From the Science Committee of FDI World Dental Federation

Honorary Minister,

Summary
The Science Committee of the FDI World Dental Federation encourage you strongly to reconsider the plans of banning dental amalgam in Sweden. We believe banning dental amalgam will greatly impact on individuals' abilities to receive optimal oral care. There are no acceptable, nor cost-effective material alternatives. Furthermore, a possible ban raises questions of both equity and ethical problems. Moreover, environmental considerations should not warrant a ban. Finally, the Swedish Chemical Inspectorate (KemI) 2004 Report, which the decision has been based on is unbalanced. For lack of better therapy options in special circumstances, toxicity and equity issues, the ethical problems induced on the care provider and environmental considerations the decision from the KemI 2004 Report seems ill-advised.

We take the liberty to address you as we are deeply concerned after reading on the website of the Swedish Chemicals Inspectorate (KemI) that the Swedish Government has proposed a ban from January 1 2007 on dental amalgam as a consequence of a complete ban on the manufacturing and handling of mercury in Sweden.

Banning dental amalgam is neither necessary nor desirable. In our opinion, such rigorous and poorly substantiated regulation jeopardizes dentists' obligation to provide adequate care to patients, especially the frail or underserved individuals. We would strongly caution against banning dental amalgam in Sweden as we believe it will negatively affect the oral health of its citizens.

The Government proposal seems to be based on the KemI report from June 2004 (KemI 2/04). We are aware that the Swedish Dental Association (SDA) has been consulted and has provided professional guidance in the preparation of this report. However, it appears that the SDA's objection to the complete ban of dental amalgam coming into full effect from 31 December 2009 has been ignored, which is regrettable.

Dental restorative material alternatives
In the KemI 2/04 report, a remarkably large proportion of references pertaining to the usage and experiences of dental amalgam are not scientifically substantiated, but are "personal communication" claims.

Claims that purport that there are now acceptable alternatives to dental amalgam for all treatment situations and operative conditions are false and misleading and not supported by scientific research.

We challenge the scientifically unsupported “personal communication claim“ in the KemI report which suggests that alternative restorative materials can be used for frail patients. For frail individuals the dentist will be forced to choose options between extraction of teeth, with an inherent risk of critical medical complications, versus repeated replacements of inadequate restorations due to operational difficulties with such patients. Many hospitalized patients cannot tolerate lengthy treatment sessions which are required when using alternative materials for dental restorations. Moreover, some patients with special needs, such as short treatment time, will need to be treated under general anesthesia, which besides risk of medical complications causes moisture control difficulties. In these circumstances the dental amalgam restoration will be the best alternative

Toxicity

There are no responsible professional dental associations anywhere in the world that supports a ban on dental amalgam. Researchers have spent years to elucidate toxicological concerns with dental amalgam and other biomaterials. Multiple systematic reviews and national reports unequivocally conclude that there are minimal or no health risks to patients from dental amalgam. The latest research in this respect reinforces the view that amalgam is a safe and efficacious material for children and adults.

The joint FDI World Dental Federation/World Health Organization (FDI- WHO) statement on dental amalgam from 1997 is in effect and can be found on our FDI website:
http://www.fdiworldental.org/federation/assets/statements/ENGLISH/Amalgam/Dental_amalgam.pdf . We are enclosing a copy of the statement for your information.

Recent scientific studies that support the safety of dental amalgam include the following:

Mercury derived from dental amalgams and neuropsychologic function. Factor-Litvak P, Hasseelgren G et al. Environmental Health Prospectives 2003; 111:719-723.

The potential adverse health effects of dental amalgam. Brownawell AM, Berent S et al. Toxicologic Reviews 2005; 24:1-10.

Neuropsychological and renal effects of dental amalgam in children – a randomized clinical trial. Bellinger DC, Trachenberg F et al. Journal of the American Medical Association 2006; 295:1775-1783.

Neurobehavioral effects of dental amalgam in children – a randomized clinical trial. DeRouen TA, Martin MD et al. Journal of the American Medical Association 2006; 285:1784-1792.

Equity
Dental amalgam is without doubt the restorative material that enables the maximum number of people to afford dental restorative care. As a wealthy country, Sweden has chosen to subsidize dental restorations made from any non-amalgam material, which is reflected in the remarkable low usage of amalgam in Sweden. Still, we believe that banning dental amalgam in Sweden will have a significant negative effect on the oral health of some segments of its population, especially amongst the poorer socioeconomic levels. Moreover, allocating scarce health funds to subsidize more expensive restorative materials than amalgam is a priority of funding that is difficult to uphold in societies with more pressing population health issues. It is not improbable that other, and less affluent, countries will follow Sweden's example to ban amalgam and thus force dentists to use more expensive restorative materials that will remain non-affordable for most of its citizens.

Ethical problem
A Governmental decision to ban dental amalgam can place Swedish dentists in a difficult ethical situation versus their patient under certain treatment circumstances. The dentist may in such situations be forced to choose between extracting the patient's teeth, place inferior restorations or leave the defective tooth un-restored.

We are alarmed that a country like Sweden, which has a historical record of concern for the least resource-strong segments of the population seems to embark on a route that disregard their needs, under a guise of "overruling environmental considerations".

Environmental considerations
The concern about bioaccumulation of organic mercury in the ecosystems is of course shared by us all, but banning dental amalgam for such reason seems completely out of proportion as the health loss will be significant.

Dental associations in many countries have consciously and proactively worked together with environmental agencies to mandate measures that eliminate uncontrolled amalgam waste from dental offices. Numerous scientific studies have documented that such measures reduce amalgam waste to minimal levels. All forms of amalgam waste, both contaminated and unused, can today be recycled using modern recycling technologies.

The mercury release from uncontrolled amalgam waste and from non-filtered crematoriums should not be ignored. However, banning dental amalgam will greatly impact on individuals' abilities to afford dental care, while the effect on

mercury pollution into the environment will be insignificant. Mercury is a naturally occurring contaminant to natural gas and petroleum and contaminates systems that process hydrocarbons. Far more important mercury-reducing strategies should rather be directed towards reducing the enormous amounts of mercury that is emitted into the atmosphere when coal is burned in power plants and from the combustion of automotive and housing fuels in modern society.

The Swedish Chemical Inspectorate (KemI) Report

Based on our own concerns for much of the contents in the KemI 2004 Report, we have consulted with researchers in the international community. We enclose comments that we have received as an attachment to this letter. They are in general support of feeling that this KemI report is unbalanced. Moreover, it ignores current scientific knowledge on dental materials and their appropriate uses. Finally, and most importantly, it does not give due consideration on the oral health and welfare of the patients, especially the frail or underserved individuals.

In summary, we would strongly encourage you to reconsider the plans of banning dental amalgam for the reasons stated above. For lack of better therapy options in special circumstances, toxicity and equity issues, the ethical problems induced on the care provider and environmental considerations the decision seems ill-advised. The FDI World Dental Federation's Science Committee endorses the Swedish Dental Association's stance on this matter, which we know is shared by a vast number of other national dental associations worldwide.

Copy:
Minister for Health and Elderly Care. Ylva Johansson, Stockholm
National Chemicals Inspectorate, Sundbyberg
The National Board of Health and Welfare, Stockholm.

* The Federation Dentaire Internationale, FDI, is the global federation of National Dental Associations. FDI's main roles are to bring together the world of dentistry, to represent the dental profession of the world and to stimulate and facilitate the exchange of information across all borders with the aim of optimal oral health for all peoples.

Table 1. Comments from the international research community regarding the Swedish Chemicals Inspectorate KemI report.

KemI prepared a report “Mercury – investigation of a general ban” in response to a commission from the Swedish Government. The 2004 report reviewed the use and choice of dental materials, patient needs for restorative materials, alternative dental procedures to amalgam placement including extraction of teeth, environmental considerations, cost and dentist training. It concluded with a proposal that dental amalgam should be covered by a general national ban.

There are several instances where the conclusions of the report do not accurately reflect facts, the knowledge of the dental profession or current scientific information. The KemI report does not reflect any of the information provide by the Swedish Dental Association and the Association of Hospital Dentists. More personal communications are cited than reference to scientific literature. The qualifications of the persons cited or their special interest are not given in the report. Most importantly, the report places little or no consideration of the resultant oral health and welfare of the patient.

A 2002 survey conducted by Statistics Sweden for the Dental Materials Investigation reported that 33% of dentists do not consider that there are currently satisfactory alternatives to amalgam (page 32). The report does not provide reference to scientific based conclusions whether there are satisfactory alternatives to amalgam to cover all cases. Even the report’s conclusion stated that there may be a few situations the use of amalgam on adults patients in hospitals is the only alternative to extracting the tooth, which in some cases may be unethical (page 42), nevertheless the report proposes a general ban of mercury to include amalgam.

On page 32, the report also suggests that if amalgam is considered the tooth’s future importance for the biting function should be tested since removal of the tooth can in certain cases be a better alternative than repairing it with amalgam. This statement is not supported by any reference. It is quite unlikely that extraction of a tooth is preferred over the placement of a restoration irrespective of the type of restorative materials used.

The report indicates that for normal dental care it is the judgment of KemI and the national Board of Health and Welfare that a ban on amalgam will not lead to any adverse effects on treatment (page 35). The report, however, does not give information on how this judgment was arrived at or the scientific basis of this judgment. Two recent publications reported that amalgam restorations last almost twice as long as composite restorations. Tyas reported that the average age of amalgam and composite restorations at replacement are 13.6 years and 7.1 years respectively (Tyas MJ, Placement and replacement of restorations by selected practitioners. Australian Dental Journal J 2005; 50:81-89.) Forss and Widstrom reported that the median age of failed restorations was 15 years for

amalgam and 6 years for composite (Forss H. Widstrom E. Reasons for restorative therapy and the longevity of restorations in adults. Acta Odontologica Scandia 2004; 62:82-86.)

On page 35 of the report stated that the Swedish Dental Association and the Association of Hospital Dentists do not consider the use of mechanical methods of suction, cotton rolls or rubber dams to be sufficient in maintaining a dry field in some cases of patients with special needs. A ban on the use of amalgam would therefore mean that in the case of these patients teeth would need to be extracted instead of repairs. Yet the conclusion of the report to ban amalgam does not reflect the concerns expressed by these two professional organizations.

The Swedish Dental Association and the Association of Hospital Dentists maintain that it is necessary to use amalgam for some patients that are intubated via the mouth instead of the nose (Page 36). The conclusions of the report do not reflect the concerns expressed by these two professional organizations.

The report states that the Swedish Dental Association and the Association of Hospital Dentists fear that a ban on amalgam would mean an increase in the number of episodes of general anesthesia per patient (page 36). The report takes the position of the Specialist Clinic for Anesthesia which rejects this concern.

On page 36 the report cited the International Academy of Oral Medicine and Toxicology (IAOMT) that “there is no problem with gaps in the case of a correctly performed composite filling.’ IAOMT is a well known anti-amalgam organization. No reference to scientific literature on this issue is cited in the report. Current scientific literature shows that amalgam restorations provide comparable or longer service than composite restorations. The two references in the previous paragraph are examples of studies reported in the scientific literature.

On page 37 the report states that for patients who are treated within the hospital dental service and who for medical reasons cannot be anesthetized the effects of a ban could be that the treatment takes longer and is more stressful, according to the Association of Hospital Dentists. Yet the KemI report concluded to propose a general ban on amalgam. This is a total disregard to the welfare of these patients.

The report states that dentists and dental nurses would reduce their exposure to amalgam if a ban were introduced (page 37). Occupational exposure to mercury vapor can be minimized by the practice of dental mercury hygiene such as described by the FDI World Dental Federation (FDI Statement, Recommendation for Dental Mercury Hygiene 1998). It is not necessary to reduce exposure by imposing a general ban that includes a ban on amalgam.

On page 40 the report cited that for patients with financial difficulties the impact of a ban on amalgam can become apparent if the only alternative to a new gold or porcelain crown is to extract the tooth. Tooth extractions simply because amalgam is banned would not be in the best interest of the patients irrespective of financial status. This is a blatant example of the KemI report does not consider the ban of amalgam on patients.

Page 42 of the report states that for patients with difficulties the impacts can be significant if amalgam is not available and the choice is therefore between a new gold or porcelain crown and extraction of the tooth. It ought, however, to be possible to limit such adverse effects within the framework of the dental insurance scheme and they should not prevent such a ban. Here the report acknowledges the problem but deflects the solution to dental insurance. As a solution by dental insurance is not yet addressed it is irresponsible for the report to propose banning amalgam.

The report concludes on page 42 that the mercury used in amalgam ends up in the natural environment in one way or another. This statement ignores that recycling of amalgam waste as recommended in best management practices for amalgam waste would minimize amalgam discharged to the environment. The recycling of amalgam scrap, used disposable capsules, extracted teeth with amalgam restorations and amalgam waste retained in chairside tarps, vacuum pump filters and amalgam separators would result in the majority of mercury used in amalgam not discharged to the environment. A mass-balance based study estimated that in the United States 78% of mercury in the form of amalgam in dental waste water is retained by chairside traps and filters (Vandeven JA, McGinnis SL. An assessment of mercury in the form of amalgam in dental wastewater in the United States. Water, Air and Soil Pollution 2005; 164:349-366.) This mercury in the form of amalgam would not be discharged to the environment when chairside traps and filters are recycled.

The report also concludes that from a health point of view there is every reason to apply a precautionary approach. This is contrary to the health care approach where considerations are based on benefits and risks. The safety of amalgam is well established. Two recent articles in the Journal of the American Medical Association further support the safety of amalgam (Bellinger DC, Trachtenberg F, Barregard L, Tavares M, Cernichiari E, Daniel D, McKinlay S. Neurophyschological and renal effects of dental amalgam in children amalgam in children – a ramdomized clinical trail. Journal of the American Medical Association 2006; 295:1775-1783. Derouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitao J, Castro-Caldas A, Luis H, Bernardo M, Rosenbaum G, Martins IP. Neurobehavioral effects of dental amalgam in children – a randomized clinical trial. Journal of the American Dental Association 2006; 295:1784-1792.)

In summary, the Swedish Chemicals Inspectorate (KemI) report does not accept inputs from professional associations such as the Swedish Dental Association, lacks scientific basis, and ignores the welfare of the patient.

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23rd June 2006

To: Minister for the Environment
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The National Board of Health and Welfare
S-106 30 Stockholm

Honourable Minister,

The FDI World Dental Federation has learnt with concern about the proposals to ban the use of dental amalgam in Sweden.

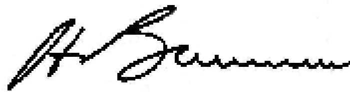
The FDI's Science Committee has drafted a brief report which is attached hereto. In summary the report states the following:

Summary
The Science Committee of the FDI World Dental Federation encourage you strongly to reconsider the plans of banning dental amalgam in Sweden. We believe banning dental amalgam will greatly impact on individuals' abilities to receive optimal oral care. There are no acceptable or cost-effective material alternatives. Furthermore, a possible ban raises questions of both equity and ethical problems. Moreover, environmental considerations should not warrant a ban. Finally, the Swedish Chemical Inspectorate (KemI) 2004 Report, which the decision has been based on, is unbalanced. For lack of better therapy options in special circumstances, toxicity and equity issues, the ethical problems induced on the care provider and environmental considerations the decision from the KemI 2004 Report seems ill-advised.

The FDI supports its Member Association, the Swedish Dental Association, in speaking against the proposed ban.

Should you require more information, please feel free to contact me or the FDI Scientific Affairs Manager, Professor Asbjørn Jokstad (science@fdiworldental.org), the key author of the report.

Yours faithfully,



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