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NEW SOUTH WALES

MINISTER FOR HEALTH

M05/6388

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Ms Jan Burnswood MLC
Committee Chair
Stranding Committee on Social Issues
Parliament House
SYDNEY NSW 2000

Dear Ms Burnswood

I write in response to your letter concerning the Inquiry into Dental Services in New South Wales being conducted by the Standing Committee.

The additional information required on technical issues associated with fluoridation that were raised in the open forum which was held recently in Port Macquarie is attached.

Yours faithfully

(John Hatzistergos)

Locked Mail Bag 961 North Sydney NSW 2059

Attachment

1 The University of York review of fluoridation evidence in the United Kingdom suggests that evidence in favour of fluoride is poor (refer to p40 of attached manuscript). What is NSW Health view on this comment and does the evidence on fluoride meet the Cochrane Standards (refer p39)?"

The classic Cochrane Standards are used to rank evidence for the effectiveness of individual clinical trials on the basis of five levels (I, II-1-3, III)

I. evidence from one or more properly conducted randomised controlled trials (i.e. A clinical study which uses concurrent controls, double-blind design, placebos, valid and reliable measurements, and well-controlled study protocols.)

II-1.evidence obtained from one or more controlled trials without randomisation (i.e. Studies using systematic subject selection, some type of concurrent controls, valid and reliable measurements, and well-controlled study protocols).

II-2 evidence from one or more well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 evidence obtained from cross-sectional comparisons between times and places; studies with historical controls; or dramatic results in uncontrolled experiments (e.g. the results of the introduction of penicillin).

III opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports or expert committees.

The University of York review included studies on the basis of their selection criteria and then graded "the evidence" into three categories:

Level A: highest quality of evidence, minimal risk of bias. Prospective studies that started at either initiation or discontinuation of water fluoridation and had followed positive findings for at least two years and negative findings for five years; studies which have addressed three possible confounding factors and made corrections in the analyses where appropriate; and studies with the lowest bias where the primary outcomes were blind to both examiners and participants.

Level B: evidence of moderate quality, moderate risk of bias. Studies that started with less than one year after fluoridation was initiated or discontinued and had a prospective follow up of outcomes; studies that measured and made corrections for less than three but at least one confounding factor; and studies that were not blind to examiners for fluoridation status, but made other provisions to prevent to prevent measurement bias.

Level C: lowest quality of evidence, high risk of bias. Studies of other designs (prospective or retrospective, concurrent or historical control) that met other inclusion criteria but failed to account for confounding factors or did not prevent measurement bias.

In 2000, the Australian National Health and Medical Research Council's (NHMRC) health advisory committee recognised the difficulties which could arise "when established methods from evidence-based medicine are used to evaluate research on public health intervention" (Rychetnik and Frommer, 2002). Subsequently the Australian National Public Health Partnership was commissioned to develop a Schema for Evaluating Evidence on Public Health Interventions and then trial the schema in applied settings. Three principles applied to judging the strengths, limitations and gaps in the available evidence for evidence-based practice:

a. Is the Public Health intervention known to be effective and does more good than harm?
b. Are the benefits and costs of the Public Health Intervention described and evaluated so that they can be weighted against other options for the use of resources?
c. People who make (or are affected by) evidence-based decisions about Public Health Interventions should be aware of the strengths, limitations and gaps in the available evidence.

The Cochrane Collaboration through the Cochrane Health Promotion and public health field collaboration (http://www.vichealth.vic.gov.au/cochrane/overview/index.htm) also recognised the limitations of the classic Cochrane standards as this applied to population interventions and that "*all evidence does not fit the Cochrane methodology*".

The public health field Cochrane Collaboration "does not contend that all health promotion and public health interventions must be justified by randomised controlled trials or a Cochrane review. This is a misconception that may have discouraged the involvement of health promotion and public health researchers in the Cochrane Collaboration. What the Field does claim is that many interventions do lend themselves to the methodology of a systematic review and in these cases we should strive for the most comprehensive review of the available evidence as possible. We also strive to ensure the content and process of a Cochrane review is reflective of the principles of health promotion and public health and contains information that is applicable and useable for health promotion practitioners and decision makers."

There have been a number of systematic reviews of water fluoridation including those by the US Preventive Services Task Force on Preventive Dentistry in 1989 and the Canadian Task Force on Personal Health Examination in 1994. The most recent and authoritative systematic review was conducted by the Centres for Disease Control and Prevention CDC).

Evidence on water fluoridation was graded as II-2 on the Cochrane Classification in the CDC Review. In addition, the CDC classified their recommendation on water fluoridation as Code A in a ranked five-code A-E system. Code A = Good evidence to support the use of the modality (in this instance, water fluoridation).

NSW Health endorses the views of both the National Public Health Partnership and the Public Health Field Cochrane Collaboration in acknowledging the limitations of strict application of the Cochrane Standards to public health interventions.

NSW Health does not accept that the evidence in favour of water fluoridation is poor.

NSW Health endorses the findings and recommendations of the US Public Health Service Centres for Disease Control and Prevention review (2001) that: "Community water fluoridation is a safe, effective, and inexpensive way to prevent dental caries. This modality benefits persons in all age groups and of all socioeconomic status (SES), including those difficult to reach through other public health programs and private dental care."

2. **Have there been any Australian studies to test the total dose of fluoride ingested which maybe adequate without fluoridation of public water? Should the NHMRC or other body do this test?**

There have been a number of reviews conducted in Australia that have addressed the issue of fluoride ingestion in people living in both fluoridated and unfluoridated areas.

Total intake of fluoride for children and adults living in fluoridated (1ppm) areas was estimated by an Expert Committee of the NHMRC in 1991.

Average fluoride intakes for Australian infants, children and adults was also estimated in a report commissioned for the NHMRC in 1999.

A report was also commissioned by the Department of Humans Services, Victoria to provide a review of the scientific evidence on the public health effects of water fluoridation was published in 2000. The comprehensive document entitled "Public Health Effects of Water Fluoridation" was prepared by Monash University Department of Epidemiology and Preventive Medicine and the Cooperative Research Centre for Water Quality and Treatment (Sinclair et al 2000). The report concluded that for older children and adults the estimated fluoride intakes fell into the recommended range of 50-70 microgram / kg body weight / day.

Conclusions on fluoride intake from the Monash report are similar to the conclusions from the 1991 and 1999 NHMRC Reviews. The NHMRC findings are reflected in their recommendations for reducing excessive fluoride intake by reducing the use of supplements and the level of fluoride in infant formulae and toothpaste.

During 2003 the NHMRC was approached by the National Advisory Committee on Oral Health (NACOH) to put fluoride on its next Triennium Work Plan but no action was taken. However, NACOH and NSW Health agreed to auspice a Workshop on "The Use of Fluorides in Australia" and resolved to seek the Australian Research Centre for Population Oral Health (ARCPOH) to organise such a workshop. This workshop was held on the 13 and 14 of October 2005 in Adelaide.

In Australia dramatic decline in decay rates in Australian children from one of the highest in the world in the 1950's to the second lowest in the OECD countries has been attributed to (Spencer 1986) water fluoridation (accounts for seventy percent of the reduction) and the use of fluoride toothpaste (accounts for 26 per cent of the reduction).

Studies nationally and internationally have demonstrated that populations that do not have access to fluoridated water have significantly higher caries experience than those living in fluoridated areas despite the universal availability of fluoride toothpaste and other forms of discretionary fluorides. In Australia differences of between 32% and 55% in the deciduous dentition and 20% and 65% in the permanent dentition have been found between fluoridated Townsville and non-fluoridated Brisbane (Slade et al., 1996).

In NSW caries experience in the deciduous dentition of 5-6-year-olds and the permanent dentition of 11-12-year-olds was significantly lower for children in fluoridated areas than non-fluoridated areas (Armfield 2005).

3. What is NSW Health view on the comments that:

a. Fluoride has a low therapeutic index but a risk of overdose which
b. Could cause dental or skeletal fluorosis and that
c. Some people are sensitive to fluoride

3a A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken, for therapeutic use. Fluoride is not a registered medicine and there is no requirement for the adding of fluoride to community water supplies to be registered as a medicine in Australia. Preparations containing less than 15mg/l or less fluoride do not require scheduling as drugs according to the National Drugs and Poisons Schedule Committee. Further, the Therapeutic Goods Administration has declared that the use of fluoride for the prevention of tooth decay, where the product is not required to be scheduled as a drug or poison, is not a therapeutic good.

NSW Health's view is that water fluoridation has a wide margin of safety.

Acute fluoride toxicity occurring from the ingestion of optimally fluoridated water is impossible because of the enormous volume of water needed to provide a sufficiently high dose (Whitford 1996, Department of Health and Children 2002). A dose of approximately 5mg/kg body weight may cause serious systemic toxicity, but this would require the ingestion of 50 litres of water fluoridated at 1mg/l (ppm) by a 1-year-old child and of 100 litres by a 5-year old child. The amount of fluoride necessary to cause death for a human adult (70 kg man) has been estimated to be 5-10 grams of sodium fluoride, ingested at one time (Hodge et al., 1965). In terms of the fluoride ion, this corresponds to an ingested dose range of between 32-64 mgf/kg of body weight (Whitford 1996). This is more than 9,655-19,310 times as much fluoride as is consumed at one time in a single 8-ounce glass of optimally fluoridated water.

NSW Health carefully monitors the performance of Sydney Water Corporation and all water utilities that fluoridate drinking water supplies.

The 2002 Code of Practice for Fluoridation of Public Water Supplies sets a fluoride target of 1 mg/litre and requires treatment plants to be designed to maintain this target. The Code of Practice requires Sydney Water Corporation (and all water utilities that fluoridate) to carry out daily tests of fluoride concentration at treatment plants and two tests per week in the distribution system. Sydney Water Corporation (and all water utilities that fluoridate) report the results of this testing to NSW Health.

Sydney Water Corporation (and all water utilities that fluoridate) are required to immediately notify NSW Health of any test result that exceeds 1.5 mg/l.

3b NSW Health's view is that water fluoridation at 1ppm does not cause skeletal fluorosis. Many substances used every day are very beneficial in small amounts, but may be harmful in large amounts. To help protect teeth against decay, only very small amounts of fluoride are needed in the water. The recommended level is about 1 mg/l, which means that every part of fluoride is diluted in about one million parts of water. Skeletal fluorosis is associated with chronic exposures of over 10 mg of fluoride per day for at least ten years. These cases maybe associated with industrial exposure or with unusually high fluoride levels in drinking water. Kaminsky et al 1990 reported no evidence of skeletal fluorosis in water fluoride concentrations lower than 4mg/l. Skeletal fluorosis has never been a problem in the United States, UK or Ireland even though for many generations there were many communities drinking water fluoridated at 1ppm (1990, Whitford 1996). In Australia there has been no reported case of skeletal fluorosis due to water fluoridation at 1 ppm.

Dental fluorosis has been defined as 'a dose response effect caused by fluoride ingestion during pre-eruptive development of teeth'. Dean (1942) reported that some 12 % of children in areas with 1ppm fluoride were affected by mild or very mild fluorosis, and that around 1% were affected in low fluoride areas. This historical standard of the prevalence of fluorosis was recorded when fluoride in water was the only main source. However, prevalence of fluorosis increased above the historical standards in both fluoridated and non fluoridated areas after the introduction of numerous fluoridtaed dental products (Spencer et al 1996).

Research conducted using children from Melbourne indicates that dental fluorosis has not increased since water fluoridation at 1.0 ppm was introduced in 1977, and the degree of dental fluorosis is within expected limits for a fluoridated community (Evans et al., 1998). The research found only 12% of 12-year-old children had very mild fluorosis.

While there is some evidence that fluoridation at 1ppm does increase the prevalence of dental fluorosis the extent of this increase is small with most fluorosis being only mild and with more severe fluorosis often the result of over-exposure to fluoride through fluoride supplements and excessive exposure to fluoride from inappropriate toothpaste consumption. Riordan (2002) showed that the increase in fluorosis prevalence was due to excess exposure to fluoride from supplements and toothpaste rather than to exposure to fluoride in public water supplies.

The view of NSW Health is that the risk of dental fluorosis is minimised by having policies in place aimed to reduce the inadvertent swallowing by young children of products that were high in fluoride and to restrict the use of fluoride supplements as a less effective caries preventive means. One of the objectives of the Workshop on "The Use of Fluorides in Australia" to be held in October this year was to review the evidence of the efficacy/effectiveness of a range of fluorides in caries prevention and their risks for creation of dental fluorosis, and to develop Guidelines for the Use of Fluorides in Australia.

3c NSW Health questions whether true sensitivity to fluoride exists. It is questionable whether true allergy to fluoride exists. Some people believe they are allergic to fluoride, but the symptoms they complain of could be due to many other causes. The weight of scientific evidence indicates that fluoride is unlikely to cause an allergic reaction (National Research Council 1993). Furthermore, given that fluoride is present in common foods, people proposing that they have an allergic reaction are essentially claiming an effect from an increase in the amount of fluoride they consume, not its presence versus its absence (NHMRC 1991).

4. Do only children (under 12) benefit from fluoridation and not adults?

Caries inhibitory effects of fluoride are not confined to childhood (Burt and Eklund 2005). Water fluoridation provides benefits to individuals of all ages.

Studies of fluoridation's effects in adulthood began early with McKay's recognition (in the 1940s) that 45 year old adults benefited from consuming fluoridated water (McKay 1948). Adults born and raised in naturally fluoridated Colorado Springs were found to have 60% lower caries score (decayed, missing, and filled teeth) and fewer missing teeth than their counterparts in non-fluoridated Boulder (Russell et al 1953).

In Australia a study of Australian Navy recruits showed significantly lower levels of caries experience in adults who had lived almost exclusively in areas with artificial water fluoridation compared to those from non-fluoridated areas (Morgan et al 1992). Benefits in Australian adults have also been documented by Hopcraft (2005).

Root caries are also less prevalent in fluoridated areas than non-fluoridated areas (Burt et al 1986, Stamm et al 1990). This finding is important, because with increasing tooth retention in an aging population the amount of root caries would otherwise be expected to increase and become a greater treatment problem in the future (Burt and Eklund2005).

Over a life-time fluoridation reduces root and coronal caries (Newbrun 1989, Grembowski et al 1997).

5. Is topical fluoride as effective as systemic fluoride?

Categorising fluoride compounds into systemic fluorides and topical fluorides is not easily done because the lines between these 2 categories gets blurred. 'systemic' vehicles like water fluoridation have shown to have topical cariostatic action, and some 'topical' vehicles like fluoride toothpaste can be swallowed inadvertently and have systemic effects.

The action of fluoride in preventing caries is multifactorial. Its effect comes from a combination of several mechanisms. The principal mechanisms by which fluoride inhibits the development of dental caries is summarised below:

Pre-eruptive
On pre-eruption exposure, fluoride is incorporated in the developing enamel into the crystal structure. On dissolution of enamel crystals triggered by an acid attack, fluoride incorporated in the structure can be released into the external fluid environment, combine with H ions (H-) and be transported at the same time as the acids to inhibit acid attack, thus having a major effect on inhibiting demineralisation and stimulating remineralisation.

Post-eruptive
Promotion of remineralisation and inhibition of demineralisation of early carious lesions. Inhibition of glycolysis, the process by which cariogenic bacteria metabolize fermentable carbohydrates.

While the post-eruptive action of fluoride relies mainly on the availability of fluoride in the plaque fluid, saliva and other oral fluids, the pre-eruptive effect is exerted by fluoride incorporated in the enamel crystal during tooth formation.

In Australia the importance of an important pre-eruptive role of fluoride is well documented (Singh et al 2003, Singh and Spencer 2004). This research shows that exposure to fluoride before eruption reduced caries levels significantly, the benefits was enhanced with ongoing exposure after eruption. For most tooth types both high pre and post-eruption exposure produce the greatest caries preventive effect. This research confirms that water fluoridation is important both systemically and topically.

Such a pre-eruptive role maybe best achieved through exposure to fluoridated water in contrast to other fluoride vehicles. The benefits of toothpaste, mouth rinses etc are related to factors such as financial availability, individual motivation, compliance all of which impacts on the social equity aspects of water fluoridation.

Since 1980s there have been numerous sources of fluoride available, toothpastes, mouth rinses, dietary fluoride supplements and professionally applied products. In spite of the availability and use of discretionary fluorides, particularly fluoride toothpaste, fluoridated water emerges as the most significant contributor to the reduced caries levels in Australian children in the Child Fluoride Study. Water fluoridation remains the most effective, equitable and cost effective way of preventing dental decay.

6. Have any countries decided not to fluoridate for public health reasons and if so, on what grounds?

No country has not fluoridated for public health reasons. The US CDC has rated water fluoridation to prevent dental caries has been rated as one of the top 10 public health achievements of the 20th century, alongside the eradication of smallpox and elimination of poliomyelitis.

Water fluoridation has been endorsed and recommended by more than 150 scientific, health and political organisations throughout the world including the ANHMRC, the US Center for Disease Control, US Surgeon General, World Health Organisation, Health Canada and numerous other public health watchdogs throughout the world.

In some countries it is not practical to fluoridate, because of very complex water systems without a single central point that could be fluoridated. Developing countries do not have water fluoridation because they do have the infrastructure to support it (technical expertise, cost etc). Some fluoride plants in Eastern and Central Europe were not given adequate attention during the political turmoil in the late 1980's, and closed through neglect (American Dental Association 1999).

7. **Has research been carried out regarding the toxicity of compounds used in fluoridating water such as sodium fluorosilicate and sodium tetra fluoride?**

Research into the toxicity of compounds used in fluoridating water has been carried out for the last 40 years.

The NHMRC is Australia's peak health organisation for the achievement of the best possible standards for public health. For fluoridating drinking water the NMHRC recommends sodium fluoride, sodium fluorosilicate and fluorosilicic acid. Under the NHMRC Guidelines, a chemical added to the drinking water must not be toxic when ingested at recommended maximum levels and has to meet very high standards of safety.

In NSW there is an extensive testing program in place to monitor the quality of community drinking water supplies. The chemical qualities of public water supply systems in NSW, which receive fluoridation, are monitored on monthly basis. This includes tests for lead, arsenic and cadmium. The quality of water supplied to these communities meets the requirements of the NMHRC's Australian Drinking Water Guidelines.

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