 13-5 with Babiuk, Sang, Saville, and Wilson in the negative and Smith abstaining**].

The question to ratify both position statements ~~in toto~~ then was passed by the Committee 144 with Babiuk, Sang and Saville in the negative and Pressey abstaining.

The task assigned to the Committee having been completed, it was decided that a third meeting of the Committee would not be necessary. The meeting was adjourned.

* It was after this vote that Dr. Vimy resigned from the Committee and left the meeting. Dr. Vimy preferred this wording for #4: *Dentists and physicians should be particularly careful in the choice of dental materials for patients who have immunological, neurological or kidney disease. There is some evidence that mercury exposure is of more significance to these individuals than the general population.*

Appendices

Appendix I

Executive Summary
of Dr. Mark Richardson's Report:

*Assessment of Mercury Exposure and
Risks from Dental Amalgam*

August 18, 1995

Executive Summary

For Canadians with amalgam-filled teeth, it was estimated that total mercury (Hg) exposure averages: 3.3 ug Hg/day in toddlers (aged 3 to 4 years); 5.6 ug Hg/day in children (aged 5 to 11 years); 6.7 ug Hg/day in teens (aged 12 to 19 years); 9.4 ug Hg/day in adults (aged 20 to 59 years); and 6.8 ug Hg/day in seniors (aged 60+ years). Of this exposure, amalgam was estimated to contribute 50% to total Hg exposure in adults, and 32 to 42% for other age groups. Estimates, based on two independent models, of exposure from amalgam alone were: 0.8-1.4 ug Hg/day in toddlers; 1.1-1.7 ug Hg/day in children; 1/9 - 2.5 ug Hg/day in teens; 3.4 - 3.7 ug Hg/day in adults; and 2.1 - 2.8 ug Hg/day in seniors.

There are insufficient published data on the potential health effects of dental amalgam specifically to support or refute the diverse variety of health effects attributed to it. Numerous studies constantly report effects on the central nervous system (CNS) in persons occupationally exposed to Hg. Virtually all studies failed to detect a threshold for the effects CNS measured. A tolerable daily intake (TDI) of 0.014 ug Hg/kg body weight/day was proposed for mercury vapour, the principal form of mercury to which bearers of amalgam fillings are exposed. This TDI was based on a published account of sub-clinical (i.e. not resulting in overt symptoms or medical care) CNS effects in occupationally exposed men, expressed as slight tremor of the forearm. An uncertainty factor of 100 was applied to these data, to derive a reference dose (TDI) which should, in all probability, prevent the occurrence of CNS effects in non-occupationally exposed individuals bearing amalgam fillings.

The number of amalgam-filled teeth, for each age group, estimated to cause exposure equivalent to the TDI were: 1 filling in toddlers, 1 filling in children; 3 fillings in teens; and 4 fillings in adults and seniors. It was recognized that filling size and location (occlusal versus lingual and buccal) may also contribute to exposure. However, data suggest that no improvement in prediction of exposure is offered by any particular measure of amalgam load. Therefore, the estimates of exposure derived from the number of filled teeth were considered as reliable as those that might be based on size and position of amalgam fillings, were such data available for the Canadian population.

Effects caused by allergic hypersensitivity to amalgam or mercury, including possible auto-immune reactions, cannot be adequately addressed by any proposed tolerable daily intake. Individuals suspecting possible allergic or auto-immune reactions should avoid the use of amalgam by selecting suitable alternate materials in consultation with dental care (and possibly health care) professionals.

Appendix II

Members of the
Stakeholder Review Committee
on the Safety of Dental Amalgam

Health Canada Study on Dental Amalgam

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Representing Health Canada were:

Dr. Richard Tobin, Director, Medical Devices Bureau
Dr. Philip Neufeld, Medical Devices Bureau

Invited Observers to the February 16-17, 1996 meeting:

Dr. Anders Berglund, University of Umea, Sweden
Mr. Brian Henderson, Canadian Dental Association
Dr. Richard Riley, private practice, Huntsville
Mr. Steve Tomassi, legal counsel, Sybron Corporation
Dr. Ken Wolch, private practice, Scarborough (did not attend February 16/96)
Mr. Lee Zagar, legal counsel, Dentsply International

Mediator/Chairman of the February 16-17, 1996 meeting:

Dr. D. Wayne Taylor, Michael G. DeGroote School of Business, McMaster
University, Hamilton

Appendix III

Submission of
Health Action Network Society

President, DAMS Canada
Toxic-free Dental Consultant
March 4, 1996

Dr. Richard Tobin, Director, Medical Devices Bureau
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Dear Dr. Tobin

Thank you for inviting DAMS Canada to submit an alternate position and recommendations regarding the use of mercury amalgam in Canada.

Due to the toxic nature of mercury, its negative effects on human health and its contribution to pollution in our environment, we believe that mercury used in dentistry should be phased out as soon as possible and facilities made available to the public for education and treatment for symptomatic individuals. Our recommendations are as follows:

1) STAGED ELIMINATION OF MERCURY AMALGAM

a) immediate discontinuation of mercury amalgam use in female patients (the body burden of mercury in females will stay in their bodies past childbearing age, therefore, mercury amalgam should not be placed in females unless they have reached menopause. Mercury amalgam should not be placed in male patients who plan to father children in the future, since the female is the recipient of the male body fluid (sperm).

b) discontinuation of use in children. (University of Pittsburgh recent research implicates heavy metals as a cause of behaviour problems in children due to the interference in the development of the central nervous system, which in turn leads to learning disabilities, restlessness and attention deficit).

c) mercury amalgam phased out or no longer used in Canada by the year 2000

Dr. Richardson's report gave TDI levels which he felt was the level at which neurologic symptoms could be observed. His findings may be accurate, however, some individuals suffer irreversible damage with 4 fillings.

2)INFORMED CONSENT

a)warning posters displayed in all dental offices. They must state that:

-mercury amalgam is used in this office.

-amalgam contains 50% mercury

-mercury is a neurotoxic substance known to cause neurologic disfunction, birth defects and other reproductive harm.

3)Dental Devices Division

a)manufacturers and the dental regulating associations have failed to advise and protect public health, therefore, a dental devices division should be established to monitor all dental devices and materials.

b)a reaction hotline (1-800#) should be made available to the public, hospitals, and medical practitioners.

The CDA president, James Brookfield, contends that a very small portion of the population (approx. 2%) is allergic to mercury amalgam. The Canadian population is approx. 27.2 million people which means that 544,000 people react to amalgam. Many scientists report a much higher figure. How many people react to their dental restorations and do not know their symptoms are a reaction to their dental work? Most doctors would not suspect dental restorations as the culprit.

4)ENCOURAGE MANUFACTURERS TO USE AND DEVELOP BIOCOMPATIBLE MATERIALS

a)Eliminate the use of metals which are used to develop restorative materials. Nickel, copper and a host of other metals are used to manufacture dental restorations. The longevity of these restorations is outstanding, however, the human body does not tolerate these foreign metals well.

5)DIAGNOSTIC AND TREATMENT CENTRES

a)Encourage the development of heavy metal treatment centres across Canada. Testing and treatments must be paid for by Provincial Health Care Programs.

b)The exchange of dental materials to biocompatible restorations must also be done prior to treatment and is crucial for the individuals recovery. This dental exchange must be paid for by our socialized health care program. A physician's report should specify the need for the exchange and indicate a positive response to metals ie. MELLISA testing. This will provide access to provide access to people of all means.

c)Encourage expansion of training for medical personnel to better recognize and more safely and successfully treat the toxic effects of mercury amalgam poisoning.

The amalgam clinic in Sweden, has helped hundreds of symptomatic individuals to regain their health. Results will be published in April '96. Please review Dr. Lindvall's paper which I presented at the Stakeholder meeting in February '96.

Enclosed is a copy of a recent Mercury Conference that was held in Florida. I recommended that Health Canada organize a similar conference to help educate the public, and the medical/dental community, about the prevalence and consequences of using mercury in our environment.

I am sending more literature to you by mail. I truly hope our recommendations will help Health Canada to change legislation regarding the use of dental materials in Canada.

Please forward copies of all literature to Mr.Dingwall and the Provincial Health Care Ministers.

Sincerely,
Cynthia Saville
President, DAMS CANADAHEALTH ACTION NETWORK SOCIETY
202 5262 Rumble Street, Burnaby BC V5J 2B6

**FURTHER COMMENTS ON HEALTH CANADA'S
PROPOSED POLICY ON DENTAL AMALGAM
AND DR. MARK RICHARDSON'S REPORT ENTITLED:
"ASSESSMENT OF MERCURY EXPOSURE AND RISKS
FROM DENTAL AMALGAM"**

To Dr. Philip Neufeld, Chief, Research and Surveillance Division,
Medical Devices Bureau, Health Canada
and
Dr. Richard S. Tobin, Director, Medical Devices Bureau, Health Canada

by Elke Babiuk, Director, Health Action Network Society,
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MARCH 6, 1996

INTRODUCTION

We know from occupational studies that exposure to mercury vapour is positively correlated with cognitive impairment, mood changes, depression, anxiety, aggression, confusion, impaired motor function, etcetera (reviewed by Dr. Richardson). A no-observed-effect-level has not been demonstrated. Documented cases of acrodynia from exposure to mercury in paints, a mercury spill in an apartment by a previous tenant, and the recent exposure to elemental mercury in a residential community gives us more symptoms - headaches; insomnia; hypertension; swelling; redness, and peeling of hands, feet and nose; abdominal pain; chest pain; muscle cramps and weakness; rash; etcetera (CDC's MMWR, Vol. 39/No.25, June 29,1990; MMWR, Vol.39/No.8, March 2, 1990; MMWR, Vol.44/No.23, June 16, 1995). Other studies also reveal that there is no simple dose-effect-concentration in Acrodynia. While most affected children have high levels of mercury in urine, a small number who have been diagnosed with overt acrodynia, have had low levels of mercury in urine. Furthermore, some children are more affected by accidental mercury exposure than others despite being equally exposed. This may be because of genetics, individual susceptibility, total body load, nutrition status, or a combination of these.

JUSTIFICATION FOR RESTRICTIONS

We know that the blood-brain barrier of the premature infant is more permeable. Even after birth, the blood-brain barrier is not yet fully formed. We also know that mercury crosses the placenta and is excreted in breast milk. Case studies of accidental exposure have also shown that children are physiologically more susceptible to health hazards of mercury vapour than adults. We don't know what the impact is of chronic exposure to mercury vapour from amalgam on the developing central nervous system of young children and neonates. We also don't know how to identify which children would be more sensitive to mercury vapours and might be adversely affected by chronic low-dose long-term exposure to the mercury emitted from amalgams. **Therefore, we feel that it is reasonable that HC impose restrictions on amalgam placement for pregnant women, lactating women and for children up to age twelve or thirteen. (ie. no amalgam fillings).**

It is well known that tooth decay rates can be much higher in the lower socioeconomic groups. In fact, surveys show that a small percentage of children (about 9.3%) are responsible for most of the decayed teeth recorded on examination (≥ 3.0 decayed teeth). Restricting amalgam fillings in the 12 year-old and under age bracket, would protect the small percentage of children who do have increased caries rates and may be more susceptible to mercury toxicity because of poor nutrition status. For example, in the Alberta study of 1985, 1.6% of 13 year-old children had six or more decayed teeth; 0.1% had 13 decayed teeth! For those children who now have a large number of amalgam fillings, it is reasonable to use the data from Dr. Richardson's report to restrict dentists from using more amalgam when either placing a new filling or when replacing an old amalgam filling due to wear or recurrent decay. **Despite the uncertainty in the toxicological data, it is incumbent on HC to prevent the small percentage of children that would still be exposed to a large body burden of mercury if amalgam fillings are not restricted.**

Based on the recent Ontario Statistics given at the stakeholder meeting, the average child

now has less than one decayed tooth so restricting amalgams in the under 12-year-old age group would have little if any economic impact. In fact, even in the 1985 Alberta survey, 65.4% of those children examined had no current decay, 17% had one decayed tooth, and 8.4% had two decayed teeth. It is obvious that the costs of using an alternate material in the large majority of young children will be negligible.

Further support for restricting amalgams in children is available. Amalgams are contraindicated as a first filling in children, according to a 1993 statement by Dr. Harold Loe, then Director of the National Institute of Dental Research in the U.S.:

"That first filling is a critical step in the life of a tooth. Using amalgam for the first filling requires removing a lot of the tooth substance, not only diseased tooth substance but healthy tooth substance as well. So, in making the undercut you sacrifice a lot, and this results in a weakened tooth. The next thing you know, the tooth breaks off, and you need a crown. Then you need to repair the crown... and so it continues to the stage where there is no more to repair and you pull the tooth. With the first filling you should do something that can either 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 tooth is still there." [Bio-Probe newsletter, November 1993; their reference: September edition of "Dental Products Report"]

The fact that amalgam can severely weaken the tooth, while bonded composite actually strengthens remaining tooth structure is well documented in the literature. Amalgam requires a mechanical dovetail undercut to achieve retention, whereas resin bonds well to sound enamel and dentin.

It is perhaps interesting to note that the amalgam stakeholder committee specifically acknowledged that preserving tooth structure is important (policy recommendation 7). Yet, using amalgam as a first filling is not conducive to accomplish this end. Cavity preparation for an amalgam placement is a non-conservative technique which uses the concept "extension for prevention". This is especially true for young patients with poor oral hygiene habits. (Bell & Grainger, 2nd ed., "Basic Operative Dentistry", 1971). "Extension for prevention" means that a cavity is prepped so that the margin is placed in sound tooth structure, continuous non-coalesced pits and fissures are eliminated, and margins are placed in areas of lessened caries susceptibility. While this is generally true of all materials, however, since resin bonds well to sound enamel and dentin, location of margins are not that critical. Also, the grooves of the fissures can be sealed with resins so there is no need to cut healthy tooth away as is done with an amalgam restoration.

It is reasonable for Health Canada to restrict amalgam fillings in children for both safety reasons and for practical purposes.

UPGRADING SKILLS RESPONSIBILITY OF DENTISTS

The skill level (or more appropriately, the lack thereof) of many Canadian dentists should **not** be a determining factor in formulating government policy for restrictions on amalgam fillings. It is incumbent on dentists to upgrade their skills to reflect newer technology in the marketplace, regardless of the cost to them, the dental industry, or the associations. This is necessary in any case because amalgam sales have been declining for years as acknowledged by the industry at the Stakeholder meeting. According to a Swedish

participant on the AMALGAM Internet mailing list, in Sweden where the amalgam debate was a hot media item because of Swedish and Canadian research, sales of amalgam declined from 60% of all tooth fillings in 1985, to about 30% in 1991. From 1991 to 1993, the use of amalgam decreased by another 30%. It is clear that it is incumbent on the dental schools to provide graduates with the educational and mechanical tools necessary to work exclusively with alternate materials. **Even if Canadian universities are not changing their curriculum fast enough to accommodate changing marketplace trends, this does not mean that HC should absolve them of that responsibility making allowances for dentistry's inadequacy.**

RESEARCH DATA - SAFETY

The lack of available research on the "safety" of mercury amalgam tooth fillings can not be excused and should not be a justification for maintaining status quo. There are more than enough studies on the pharmacokinetics of mercury vapour at the organ, tissue, cellular and biochemical levels that show pathophysiology. **This evidence, together with the risk assessment, and the fact that there is a lack of safety data, is ample reason for HC to put manufacturers on probation until they provide (and pay for) biological evidence of safety.**

A timeline should accompany a HC directive - research should begin **within three months** and be completed within two years. That said, however, we don't want amalgam manufacturers designing their own study protocol. A multidisciplinary stakeholder committee should be set up so that research protocol incorporates that recommendations of some of the experts in the field who have already done research on the **biological** effects of mercury. There are two possible consequences from taking this action that we foresee at the present time:

(1) A completed study will show that amalgam is safe or that it carries negligible risk (although this still would not address the environmental concerns), a scenario we consider unlikely; or,

(2) amalgam manufacturers will realize that if they do a study and it proves harm, they will be at grave danger of increased legal action. With declining amalgam sales anyway, we believe the logical corollary to a HC directive for definitive studies, would be that the amalgam manufacturers will voluntarily comply with an amalgam phase out (a date should be specified), much like Degusa did in Germany.

INFORMED CONSENT-DEAR DENTIST/PATIENT LETTER

Informed consent speaks to the patient's right to know. While many doctors and dentists have traditionally opposed any attempt to inform the public of the risks and the benefits of certain medical and dental procedures, the courts have repeatedly upheld the right of the patient to be clearly and coherently informed. Should the patient rely on the word of the dentist (who is qualified medically or toxicologically) that the mercury which is chronically released from a "silver" filling is harmless to the body except in " rare" cases of allergy? We think not. **It is necessary that HC take the initiative to prepare a "Dear**

Dentist/Patient"letter.

Truth is an important message. Yet, every day in every city, dentists repeatedly and shamefully misrepresent the information on mercury amalgams to inquiring patients. Dr. Derek Jones and his statement of 1290 mercury fillings is just one example of blatant and negligent misrepresentation (**Globe and Mail**, February 21, 1996). There are thousands more including some dentists who steadfastly deny that there is any mercury released from amalgams (recent court case in the US); those that do admit to some mercury release, claim it is minuscule compared to other sources (Internet: American Dental Association 1995/96 and others). California attempted to correct this deplorable situation by passing the Informed Consent Bill SB933. The bill directed the dental board to prepare a one page handout that discussed the risks and benefits of toxic dental materials. The California State Board of Dental Examiners has prepared the one page flyer but has **refused** to send it to the dentists of this state. The Dental Board claims that the state only directed them to prepare the risk/benefit paper but did not order them to give it to their patients. Dentists have thus thwarted the intent of the legislature. **I mention this so that HC realize that they must not abrogate their responsibility to inform dentists and patients of the potential risks of mercury amalgams.**

Many prescription drugs now include an information leaflet in the package. Further information on documented side effects and contraindications is obtained from the Compendium of Pharmaceuticals or from the pharmacist. While a drug's side effects are not always realized, being forewarned means that a patient can contact their doctor for a substitution if untoward side effects occur. Medical patients are thus protected by laws which specify that contraindications and side effects of unprotected in this respect. **it is reasonable for dental patients to have information sheet on the potential risks of mercury so that they can make an informed choice when it comes to choosing the filling which will become part of their body.** This is especially important when one knows that mercury is a cumulative poison and adverse effects may not show up immediately, unlike prescription drugs.

Dentists are required to inform their staff of the hazardous material in the workplace (Workplace Hazardous Materials Information System). The law states that Material Safety Data Sheets must be available for all staff to see. **Therefore, it is reasonable that patients should also be informed that the "silver" substance implanted in their bodies, is a hazardous material that is 50% mercury.**

To encompass the three points mentioned above, an instructive letter should be distributed by Health Canada to all dentists informing them of their responsibility to distribute this letter to all patients seeking dental care. It should contain the following points:

- 1) that an amalgam or "silver" filling contains 50% mercury and that mercury is a hazardous material.
- 2) that mercury vapour will be emitted from the filling for the lifetime of that filling; filling;
- 3) that for most people with fillings, mercury from dental amalgam constitutes the major body burden of mercury;
- 4) that there is no biological evidence of safety for this filling material;

- 5) that there are suitable alternative materials available;
- 6) that high-dose non-continuous exposure to mercury vapour, as demonstrated in occupational studies of dentists and other workers (five days per week, eight hours per day) and the acute accidental exposure studies on children (acrodynia), have shown that side-effects include...(see Introduction). Therefore, allergic or sensitive patients can experience many of the same symptoms from the low-dose chronic (24 hours per day, seven days per week) exposure of mercury vapour emitted from amalgam fillings. Any symptoms should be reported to the patient's **physician**;
- 7) that mercury crosses the placenta and is excreted in breast milk; therefore, pregnant or lactating women should not be exposed to mercury vapours during this time;
- 8) that because young children are physiologically more susceptible to mercury vapour, children aged twelve and under should avoid exposure to mercury and be given alternate filling materials. Those children with many mercury amalgams should also be given alternatives;
- 9) that since mercury is a known neurotoxin and because the kidney is the primary site of mercury accumulation in the body, people with kidney impairment and neurological disorders should choose another filling material;
- 10) that the mercury in amalgams can cause gingivitis or gum inflammation, cause oral lichen planus, result in amalgam tattoos in gum tissue, and cause contact dermatitis; and,
- 11) that animal and occupational studies have shown that mercury vapour can adversely affect the immune system. Therefore, people with immune disorders should choose an alternate material.

DEAR DOCTOR LETTER

There is a growing body of anecdotal reports of illness attribute to dental amalgam as related by Dr. Richardson in his report, as evidenced by the adverse reaction reports submitted to the US Food and Drug Administration, and as documented in the scientific literature in individual case reports. While the alleviation or elimination of effects following amalgam removal have been dismissed by some in the scientific community as placebo or psychosomatic, common-sense dictates this is, at best, illogical. The **same** adverse effects which are common to these individuals have been recorded for mercury exposure in occupational studies and in children diagnosed with acrodynia. Many and sometimes all of these adverse effects have been alleviated or eliminated by removing the source of exposure (occupational or accidental) and detoxifying with chelation therapy. The same holds true for those who have had their amalgams removed.

It is well known that some people(whether by genetics, nutrition status, total body load, lifestyle, individual variation, etc.) are more susceptible to toxic substances than the average person. We have no way of knowing how many Canadians are adversely affected by the mercury emitted from amalgam. We don't know how much human suffering can be laid at amalgam's doorstep. We have no idea how much this affects our escalating health care costs. Data from Sweden indicates it could be significant. **Since allergy and/or sensitivity to amalgam could be as high as 16.1% overall (Richardson report), it is reasonable that HC issue a "Dear Doctor" letter advising physicians:**

- 1)that an amalgam or "silver" filling contain 50% mercury and mercury vapour will be emitted from the filling for the lifetime of that filling;
- 2)that for most people with fillings, mercury form dental amalgam constitutes the major body burden of mercury;
- 3)that there is no biological evidence of safety for this amalgam, despite claims made by dentistry;
- 4)that there are suitable alternative materials available;
- 5)that the department recognises that mercury sensitivity is an established disorder which can lead to disabling symptoms in a subsection of the population;
- 6)that if comprehensive medical tests have ruled out other possibilities, a physician should suspect mercury sensitivity in their patients, despite the fact that mercury urinary levels may be low;
- 7)that mercury amalgams can cause oral lichen planus, chronic gum inflammation, and contact dermatitis; and,
- 9)that there is evidence to indicate that the mercury emitted from amalgam tooth fillings may be of more significance to people with kidney impairment, neurological and immunological disorders than to a healthy individual.

I would be willing to work with the Department on drafting this letter if it is requested. I do network with several doctors here in town who are familiar with mercury poisoning.

ENVIRONMENTAL

Internationally, governments recognize that mercury is a persistent toxic substance. One tablespoon in a body of water the size of a football field and 4.6m deep, is enough to render fish in that water unsafe to eat. Birds are especially sensitive to mercury pollution.

In Canada, the total quantity of Hg sold by the five amalgam manufacturers in 1994 was 2129.5kg (Richardson report). Using a conservative average urinary and faecal excretion rate of 60 micrograms mercury/day (FASEB, April 9, 1995) and applying it to the approximately 12 million Canadians who have amalgam fillings, would indicate that .72kgs of mercury are excreted every day. That's 262.8kgs per year (a lot of tablespoons). Where is the rest going? Some of it is going up in smoke. Elevated mercury levels have been noted around crematoriums. Some is discharged into sewer systems from dental offices. It is significant to note that in Seattle, 14 percent of the local mercury load in the sewage system comes from the dental profession. The mercury concentrations were, in 1991, 750 times the local discharge limit. In addition, some solid waste is retrieved from the dental traps; scrap amalgam left over after the dentist completes filling the tooth; and, old fillings which have been drilled out must all be disposed of properly.

We have two concerns at the present time with respect to mercury amalgam and our environment. Since mercury is an environmental contaminate after all, and because alternative dental materials are available, it's entirely reasonable from an environmental perspective to phase out mercury amalgams.

The second concern is that baby boomers - the population with the largest number of amalgam fillings - are preparing for the big sleep. If the trend in Calgary is any indication, Canada will see an increasing amount of mercury pollution around crematoriums in the years to come. One of the Funeral Service centres here in Calgary reported that cremation accounts for 80 percent of the services provided, compared to 20 percent one decade ago!

There are several possible reasons given for this ("Boomers favouring cremation", **Calgary Herald**, March 1, 1995):

- 1) A traditional burial costs between \$5,000 and \$10,000. Cremation costs as little as \$1000;
- 2) as our society becomes more secular, people are moving away from traditional religious burials;
- 3) and, the price of land is escalating. Most city lots now provide for two burials in one plot;

As the baby boom generation ages, the death rate will increase. If the trend towards cremation here in Calgary is any indication of what will happen nationwide, atmospheric pollution of mercury around crematoriums will increase significantly in Canada. **It is reasonable for HC to issue a directive that all mercury amalgams be removed before cremation to reduce the threat to our environment.**

MEDICAL DEVICES REGULATIONS

Dental materials are placed in continuous contact with the absorptive surfaces of the oral mucosa, and mucosal tissues readily allow these materials to pass into the bloodstream and lymphatic system, thus gaining access to all the organs in the body. We feel that any dental material to be implanted in the mouth resulting in long term exposure (filling materials, crown and bridge materials, casting metals and denture materials, etc.) should be thoroughly tested for safety before they are allowed to become part of the human body.

Therefore, in the health interests of all dental patients, we request that Health Canada accept responsibility for public safety by requiring manufacturers to provide pre-market safety studies for these dental products. We believe that the current exceptions from pre-market review that exist for dental materials are ill-advised and inappropriate.

PUBLICATION OF THE RICHARDSON REPORT

There is obviously considerable interest in this issue, as evidenced by the number of copies of the risk assessment already distributed, the Environmental Health Directorate should consider publication of the Richardson report. It would then be readily locatable for Universities, researchers and the public.

CONCLUSION

It must be emphasized that there was no interspaces extrapolation involved in the calculation of the tolerable daily intake (TDI) for mercury vapour, as is routinely the case when toxicologists establish regulatory reference doses for humans. Dr. Richardson extrapolated from humans occupationally exposed to mercury vapour to other humans not similarly exposed. Despite this, we acknowledge that there is still some uncertainty in the key toxicological study used to calculate the TDI in the risk assessment; and, that this precludes making the distinction between health and disease for individual who exceed that TDI. However, we believe this risk assessment is based on solid scientific principles and that it alone is enough to warrant some restrictions on mercury amalgam fillings. Furthermore, taken together with the human and animal studies on the pharmacokinetics of mercury vapour at the organ, tissue, cellular and biochemical levels and the fact that many

of these studies show pathophysiology, it is clear that HC must be pro-active and err on the side of caution in order to protect the public. **Moreover, since the lack of safety data can not be excused and should not be a justification for maintaining the status quo, and because durable safe alternate material is, we recommend that Health Canada take the sensible approach and set a date to phase-out mercury amalgam fillings with some restrictions applicable now.**

To summarize many of the recommendations in this submission:

- 1) It is reasonable that Health Canada impose restrictions on amalgam placement for pregnant women and lactating women;
- 2) It is reasonable for Health Canada to restrict amalgam fillings in young children for both safety and practical purposes (tooth conservation), and to protect the small percentage of children that would still be exposed to a large body burden of mercury if amalgam fillings are not restricted;
- 3) Since mercury is a known neurotoxin and its effects are cumulative, restrictions on mercury amalgams are warranted for people with neurological disorders;
- 4) Since animal and occupational studies have shown that mercury can adversely affect the immune system and affect kidney function and because mercury accumulates in the kidney, amalgam should not be implanted in people with immunological disorders or kidney impairment.
- 5) The skill level (or more appropriately, the lack thereof) of many Canadian dentists should not be a determining factor in formulating government policy for restriction on amalgam fillings;
- 6) It is reasonable for the dental patient to have an information leaflet on the potential risks of mercury so that they can make an informed choice when it comes to choosing the filling which will become part of their body. It is necessary that HC take the initiative to prepare a "Dear Dentist/Patient" letter;
- 7) That Health Canada recognize sensitivity to mercury in amalgam as a medical disorder;
- 8) Since allergy and/or sensitivity to amalgam could be as high as 16.1% overall and much human suffering could be alleviated, it is reasonable that HC issue a "Dear Doctor" letter advising physicians to be on the lookout for mercury as an etiological or contributing factor in some of their patient's disorders.
- 9) It is reasonable for Health Canada to issue a directive that all mercury amalgams be removed before cremation to reduce the threat to our environment and therefore human health;
- 10) It is reasonable for Health Canada to phase-out mercury amalgams on environmental grounds;
- 11) Together with the risk assessment and the significant medical research which exists to date, it is reasonable for Health Canada to start phasing out mercury amalgams now;
- 12) To settle any lingering doubts and since the lack of safety data can not be exceeded and should not be justification for maintaining the status quo, it is reasonable for Health Canada to demand that manufacturers provide (and pay for) biological evidence of safety within a specified time frame.
- 13) In the health interests of all dental patients, we request that Health Canada accept responsibility for public safety by requiring manufacturers to provide pre-market safety studies for all dental products which are implanted in the mouth. We believe that the current exemptions from pre-market review that exist for dental materials are ill-advised and inappropriate.

Appendix IV
Submission of
Dental Amalgam Mercury Syndrome Canada

Cynthia Saville, CBA
President, DAMS Canada
Toxic-free Dental Consultant

March 4, 1996

Dr. Richard Tobin, Director, Medical Devices Bureau
Environmental Health Directorate, Health Protection Branch
Room 1605, Statistics Canada Main Bldg.
Postal Locator 0301H1
Ottawa, Ontario
K1A 0L2

Dear Dr. Tobin

Thank you for inviting DAMS Canada to submit an alternate position and recommendations regarding the use of mercury amalgam in Canada.

Due to the toxic nature of mercury, its negative effects on human health and its contribution to pollution in our environment, we believe that mercury used in dentistry should be phased out as soon as possible and facilities made available to the public for education and treatment for symptomatic individuals. Our recommendations are as follows:

1) STAGED ELIMINATION OF MERCURY AMALGAM

a) immediate discontinuation of mercury amalgam use in female patients (the body burden of mercury in females will stay in their bodies past childbearing age, therefore, mercury amalgam should not be placed in females unless they have reached menopause. Mercury amalgam should not be placed in male patients who plan to father children in the future, since the female is the recipient of the male body fluid (sperm).

b) discontinuation of use in children. (University of Pittsburgh recent research implicates heavy metals as a cause of behaviour problems in children due to the interference in the development of the central nervous system, which in turn leads to learning disabilities, restlessness and attention deficit).

c) mercury amalgam phased out or no longer used in Canada by the year 2000

Dr. Richardson's report gave TDI levels which he felt was the level at which neurologic symptoms could be observed. His findings may be accurate, however, some individuals suffer irreversible damage with 4 fillings.

2) INFORMED CONSENT

a) warning posters displayed in all dental offices. They must state that:

- mercury amalgam is used in this office.

- amalgam contains 50% mercury

- mercury is a neurotoxic substance known to cause neurologic dysfunction, birth defects and other reproductive harm.

3)Dental Devices Division

a) manufacturers and the dental regulating associations have failed to advised and protect public health, therefore, a dental devices division should be established to monitor all dental devices and materials. b) a reaction hotline (1-800#) should be made available to the public, hospitals, and medical practitioners.

The CDA president, James Brookfield, contends that a very small portion of the population (approx.2%) is allergic to mercury amalgam. The Canadian population is approx. 27.2 million people which means that 544,000 people react to amalgam. Many scientists report a much higher figure. How many people react to their dental restorations and do not know their symptoms are a reaction to their dental work? Most doctors would not suspect dental restorations as the culprit.

4)ENCOURAGE MANUFACTURERS TO USE AND DEVELOP BIOCOMPATIBLE MATERIALS

a)eliminate the use of metals which are used to develop restorative dental materials. Nickel, copper and a host of other metals are used to manufacture dental restorations. The longevity of these restorations is outstanding, however, the human body does not tolerate these foreign metals well.

5)DIAGNOSTIC AND TREATMENT CENTRES

a)Encourage the development of heavy metal treatment centres across Canada. Testing and treatments must be paid for by Provincial Health Care Programs.

b)The exchange of dental materials to biocompatible restorations must also be done prior to treatment and is crucial for the individuals recovery. This dental exchange must be paid for by our socialized health care program. A physicians report should specify the need for the exchange and indicate a positive response to metals ie. MELLISA testing. This will provide access to people of all means.

c)Encourage expansion of training for medical personnel to better recognize and more safely and successfully treat the toxic effects of mercury amalgam poisoning.

The amalgam clinic in Sweden, has helped hundred's of symptomatic individuals to regain their health. Results will be published in April '96. Please review Dr. Lindvall's paper which I presented at the Stakeholder meeting in February '96.

Enclosed is a copy of a recent Mercury Conference that was held in Florida. I recommend that Health Canada organize a similar conference to help educate the public, and the medical/dental community, about the prevalence and consequences of using mercury in our environment.

I am sending more literature to you by mail. I truly hope our recommendations will help Health Canada to change legislation regarding the use of dental materials in Canada.

Please forward copies of all literature to Mr. Dingwall and the Provincial Health Care Ministers.

Sincerely,

Cynthia Saville
President, DAMS CANADA

Appendix V

Submission of
International Academy
of Oral Medicine and
Toxicology

HEALTH CANADA RISK ASSESSMENT OF DENTAL AMALGAM MERCURY

INTERNATIONAL ACADEMY OF ORAL MEDICINE AND TOXICOLOGY POSITION

The International Academy of Oral Medicine and Toxicology (IAOMT) believes that the dental amalgam risk assessment by Dr. Mark Richardson was conducted in a careful and conscientious manner with methods appropriate for this type of risk assessment. It is appropriate to conclude that a TDI set using this approach represents a valid consideration for risk assessment, specifically that offer general population exposure to mercury from amalgam dental fillings.

POLICY RECOMMENDATIONS TO HEALTH CANADA

1) Scientifically, it is undeniable that mercury, especially in its vapour form, is extremely toxic and that the presence of amalgam dental fillings provides a continuous daily exposure to patients. No expert mercury toxicologist is willing to go on record stating a level of exposure to mercury vapour below which no harm will occur. Further, there now exists sufficient evidence that dental amalgam derived mercury may contribute to immunological, neurological or kidney disease in human populations. This information should be communicated forthwith to members of the dental and medical professions as well as to the citizens of Canada.

2) Sufficient clinical evidence now exists to indicate that some portion of the population will have positive health benefits from the removal of existing amalgam fillings. Health Canada should establish guidelines for physicians and dentists for the evaluation of exposure to mercury, including the distinction between hypersensitivity (allergy) and sensitivity (relative susceptibility to a toxin). These guidelines should include directions for risk assessment, which might include the Protocol established by IAOMT.

3) All individuals have the right to participate in the selection of the materials that will be placed in their mouth, particularly if that placement results in the continuous exposure to a material known to be toxic. Health Canada should ensure the utilisation of "right to know" and "freedom of choice" for the citizens of Canada where risk has been established, as it has for mercury exposure from dental amalgam. Further, a formal reporting system for adverse effects to dental materials should be established, including a specified periodic follow up in cases where dental materials have been eliminated or replaced.

4) Funding should be made available to support further research on the use of dental amalgam or alternatives. This research should focus on human evaluation and be under the strictest of supervision of Health Canada to ensure adherence to vital criteria, such as the proper utilization of controls and valid selection of medical evaluation and testing.

5) In view of the extensive clinical and experimental evidence questioning the safety of dental amalgam, Health Canada should immediately initiate a policy to phase out the use of the material. Initial consideration must be directed to cessation of its use in children and pregnant or nursing females. Consideration should also be directed to individuals with kidney, neurological, or immunological disorders.

6) The cost benefit of eliminating the use of dental amalgam must also be addressed. Valid documentation has demonstrated that the use of bonding with dental composite restorations strengthens remaining tooth structure, thereby reducing the risk of tooth fractures and subsequent need for expensive reconstruction. It is also documented that the "spreading" characteristics of dental amalgam encourages tooth fracture and the need for expensive reconstruction. Further, cavity preparation for dental composite is far more

conservative, thereby preserving sound tooth structure. These factors would contribute to a considerable reduction in dental health care costs derived from the elimination of exposure to mercury. Health Canada should encourage the preventative benefits of the use of composite over that of amalgam for dental fillings.

This date, 20 February 1996,

Walter W. Pressey, D.D.S.
Executive Vice President

Appendix VI
Submission of
Pollution Probe

February 22, 1996

Dr. Richard Tobin, Director, Medical Devices Bureau
Environment Health Directorate, Health Protection Branch'
Room 1605, Spastics Canada Main Building
Postal Location 0301H1
Ottawa Ontario K1A 0L2

Re: Resignation from the Dental Amalgam Committee on the Safety of Dental Amalgam

Dear Dr. Tobin:

It is with much regret that I must inform you of my resignation from the Dental Amalgam Stakeholder Committee on the Safety of Dental Amalgam.. Both Health Canada's representatives and the pro-amalgam majority in the Committee have failed to address the real issue and reason for the existence of this Committee,; that is, to evaluate the use of mercury (a known poison) in dental restoration materials. Despite the title of your final policy recommendations, **Committee Consensus Position Regarding Policy Recommendations to Health Canada**, there was no consensus on the final set of recommendations, and nt all of the policy recommendations were passed unanimously. The Committee has also failed to address the following concerns:

- 1) That mercury vapour, released from dental amalgam, is a well-known heavy metal poison and potentially hazardous to human health.
- 2) That all amalgam bearers are at risk because of continuous exposure to low levels of mercury vapour form their dental amalgam.
- 3) That the recommendation of a gradual phase-out of dental amalgam for all Canadian, and especially for populations at risk including children, pregnant women, and lactating mothers was not included in final recommendations.
- 4) That the use of mercury in dental practices will put the health of all Canadians at risk by discharging mercury - contaminated effluent from the dental offices to the sewage treatment plants and form there into air, water, and ultimately into human bodies via inhalation of contaminated air and consumption of contaminated water and fish.

Pollution Probe, through its Mercury Elimination and Reduction Challenge project, is committed to the phase-out of all deliberate use of mercury (including mercury in dental amalgam). Pollution Prove will not compromise the health of the Canadian public and the health of the environment in favour of the amalgam industry and the Canadian Dental Association. Therefore, we request that our name be taken off the list of stakeholders and the consensus document produced as a result of this two day meeting.

Sincerely,

Susan Sang, Ph.D.
Toxic Researcher

cc: The Honourable David Dingwall, Minister of Health
Dr. Philip Neufeld, Chief, Research and Surveillance Division, Medical Devices Bureau
Dr. Murray Vimy, Clinical Associate Professor, University of Calgary
Dr. Walter Pressey, V.P., International Academy of Oral Medicine & Toxicology

Ms. Cynthia Saville, representative, Dental Amalgam Mercury Syndrome, Canadian Chapter
Ms. Geraldine Wilson, President, Citizen for Mercury Free Dentistry
Ms. Elke Babiuk, Director, Health Action Network Society

March 1, 1996

Dr. Richard Tobin, Director, Medical Devices Bureau
Environment Health Directorate, Health Protection Branch'
Room 1605, Spastics Canada Main Building
Postal Location 0301H1
Ottawa Ontario K1A 0L2

Re: Dental Amalgam Stakeholder Committee on the Safety of Dental Amalgam

Dear Dr. Tobin:

Thank you for your telephone call on February 22, 1996, in response to Pollution Probe's resignation from the Dental Amalgam Stakeholder Committee. We appreciate your invitation to continue working with Health Canada, concerning the safety of amalgam and are reconsidering our position.

Mercury has been identified as a persistent toxic substance by the federal government under the Priority Substances List (PSL) of the Canadian Environmental Protection Act (CEPA), the Ontario Ministry of Environment and Energy (MOEE), the Tier I substances of the Canada Ontario Agreement (COA), and the International Joint Commission (IJC) under the Great Lakes Water Quality Agreement (GLWQA). The MOEE lists mercury as one of 27 chemicals targeted for bans and phase-out, while the IJC identified mercury as one of 11 Critical Pollutants. Mercury concentrations in occasional samples of water, sediments and biota of Lakes Superior, Erie, and Ontario, the St. Mary's River System, and the St. Clair/Detroit River System have often exceeded the current Provincial Water Quality Objectives (PWQO) and Great Lakes Water Quality Agreements (GLWQA), sediment quality and sport fish or other biota criteria in localized areas (200ng/L, 0.2mg/kg, and 0.5mg/kg respectively). Similarly, concentrations in sediment and biota in Lake Huron, the Niagara River, and the St. Lawrence River have also exceeded the current criteria.

Given the clear position of the government's in Canada and internationally, Health Canada must acknowledge that mercury is a serious human health and environmental threat and that the goal of the Committee should be to work toward the phase-out of mercury. Following are our specific recommendations for use of mercury in dental amalgam:

- 1) We firmly believe that Dr. Richardson's report is scientifically sound and that his methodology used for risk assessment is accurate and scientifically valid. His report is the only well research document presently available in Canada. We recommend that Dr. Richardson's report be considered in the future for dental amalgam development.
- 2) We disagree with setting any **Tolerable Daily Intake (TDI)** for mercury, we believe that: **there is no safe level of mercury. No one has actually shown that there is a safe level**, as stated by the World Health Organization(WHO).
- 3) There is indisputable scientific evidence including animal studies, and human case studies, that point to dental amalgam as a potential health hazard. Therefore we recommend that Health Canada immediately issue a policy announcing the planned phase-out of dental amalgam, in particular for the sensitive portion of the Canadian population (including children, pregnant women, lactating mothers, and individuals with kidney diseases and neurological and immunological disorders). Further, we recommend gradual

phase-out of dental amalgam of all amalgam bearers in Canada.

4) We recommend that Health Canada issue a health hazard warning of mercury use in dental amalgam , posted in all dental and medical doctor's offices.

5) We recommend that the Canadian Dental Association, and all dental schools, in association with the International Academy of Oral Medicine and Toxicology, provide proper protocol to their members and to students for the removal of dental amalgam, so amalgam can be removed safely without further endangering the health of patients and dental personnel.

6) We recommend that proper procedures be taken by dentists in disposing of the dental amalgam, to prevent further contamination of the environment.

We appreciate the efforts that you are making to address the dental amalgam issue. We hope that by working with Health Canada and other concerned organizations, together we can bring about a practical solution to this sensitive issue, which will be advantageous to all Canadians.

Sincerely,

Susan Sang, Ph.D.
Toxic Researcher, Pollution Probe

cc: The Honourable David Dingwall, Minister of Health
Dr. Philip Neufeld, Chief, Research and Surveillance Division, Medical Devices Bureau
Dr. Murray Vimy, Clinical Associate Professor, University of Calgary
Dr. Walter Pressey, V.P., International Academy of Oral Medicine & Toxicology
Ms. Cynthia Saville, representative, Dental Amalgam Mercury Syndrome, Canadian Chapter
Ms. Geraldine Wilson, President, Citizen for Mercury Free Dentistry
Ms. Elke Babiuk, Director, Health Action Network Society

Appendix VII
Submission of
Citizens for Mercury Free Dentistry

22 February 1996

RECOMMENDATIONS

1. If the medical, physiological, toxicological and other pertinent branches of the scientific community cannot agree within itself on the safety of mercury-containing amalgam, it is the moral duty of Health Canada to halt its use and encourage safe replacement of existing amalgams. Anything else would be the taking of an arbitrary position. 160 years of scientific debate is sufficient. The issue of validation belongs to the scientific community to resolve. In the meantime no risks can be taken with human health, purely on the say-so of the vested interest community.

Under current HPB guidelines, as pointed out by Dr. Vimy, mercury-containing amalgam would be prohibited entry to the Canadian market.

No confusion with "aspirin" should be made. Aspirin is usually and intended to be "occasional dose" medication. Mercury vapour is constant, 24-hour, lifetime exposure.

It has been acknowledged by all groups that at the very least, some people are more susceptible than others, and symptoms can take upwards of 30 years to manifest. It has also been acknowledged that there exists no current method to determine who those people are, nor when symptoms will occur. On this basis as well, mercury-containing amalgam should be banned, as these people run a 100% risk of poisoning.

2. That it be recommended that existing mercury amalgam fillings be replaced safely.

3. That dental schools retain in resin placement techniques and correct amalgam removal protocol for the client's safety as well as that of the dental personnel.

4. That medical and nursing schools be encouraged to train and retrain their doctors and nurses to recognize possible toxicity symptoms and also train in detoxification protocol.
5. That present review criteria on all dental restorative materials be urgently reviewed.
6. "Preventive" health care costs of mercury amalgam removal should be borne by the dental community/associations and the amalgam manufacturers for those people whose dental plans will not cover the cost and for those who have no dental plan.
7. A federal committee or agency be create to monitor for identify existing comprehensive detoxification programs so that those acknowledged "few" susceptible people, who are now among us, can receive much needed help.

G. Wilson
CFMFD

