IN THE HIGH COURT OF NEW ZEALAND
NEW PLYMOUTH REGISTRY CIV 2013-443-107

UNDER	**the Judicature Amendment Act 1972 and the Declaratory Judgments Act 1908**
IN THE MATTER	**of an application for judicial review and an application for a declaration**
BETWEEN	**NEW HEALTH NEW ZEALAND INC**
	Plaintiff
AND	**SOUTH TARANAKI DISTRICT COUNCIL**
	Defendant

AFFIDAVIT OF DAVID BENJAMIN MENKES

Dated 2 August 2013

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I, David Benjamin Menkes, academic psychiatrist of Hamilton, affirm:

Introduction and professional background

1. I am an Associate Professor at the Waikato Clinical School of the University of Auckland and honorary Consultant Psychiatrist at the Waikato District Health Board.

2. I have an MD from Yale School of Medicine (1982), and a PhD in Pharmacology (Yale 1983). I am a Fellow of the Royal Australian and New Zealand College of Psychiatrists (FRANZCP 1989). My CV is attached and marked with the letter "A".

3. I have studied drugs, their effects and mechanisms of action since the late 1970s. After completing postgraduate training in 1989, I have worked as an academic psychiatrist in a variety of settings, and accumulated further research, teaching and clinical experience with regard to the uses and adverse effects of drugs. In 2011 the NZ Minister of Health (Hon. Tony Ryall) appointed me to the Ministry's Medicines Adverse Reactions Committee. In 2013 I was also appointed to the Mental Health Sub-Committee of the Pharmacology and Therapeutics Advisory Committee (PTAC) which advises the NZ Government's drug purchasing agency, PHARMAC.

4. My medico-legal experience includes preparation of over forty reports on drugs, their effects and mechanisms of action, as requested by the NZ Government, and by lawyers in the UK, USA, NZ, Australia, and Israel. In my role as consultant psychiatrist with the Waikato District Health Board, I am frequently asked to provide advice regarding pharmacological and other medical treatment. This includes providing formal 2nd opinions on compulsory treatment under the Mental Health (Compulsory Assessment and Treatment) Act 1992, having been approved for this role by the Mental Health Review Tribunal of the Ministry of Health.

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Purpose of my evidence

5. I have been asked by the plaintiff to give an expert opinion on whether artificial fluoridation of community water supplies up to 1 part per million (ppm, equivalent to 1 mg per litre) could be said to constitute medical treatment and, if so, what the implications of this would be, including for informed consent.

6. I have read, understood, and agree to comply with the Code of Conduct for expert witnesses. The question at issue is within my area of expertise based on my background in pharmacology, my training in medical teaching and research, and my experience as a medical consultant. The opinions expressed in this report are mine alone, include all relevant facts of which I am aware, and reflect my commitment to assist the Court rather than the party who has engaged me. I confirm that payment of my fee is in no way dependent on the outcome.

7. Before setting out my conclusions, I set out the premises underlying my opinion. I also set out the definitional parameters against which I am considering the issue.

Underlying premises

8. My opinion is premised on the following facts.

9. Community water fluoridation (CWF) involves the addition of a chemical substance to increase the concentration of fluoride ions in drinking water up to 1 ppm.

10. In New Zealand, CWF relies mainly on the use of either sodium silicofluoride (SSF) or hydrofluorosilicic acid (HFA) to release fluoride ions, and thereby increase their concentration, when dissolved into communal water supplies.

11. The purpose of CWF is to help prevent dental caries, based on the action of fluoride ions which, in sufficient concentration, can promote the mineralization and hardening of tooth enamel.

12. Dental caries is a multifactorial disease in which bacteria (especially *streptococcus mutans* and related species) metabolize dietary sugars and produce lactic acid. A local

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acidic environment promotes caries by dissolving tooth enamel. Individuals with significant numbers of oral *mutans* bacteria are at increased risk of caries, especially with repeated consumption of sugary food and beverages, and in the absence of good dental hygiene.

Does water fluoridation constitute medical treatment?

13. Mosby's Dictionary of Medicine, Nursing and Health Professions, 2nd Australian and New Zealand Edition (2009) defines medical treatment as

> A method of combating, ameliorating or **preventing a disease**, disorder or injury. Active or curative treatment is designed to cure; palliative treatment is directed to relieve pain and distress; **prophylactic treatment is for the prevention of a disease or disorder;** causal treatment focuses on the cause of a disorder; conservative treatment avoids radical measures and procedures; **empirical treatment uses methods shown to be beneficial by experience; rational treatment is based on a knowledge of a disease process and the action of the measures used**. Treatment may be pharmacological, using drugs; surgical, involving operative procedures; or supportive, building the patient's strength. It may be specific to the disorder; or symptomatic, to relieve symptoms without effecting a cure.
>
> (emphasis in **bold** added where relevant to the present issue)

14. Similarly, Dorland's Illustrated Medical Dictionary, 32nd edition (2012) defines treatment as: The management and care of a patient for the purpose of combating disease or disorder. This includes **prophylaxis.**

15. I have also had regard to the following definitions in the New Zealand Medicines Act 1981:

> **"Therapeutic purpose"** is defined in Section 4 of the Medicines Act 1981, and includes the treatment, diagnosis and prevention of disease or the modification of a physiological function.
>
> **"Medicine"** is defined in Section 3 of the Medicines Act. A product is a medicine if it has a pharmacological effect and is used in humans primarily for a therapeutic purpose.

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16. It is my opinion that CWF has a 'therapeutic purpose' as defined in the Medicines Act and is consistent with the standard definitions of medical treatment given above.

17. To confirm the notion that CWF constitutes medical treatment, several factors can be explicitly considered:

1. The practice is deliberate; it uses the addition of a chemical substance (HFA or SSF) specifically to increase the concentration of fluoride ions in drinking water to produce an intended effect.

2. It is done for a therapeutic purpose, namely the prevention or prophylaxis of tooth decay (caries) in the target population.

3. The practice has a rational basis, based on known properties of fluoride and effects, *inter alia*, on dental physiology, mineralisation of tooth enamel, and observed changes in the incidence of caries in treated populations.

4. There is a dose-response relationship characteristic of medicines: the current target range of 0.7 – 1.0 ppm in tap water is based on evidence that this range offers the optimum balance between a desired effect and unintended adverse or toxic side-effects. Regular monitoring is required to ensure that the concentration of fluoride ions in tap water stays within this target range. Lower levels are less likely to be effective, while higher levels are more prone to produce adverse effects. In other words, the 0.7 to 1.0 ppm concentration range has been specifically chosen to achieve an optimum dose-response for this intervention. In light of this, the current practice of CWF would not be considered a trivial or *de minimis* intervention.

5. According to Section 2 of the Medicines Act 1981, "administer" includes administering a medicine to people, either orally, by injection or by introduction into the body in any other way, either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is

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to be administered. In my opinion these characteristics of drug administration apply to the delivery of fluoride via CWF. It is thus my view that fluoride can be considered a medicine when used in CWF. This accords with the definition of a medicine in Section 3 of the Act (see above) as well as its standard dictionary definition: *a drug or other preparation for the treatment or prevention of disease* (http://oxforddictionaries.com/definition/english). I note that dietary or nutritional supplements are generally not considered medicines, even though they may help prevent disease. This exclusion does not, in any case, apply to fluoride which is not considered a nutrient (see below).

18. In NZ, CWF relies mainly on the use of either sodium silicofluoride (SSF) or hydrofluorosilicic acid (HFA) to release fluoride ions when dissolved into communal water supplies. To date it appears that Medsafe has not specifically described such fluoride-releasing salts as medicines, even though a variety of other fluoride-containing products are so classified.[1] For example, the NZ Formulary lists sodium fluoride tablets as a pharmacy only medicine indicated for the prophylaxis of dental caries.[2]

19. In my opinion, HFA and SSF, when used for CWF, would readily fall within the relevant definition of "medicine", namely because they have "a pharmacological effect" (mineralisation of tooth enamel) and are "used in one or more humans primarily for a therapeutic purpose" (prevention of caries). However, these salts are by-products of the fertilizer industry, and as such are of an industrial or 'water

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[1] Under the Medicines Regulations 1984, fluorides "for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council" are classified as prescription medicines.
http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM96863.html

[2] http://www.nzf.org.nz/nzf_5320.html

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treatment grade' (www.waternz.org.nz/), not the purer (and more expensive) pharmaceutical grade.

20. In my opinion, every aspect of CWF meets the definition of and criteria for medical treatment. Fluoride concentration in tap water is deliberately elevated to produce a physiological effect for a therapeutic purpose, in this case the *prophylactic* treatment of the disease dental caries.

21. This is analogous to the now abandoned treatment of a South American population with dietary salt containing the drug chloroquine to prevent the spread of malaria.[3] As with CWF, the combination of a therapeutic purpose and a pharmacological mechanism of action defines the practice as a medical treatment. These examples could both be considered *mass drug administration* in light of their application to whole populations in a defined geographical area. The ethical issues surrounding mass drug administration are important, as discussed below.

22. CWF can be distinguished, in my opinion, from the practice of fortifying foodstuffs with essential nutrients, such as adding iodine or folic acid to bread, due to the fact that fluoride is not a dietary nutrient. Both fluoride and essential nutrients may be used to prevent disease but, as demonstrated above, the former is used as a medicine in CWF whereas the latter are considered dietary supplements. Many essential nutrients, such as folic acid, iodine, iron or zinc, can also be used as medicines, depending on the dose and the route of administration.

23. As with the salts of certain other atomic elements (e.g., antimony, bromide, gold, lithium, mercury) that have been used as medicines, there is no physiological reaction in the human body that requires fluoride. Nor is fluoride required for any aspect of human growth, development, or reproduction. Accordingly, fluoride cannot be considered a nutrient or dietary supplement.

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[3] Giglioli G et al. Interruption of malaria transmission by chloroquinized salt in Guyana. *Bulletin of the World Health Organisation* 1967; 36: 283–301.

24. I have also considered whether the fact that fluoride exists in the environment, and is found naturally in water, means that it should not be considered a medicine. In my opinion this is incorrect. Many other atomic elements found naturally in water have also been used as medicines (e.g., antimony, arsenic, bromide, lithium) and, in sufficient concentration, are known to be toxic. Fluoride, like other ions (or their salts) that have been used as medicines, can be considered medicinal or toxic, depending on the concentration. According to the guidelines of the World Health Organisation, levels of fluoride in drinking water that help prevent tooth decay are in the range of 0.7 – 1.0 ppm.[4] Because the natural levels of fluoride in fresh water in most parts of NZ are considered too low to have a measurable effect on dental health, the Ministry of Health recommends that the levels of fluoride in community water supplies be 'adjusted' to 0.7 - 1.0 ppm. In NZ, the Maximum Acceptable Level of fluoride in drinking water is set at 1.5 ppm, in order to prevent the toxicity associated with exposure to higher concentrations. In other countries, high levels of fluoride (generally above 2.0 ppm) are considered toxic and are subject to fluoride abatement (removal).

Informed consent

25. Right 6 of the Health and Disability Commission Code of Disability Services Consumers' Rights Regulation 1996 states that every consumer has the right to be fully informed about their situation. They must be given the information they need to make an informed choice or give informed consent. Right 7 states that every consumer has the right to make an informed choice and give informed consent to any medical treatment.

26. Informed consent is fundamental to ethical medical practice. This principle applies to all medical treatment where those capable of consent are given the option of whether or not to receive treatment. Exceptions are made for young children and others who are unable to understand the treatment and its implications. Exceptions

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[4] http://www.who.int/water_sanitation_health/dwq/nutfluoride/en/

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are also made in certain cases where treatment may be given even where declined or actively refused. The Mental Health (Compulsory Assessment and Treatment) Act 1992, for example, requires detailed procedures including a careful assessment and documentation by two medical practitioners in order to subject an individual to a compulsory treatment order (CTO). Even under a CTO, patients are informed about recommended treatment and are asked to give signed consent to such treatment. If they decline, under Section 59, they are entitled to an independent 2nd opinion regarding the need for such treatment. In my role as consultant psychiatrist with the Waikato District Health Board, I am frequently asked to provide such 2nd opinions under Section 59(2)(b). It is apparent from the foregoing that the principle of informed consent to medical treatment is taken very seriously in NZ.

27. In addition to the provisions of the Mental Health Act, and allowance made for parents or guardians to consent on behalf of young children, there are other situations where treatment for a medical condition may given without consent. These include:

a. In a life-threatening urgent setting when consent cannot be obtained. This applies to ambulance personnel and commonly happens in Emergency Departments of public hospitals when, for example, patients arrive gravely injured or unconscious.

b. By the consent of a formally appointed guardian, via the Protection of Personal and Property Rights (PPPR) Act 1988 or via an Enduring Power of Attorney if someone is judged to be incompetent (unable to understand the treatment and the reasons for it). This may happen, for example, in the setting of moderately severe intellectual disability, or in the case of acquired cognitive impairment (e.g., from traumatic brain injury, or senile dementia).

c. By a formal court order, in exceptional circumstances, this may be applied for by the clinical team or service seeking to administer treatment, via the relevant DHB legal representative.

d. I am also aware that, under Section 70 of the NZ Health Act 1956, Medical Officers of Health have special powers to effect compulsory treatment in epidemics and national emergencies.

28. It is apparent that the legal framework in NZ, like many Western countries, allows medical treatment without consent only in specific circumstances. In the case of treating whole populations without consent, as in the above example of mass drug administration, the ethical requirements are understandably even more stringent. This issue is considered in detail in the bioethical literature, and generally accepted standards for such treatment have been published.[5] To be ethically justifiable, such treatment must demonstrate a number of features. In particular, the treatment must:

a. Be clearly effective.

b. Be proportional, i.e., confer benefits in excess of harms.

c. Be necessary.

d. Infringe on individuals as little as possible.

e. Be publicly justifiable.

29. Based on these criteria, the justification for CWF has been analysed by Professor N Awofeso in an article published in *Public Health Ethics*.[6] This article is attached and marked with the letter "B". Using examples and data drawn from Australia, this analysis demonstrated doubts about the ethical justification for CWF in that country based, in part, on poor quality (and thus uncertain) evidence of both benefits and

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[5] Childress JE, et al. Public Health Ethics: Mapping the terrain. *Journal of Law, Medicine and Ethics* 2002; 30: 170–178

[6] Awofeso N. Ethics of Artificial Water Fluoridation in Australia. *Public Health Ethics* 2012; 5: 161-172

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harms, the availability of alternatives, and the impracticality of gaining informed consent from individuals in treated populations.

30. If CWF is considered medical treatment, as I believe it should be, then in addition to warranting ethical review (as above), it should also be reviewed from the standpoint of pharmacology in order to optimize outcomes for treated populations. In this respect there are four issues.

a. Control of dosage. Whereas the fluoride ion concentration of tap water in CWF is regularly monitored and adjusted to the target range of 0.7 – 1.0 ppm, ingested doses of fluoride vary appreciably across individuals, depending on water consumption, intake of fluoride containing foods, and use of fluoride-containing dental products -- which may be swallowed, especially by children. Additional use of fluoride tablets is contraindicated for those living in areas with CWF, due to the risk of toxicity. The combination of poorly controlled ingested dosage and little difference between the therapeutic (0.7 – 1.0 ppm) and potentially toxic range (above 1.5 ppm) of fluoride concentration in water is a key reason why Germany decided to abandon fluoridation in 1992.[7] A copy of the article referred to in footnote 7 is attached and marked with the letter "C".

b. Vulnerable sub-populations. Certain individuals, notably formula-fed infants and those with renal disease, are prone to fluoride toxicity because of higher unit (mg/kg) intake and impaired excretion, respectively. Adequate warnings and alternative water sources should be available for such individuals, and for those with fluoride allergy, living in areas with CWF.

c. Systemic exposure despite a topical mechanism of action. This is a further feature of CWF that interacts with the two previous issues, and which raises

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[7] English version: www.dvgw.de/fileadmin/dvgw/angebote/publikationen/infoschriften/wasserinfo34_e.pdf

fundamental questions about the practice. Since the caries-protective benefit of fluoridated water derives preponderantly from topical contact with the teeth, there is an issue that whole populations are exposed to systemic ingestion of fluoride, which confers risks of toxicity (including skeletal and thyroid) but with little if any additional benefit. The ready availability of alternative sources of topical fluoride is thus a key feature of the ethical critique of CWF.[8]

d. Quality of medicine. As noted above, CWF in NZ relies on industrial sources of the salts (HFA or SSF) used as a source of fluoride ions. It could be argued that, as a medicine, these salts or other sources (such as sodium fluoride) should be pharmaceutical grade if used to treat human populations.

AFFIRMED at Hamilton this

2nd day of August 2013

D Mathers

before me:

C A Hardy
Deputy Registrar
District/High Court
Hamilton

A Registrar/Deputy Registrar of the High Court of New Zealand

[8] Awofeso N. Ethics of Artificial Water Fluoridation in Australia. *Public Health Ethics* 2012; 5: 161-172

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'A'

THIS is the Exhibit marked with the letter "A" referred to in the annexed affidavit of David Benjamin Menkes AFFIRMED/SWORN at Hamilton this 2 day of August 2013 before me:

Registrar
A Solicitor of the High Court of New Zealand

C A Hardy
Deputy Registrar
District/High Court
Hamilton

CURRICULUM VITAE

June 2013

1. PERSONAL INFORMATION

Name: David Benjamin MENKES **Born:** 24 June 1953 **Sex:** male

2. QUALIFICATIONS

(a) Qualification name: Institution: Year conferred:

BA (highest honours)	UC San Diego	1975
MD	Yale School of Medicine	1982
PhD (pharmacology)	Yale University	1983
FRANZCP	Royal Australian and New Zealand College of Psychiatrists	1989

(b) Medical Specialist Registration:

New Zealand Medical Council NZMC 13748	1989
General Medical Council UK GMC 5173807	2001

3. PROFESSIONAL AFFILIATIONS/MEMBERSHIPS

American Association of General Hospital Psychiatrists
Australasian Society for Psychiatric Research
Collegium Internationale Neuropsychopharmacologicum (CINP)
Cochrane Adverse Effects Methods Group
Healthy Skepticism
International Society of Drug Bulletins (www.isdbweb.org)
International Standards Organisation Committee on Health Informatics
Medical Protection Society
Royal Australian and New Zealand College of Psychiatrists (RANZCP)

4. LANGUAGES

German, fluent
Russian, basic

5. EMPLOYMENT HISTORY

(a) **Present Position** (from August 2006)

Associate Professor of Psychiatry, University of Auckland, and Honorary Consultant Psychiatrist, Waikato District Health Board, Private Bag 3200, Hamilton 3240, New Zealand. Phone +64 7 8398750 mobile +64 21 2297830
david.menkes@waikatodhb.health.nz
www.fmhs.auckland.ac.nz/faculty/staffct/staff_details.aspx?staffID=646D656E303139

(b) **Employment History**

Professor of Psychological Medicine, University of Wales, 2001-2006
Honorary Consultant Psychiatrist, North East Wales NHS Trust, 2001-2006
Senior Lecturer in Psychological Medicine, University of Otago, 1989-2001
Consultant Liaison Psychiatrist, Dunedin Hospital (NZ), 1989-2001
Lecturer in Psychological Medicine, University of Otago, 1987-1989
Psychiatric Registrar (Resident), Otago Hospital Board, 1983-1987
House Surgeon (Intern), Dunedin Hospital, 1982-1983

6. **PUBLICATIONS**

(a) **Book chapters: 11**

(b) **Refereed journal articles: 92**

(c) **Refereed abstracts and letters: 41**

7. **Conference Involvement since 2009**

Chair, Scientific Programme Committee, RANZCP New Zealand Conference (Rotorua, 14-16 October 2009). My involvement also included developing and implementing:

1. 'Evidence Alley' later renamed 'Te Ara Matauranga - Best Evidence', a set of 8 exhibits supporting evidence-based decision making in psychiatry
2. a symposium on commercial sponsorship of psychiatrist education http://ranzcp.cmsaustralasia.com/index.php
3. a programme for medical students from all 5 NZ clinical schools to attend the entire conference, supported by Te Pou and the University of Auckland http://www.ranzcp.org/psych-e-bulletin/november-2009.html

Invited keynote presenter, Information Utility Compass for Change Forum, 25 November 2009, Auckland. "Use of information in mental health: challenges and opportunities". www.tepou.co.nz/page/tepou_817.php, www.tepou.co.nz/page/817-Outcome-forums+Information-Utility-Compass-for-Change#video, and www.tepou.co.nz/file/Information-Programme/Compass-for-change-forum/evaluation-of-forum-compass-for-change-nov-09.pdf

Scientific Committee member, Australasian Mental Health Outcomes Conference "Into Uncharted Territory", Auckland, 17-19 November 2010.
Also presented a paper at this meeting: http://www.tepou.co.nz/file/Information-Programme/AMHOC2010/menkes-d.-access-to-health-records-by-patients-with-severe-mental-illness.pdf

Scientific Committee member, RANZCP Congress "Minding the Brain", Hobart 2012

Conference Committee, RANZCP New Zealand Conferences (Wellington 2012 and Auckland 2013). My involvement included developing and implementing:

1. 'Evidence Alley', a set of 11 exhibits supporting evidence-based decision making in psychiatry (http://www.ranzcp2012.co.nz/supporters-exhibitors/)
2. a programme for medical students from all 5 NZ clinical schools to attend the entire conference, supported by the Universities of Auckland and Otago

8. **Relevant Committee Work**

NZ National Committee, RANZCP, 2008 to present

Medicines & Therapeutics Committee, Waikato District Health Board, 2010 to present

Medicines Adverse Reactions Committee, NZ Ministry of Health, 2011 to present

Member, Recruitment into Psychiatry Working Party, RANZCP, 2012 to present

Member, Mental Health Sub-committee, PHARMAC, NZ Government, 2013 to present

'B'

PUBLIC HEALTH ETHICS VOLUME 5 • NUMBER 2 • 2012 • 161–172

Ethics of Artificial Water Fluoridation in Australia

Niyi Awofeso*, School of Population Health, University of Western Australia, and School of Public Health, University of New South Wales, Australia

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A recent decision by several Australian State politicians to support a parliamentary review of artificial water fluoridation has an intensified debate on the public health intervention. While there is a majority agreement among Australian dentists and other health professionals that adequate enamel fluoride is essential for dental health, the ethics of artificial fluoridation of public water supplies as a contemporary vehicle for facilitating adequate supply of fluoride to teeth is highly contested. Opponents of artificial water fluoridation insist that there are many alternative sources of fluoride, that mandatory water fluoridation violates the ethical principle of autonomy and that water fluoridation is not only expensive and unnecessary but also may endanger health by causing fluorosis and, potentially, hypothyroidism and pathological bone fractures. In contrast, proponents of water fluoridation posit that mandatory water fluoridation facilitates health equity and that the benefits accruing to society from prevention of dental caries (beneficence principle) outweighs impairment of individual autonomy. This article utilizes Childress' 'justificatory conditions' to evaluate the ethical appropriateness of artificial water fluoridation in Australia. The author concludes that there is insufficient ethical justification for artificial water fluoridation in Australia.

Introduction

Dental caries (i.e., infection and decay of teeth enamel) is a major public health problem, affecting 60–90 per cent of the world's population. The commonest contributors to dental caries in children include poor dental structure, bacterial involvement, poor oral hygiene, quantity and quality of saliva, compromised host status, dietary factors and oral infections (Berkowitz, 2003). Dental caries is Australia's most prevalent health problem, with 11 million newly decayed teeth documented in 2003. Oral diseases cost the Australian health system $2.6 billion every year (Wilson, 2004). Among adults, globally, access to oral health services is an important factor in modulating the pathogenesis of dental caries as are established risk factors such as diet, tobacco, alcohol and poor oral hygiene (Heng *et al.*, 2006). According to the World Health Organization, a primary goal of community-based public health dentistry programs should be to implement the most appropriate means of maintaining a constant low level of fluoride in as many mouths as possible (Petersen, 2005).

Fluorine belongs to the halogen family also comprising chlorine, bromine and chlorine iodine. It is listed as 9 in the periodic table and has an atomic weight of 19. It exists as inorganic and organic compounds called fluorides. Fluoride is abundant in the environment, in rocks and soils, constituting about 0.07 per cent of the earth's crust. All water sources, whether fresh or sea water, have varying levels of fluoride depending on the location and proximity to fluoride sources. In Kenya, for example, fluoride exists in a range of 0.08 and 0.8 parts per million in most natural river systems (Gikunju *et al.*, 2002). Most foodstuffs contain traces of fluorides. Food processing often concentrates on fluoride, and foods processed with fluoridated water (e.g., breakfast cereals) typically have higher fluoride concentrations than foods processed with non-fluoridated water (Encyclopedia Britannica, 2012). Rankin *et al.* (2012) showed that the quantity of fluoride absorbed from solid food may reach up to 88 per cent of recommended daily fluoride among 5-year olds in the USA, thus demonstrating the substantial contribution of dietary fluoride to total fluoride intake.

The architect of the first fluoride study was Dr. Trendley Dean, Head of the Dental Hygiene Unit at the National Institute of Health, who investigated the epidemiology of fluorosis and determination of optimal fluoride concentrations in Michigan's public water supplies. His team found that fluoride levels of up to 1.0 parts per million in drinking water did not cause

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Advance Access publication on 21 August 2012

enamel fluorosis in most people and was associated with reduced risk of dental caries. In 1945, Grand Rapids, Michigan, became the first city in the world to fluoridate its drinking water as a public health strategy to prevent dental caries. By 1955, Dean's team found that the permanent teeth caries rate decreased to more than 60 per cent among Grand Rapids' children born after the addition of 1 parts per million fluoride to the water supply (Arnold *et al.*, 1956). Similar studies undertaken in 1970s in Australia, UK, Canada, Ireland and New Zealand showed relative reductions in dental caries between artificially fluoridated and non-artificially fluoridated water supplies of between 30 and 60 per cent for deciduous dentition and 15 and 30 per cent for adult dentition (Spencer *et al.*, 1996). Currently, two-thirds of Americans drink artificially fluoridated water. About 350 million people in 39 countries have access to artificially fluoridated water globally. It is noteworthy that effect of fluoride is only topical, on teeth enamel. Scientific evidence for the protective effect of topical fluoride application is strong, while evidence for systemic application via drinking water is less convincing (Scientific Committee on Health and Environmental Risks, 2011). Fluoride enhances enamel remineralization. Under acidic conditions, it decreases the rate of enamel demineralization and lowers the solubility of enamel. It interferes with enzymatic process of caries-causing bacteria and impedes attachment of odontopathic organisms to teeth. Through these processes, fluoride retards progression of caries (Newbrun, 1999).

By the 1990s, a lively debate on the acceptability, affordability, ethical justification and effectiveness of fluoridation raged in developed nations, and the outcomes of such debate led to nations like Czech Republic, Sweden, Netherlands and Switzerland suspending artificial water fluoridation practices from 1993 onwards on the following grounds: (i) economic—it was not affordable by most private water supply companies, and only 0.54 per cent of water suitable for drinking is used as such; (ii) technical—there were recurring problems with maintaining the correct concentrations of fluoride; (iii) ethical—forced medication, thus violating individual autonomy, questionable beneficence as the full profile of side effects from water fluoridation have yet to be fully determined, particularly for specific vulnerable groups such as the elderly and children. Apart from Southern Ireland and England, European nations rely mainly on natural water fluoride levels, fluoridated toothpaste and natural fluoride sources for assuring adequate teeth fluoride levels (Havlik, 1999). In Asia, artificial water fluoridation is currently not the most prominent component of fluoride delivery strategies to teeth (Siriphant and Srisawasdi, 2011, Table 1). The percentage of the population consuming artificially fluoridated water varies in the nations in which this practice is being implemented. In Malaysia, for example, about 75 per cent of the population were provided with artificially fluoridated water as on December 2010, but the percentage of the population consuming fluoridated water is expected to exceed 85 per cent when water supplies in Sabah province is fluoridated from late 2012 onwards.

In Australia, New South Wales pioneered mandatory statewide artificial fluoridation of water supplies with the promulgation of the Fluoridation of Water Supply Act 1957. Most states followed the New South Wales approach, with Queensland being the last to enact a comprehensive water fluoridation Act in 2008. In line with other states' fluoridation laws, the Queensland water law makes exemptions for mandatory artificial fluoridation if naturally water occurring fluoride levels are within acceptable legal limits (Government of Queensland, 2008). Currently, over 90 per cent of municipal water output in Australia is artificially fluoridated. In the remainder, natural fluoride levels are high enough to ignore artificial fluoridation (Government of Victoria, Australia, 2011a, Figure 1).

The artificial water fluoridation debate has resurfaced in recent years as private companies in Australia are required to fluoridate drinking water in line with state government legislation. Anti-fluoridation advocacy groups and private water supply companies have consistently cited ethical, health, financial and legal objections to artificial fluoridation policies. For example, in *Oshlack Vs Rous Water 2011*, the private water company contracted to process and supply water to homes in Ballina and Lismore in northern New South Wales argued against artificially fluoridating public water supplies on the grounds that such an action will contravene sections 111 and 112 of the Environmental Planning and Assessment (EPA) Act with respect to potential adverse environmental and human health effects of water fluoridation. Although the presiding judge found no inconsistency between the two Acts, in relation to fluoridation, it urged all parties to investigate to the 'fullest extent possible', as stipulated in Section 111 of the EPA Act, the environmental and health effects of artificial water fluoridation (Land and Environment Court, New South Wales, 2011).

In Western Australia, plans by the state government to artificially fluoridate water supplies in Yanchep, Two Rocks and Carnarvon have been opposed by water supply organizations, community members and

Table 1. Fluoridation initiatives in Asian nations

Countries	Community Administration			ProFessional Administration		Self Administration	
	Water F	Salt F	Milk F	Fgel	F varnish	F toothpaste	F mouthrinse
Bhutan				×		×	
Brunei	×				×	×	
Cambodia					×	×	×
China				×	×	×	
Hong Kong	×			×	×	×	
India					×	×	
Indonesia						×	
Japan				×		×	×
Korea	×			×	×	×	×
Laos		×				×	
Malaysia	×			×	×	×	×
Mongolia					×	×	
Myarmr						×	
Nepal						×	
Pakistan						×	
Philippines						×	
Singapore	×			×	×	×	
Sri Lanka					×	×	
Thailand			×	×	×	×	
Vietram	×	×				×	×

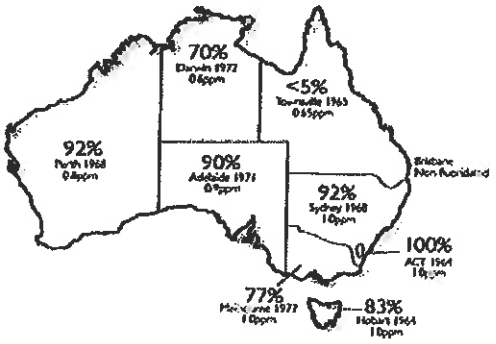

Figure 1. Water fluoridation coverage in Australia.

anti-fluoridation groups such as Perth Fluoride Free. North West MP Vince Catania, Mindane MP John Quigley and Southern River MP Peter Abetz have agreed to table the concern of their constituents in these regions in Western Australia's parliament for formal discussions by all elected representatives. The Carnarvon City Council has already indicated that it will support the efforts by advocacy groups not to fluoridate Carnarvon's water supplies based on inadequate justification for artificial water fluoridation (Shire of Carnavon Minutes, 2011). The situation in Carnarvon is particularly interesting as it is known to have high natural fluoride levels in its river systems—up to 1.5 parts per million in some wells and rivers in 1960s—as evidenced by high dental fluorosis rates (Martin-Iverson *et al.*, 2000). Data obtained from the Carnarvon water treatment plant revealed that the potable water in the city has optimal natural calcium fluoride averaging 0.5 parts per million since 1995 (Figure 2).

The increasing prominence of anti-water fluoridation groups globally, greater appreciation of natural and artificial fluoride sources and likely dangers of excessive fluoride consumption among some population necessitate a thorough analysis of the merits of water fluoridation from all perspectives. A detailed risk assessment of the physiological, health promoting and toxicological effects of artificial water fluoridation would require extensive research expertise on toxicological effects of fluorosis (dental and skeletal), neurological

Figure 2. Carnarvon's natural calcium fluoride levels, 2005–2010. *Source:* The Australian Fluoride News, October–November 2011.

effects, endocrine glands' effects, especially thyroid function, and allergy-inducing effects. Although some important reviews have been performed which show that, apart from the aesthetically unappealing fluorosis, fluoride ingestion is not associated with adverse health effects on bone (Thomas, 2000; National Health and Medical Research Council, 2007), other studies have suggested that high fluoride levels are associated with adverse health effects such as hypothyroidism, osteosarcoma, pathological bone fractures and allergies (Susheela *et al.*, 2005).

Equally controversial is the ethical debate. Advocates of artificial water fluoridation posit that its benefits—equity in opportunities for dental health improvements and reduced community-wide incidence and prevalence of dental caries (beneficence)—outweigh impairments in individual autonomy or potential cosmetic disfigurement. Opponents cite lack of good quality evidence of the benefits of water fluoridation (Scientific Committee on Health and Environmental Risks, 2011), waste of resources (less than 2 per cent of public water supplies are used for drinking) and the belief that fluoride is available from a variety of sources, so its benefits can be realized without violating the principle of autonomy. They also highlight the potential for endocrine disease, fluorosis and violation of individual autonomy. Anti-fluoridation advocates also assert that mass, fixed dose medication is ethically inappropriate. Opponents of mandatory water fluoridation highlight research studies in India that reported incidence of dental, skeletal and crippling skeletal fluorosis in Indian communities using water supplies with average fluoride concentrations as low as 0.5, 0.7 and 2.8 parts per million respectively. Fluorosis is the most widespread geochemical disease in India, affecting more than 66 million people including 6 million children aged 14 years or younger (Ayoob and Gupta, 2006). In addition, anti-fluoridation advocates argue that those most likely to benefit from water fluoridation (the poor living in areas with limited access to adequate fluoride) are not necessarily those whose health outcomes are threatened by this public health initiative, such as infants aged less than 6 months, children from socioeconomically disadvantaged communities (e.g., Blacks and Hispanics in the USA), those experiencing fluoride allergy and chronic renal disease and people living in areas with a wide variety of natural fluoride from water and tea. In the USA, dental fluorosis remains persistently high among poor Black and Hispanic population in inner areas of Boston, New York and Atlanta despite decades of artificial water fluoridation in these regions. The National Health and Nutrition Examination Surveys of 1986–1987 and 1999–2004 showed that the prevalence of dental fluorosis was 23 and 41 per cent, respectively, among adolescents aged 12–15 years. Higher prevalence was found among Blacks and Hispanics and was attributed to multiple etiologies, from biological susceptibility and malnutrition to higher fluoride intake (Beltran-Aguilar *et al.*, 2010). Thus, autonomy and beneficence are not easy to balance in this ethical debate (Cohen and Locker, 2001).

Important ethical questions related to the water fluoridation debate include: Is mass medication, which is compulsory or expensive to avoid, wrong? Is medication with an uncontrolled dose of a prophylactic drug wrong? Is it scientifically or ethically right to promote fluoridation on the basis that its risks are less than its benefits? Is it ethically right to deprive people, especially low-income earners, of a valuable preventive medication through mass fluoridation? This article aims to answer these ethical questions by adapting the conceptual model of Childress *et al.* (2002) for addressing ethical conflicts using the following justificatory parameters: effectiveness, proportionality, necessity, least infringement and public justification.

Resolving Ethical Conflict vis-à-vis Artificial Water Fluoridation

Effectiveness

The studies undertaken before 1980s in Australia, United States, Singapore and Ireland demonstrated relative effectiveness of water fluoride on dental caries compared with regions where public water supplies were not fluoridated (Spencer *et al.*, 1996). The mass rollout of fluoride toothpaste and other fluoride supplements as well as the distribution of fluids such as soda drinks produced using fluoridated water to residents in non-fluoridated regions was expected to dilute the protective impact of water fluoridation on dental caries. Indeed, this trend was well demonstrated in most industrialized nations where dental caries deceased in nations which artificially fluoridate public water supplies (e.g., Ireland) and those which did not (e.g., The Netherlands). Greater public access to fluoride sources, particularly from toothpaste, improved primary dental care services, and improvements in oral hygiene may account for the dilution of fluoride's anti-caries effect. Evidence on the effectiveness of water fluoridation in prevention of dental caries is mixed. While some studies suggest that water fluoridation is useful in reducing dental caries (Attwood and Blinkhorn, 1988; Spencer *et al.*, 1996), other studies show no significant difference in caries rates between groups drinking fluoridated and non-fluoridated water, a finding they attributed to multiple sources of fluoride in most communities (Yiamouyiannis, 1990; Künzel and Fischer, 1997). In Australia, the industrial grade fluosilicic acid is the most commonly used chemical for artificial water fluoridation, and it is promoted by health authorities as having equivalence in effectiveness in relation to caries prevention compared with naturally occurring calcium fluoride. Recent studies dispute this assertion on the grounds that naturally occurring calcium fluoride does not inhibit calcium absorption by teeth enamel while fluosilicic acid does, thus annulling the dental caries prevention effects of water fluoridated with fluosilicic acid (Whitford *et al.*, 2008). Epidemiological trends do not fully support effectiveness of artificial water fluoridation in both caries prevention and reducing relatively high rates of dental caries among vulnerable populations. A recent report by the Australian Institute of Health and Welfare revealed that Australian children from the poorest areas have about 70 per cent more dental decay compared with children from the highest socioeconomic groups. For example, in Western Australia, where over 90 per cent of water supplies are fluoridated, dental decay was 22 per cent higher in poorer cohorts compared with richer socioeconomic populations. This report also noted that caries prevalence varied from 29.3 per cent in the Australian Capital Territory to 49.7 per cent in the Northern Territory, average national prevalence of 38 per cent. (Australian Institute of Health and Welfare, 2011a). This compares with a national average of 40 per cent caries prevalence in the 1970s (Wilson, 2004). Thus, there is little epidemiological evidence to suggest that widespread adoption of water fluoridation has translated into substantial reduction in caries prevalence in Australia. The World Health Organization (WHO) appears to be shifting from water fluoridation to toothpaste fluoridation given that the effectiveness of fluoridation depends on having a constant supply of low concentration in the oral cavity. Currently, WHO promotes fluoride toothpaste as the primary strategy for optimizing community fluoride levels (Petersen, 2005).

Currently, Australia fluoridates water at a level of between 0.7 and 1.2 parts per million. In January 2011, the US Health and Human Services Department proposed the lowering of recommended fluoride levels in public water supplies from 0.6 to 1.2 parts per million to a uniform maximum level of 0.7 parts per million (United States Department of Health and Human Services, 2011). Consequently, many communities have responded to this proposal by lowering fluoride levels or stopping the fluoridation of their water supplies. The Australian government stated that the health benefits of the current 0.7–1.2 parts per million level in Australia outweigh any potential health and environmental concerns. According to the government reports, prior to fluoridation in the 1950s, the average 12-year-old Australian child had four decayed teeth. Apparently after mass introduction of water fluoridation and fluoridated toothpaste, the average Australian 12-year olds of the 1990s had one decayed tooth (Government of Victoria, Australia, 2011b). However, dental caries is assessed not only by decayed teeth but also by missing and filled teeth. Improved dental care services have reduced the prevalence of decayed teeth, but not necessarily the prevalence of dental caries, of which tooth decay is only one manifestation. The cost effectiveness of water fluoridation is stressed by this excerpt from the Australian Dental Association (2012):

> *'In 2002, Queensland Health commissioned an independent report into the cost effectiveness of water fluoridation. This 2002 Impact Analysis of Water Fluoridation stated that if all Queensland*

> *towns over 5000 people were to be fluoridated, the expected cost benefit to the state over a thirty year equipment lifespan would be more than $1 billion (at 2002 figures). In 2002, the Victorian Health Minister stated that "...every dollar invested in fluoride saves over $30 of dental treatment. The cost of dental treatment in Victoria is over $600 million each year. In the past 25 years fluoridation has saved the Victorian community nearly $1 billion in avoided dental costs, lost productivity and saved leisure time."'*

However, the assumptions underlying the cost-effectiveness calculations were not stated. It is debatable that $1 invested in water fluoridation translates to $30 saved in dental treatment, because not all those affected by dental caries will lose days off work or seek treatment. Also, it is not mentioned if the cost of fluorosis treatment (lifetime treatment costs of $100,000) is included in the cost-effectiveness calculations (Clinch, 2008). It is noteworthy that dental sealant and fluoride mouth-rinsing programs, which are significantly more expensive to implement compared with fluoridating toothpaste, were also found to be cost beneficial in reducing dental caries in two non-fluoridated regions of Victoria, Australia (Crowley *et al.*, 1996). However, a meta-analysis (McDonagh *et al.*, 2000) on the efficacy of water fluoridation found low-quality evidence of its modest effectiveness in preventing dental caries. However, the authors added a caveat:

> *'the most serious defect of the studies of possible beneficial effects of water fluoridation was the lack of appropriate design and analysis. Many studies did not present an analysis at all, while others did not attempt to control for potentially confounding factors. Age, sex, social class, ethnicity, country, tooth type (primary or permanent), mean daily regional temperature, use of fluoride, total fluoride consumption, method of measurement (clinical exam or radiographs, or both), and training of examiners are all possible confounding factors in the assessment of development of dental caries.'*

It would appear that the effectiveness of artificial water fluoridation in the 21st century is at best questionable, given its fixed-dose medication approach, quality of fluoride used and its adverse impact on calcium metabolism and largely insignificant differences in dental caries experience between areas with artificial water fluoridation and those without. These differences in effectiveness of artificial water fluoridation are likely to be more insignificant as the diffusion of fluoride supplements such as toothpaste and milk extend to areas with no artificial fluoridation of public water supplies. More recent studies indicate that, compared with fluoride toothpaste, artificially fluoridated water plays only a minimal role in prevention of dental caries in most parts of the world (Zimmer *et al.*, 2003; Fejerskov, 2004).

Proportionality

The principle of proportionality may be used to resolve the conflict between the ethical principle of beneficence (prevention of dental caries) and the non-maleficence (reduce an increased risk of fluorosis and possibly hypothyroidism and bone fractures) in the water fluoridation controversy. Applied to water fluoridation, it states that the benefits of this intervention must be proportionately greater than anticipated harm (Wein, 2000). The major benefit of water fluoridation is prevention of dental caries. A review of about 200 studies on the health effects of water fluoridation by McDonagh *et al.* (2000) found a median 14.6 per cent reduction in tooth decay—or a median 2.25 fewer decayed, missing, and filled primary/permanent teeth—amongst children living in fluoridated areas compared with non-fluoridated areas.

This contribution is significantly less than the estimated 25 per cent protection from dental caries afforded by fluoridated toothpaste (World Health Organization, 1994). Caries prevention is multifactorial, and fluoride delivery strategies will be ineffective without factors such as access to dental care and reduced consumption of refined sugars. The only indisputably proven harm of water fluoridation is dental fluorosis, for which there is no discernible threshold. However, the risk of dental fluorosis increases as fluoride concentration of water exceeds 0.3 parts per million. Fluorosis is defined as a form of enamel or dentine hypomineralization due to the excessive intake of fluoride during tooth development, specifically amelogenesis. It is best measured using a combination of Fluorosis Risk Index and another instrument such as Dean's Fluorosis Index (Levy *et al.*, 2006). Once the crowns are formed, no further damage may occur due to additional intake or by post-eruptive topical applications of fluoride. However, two other potential adverse effects of fluoride such as increased risks of hypothyroidism (Susheela et al, 2005) and bone fractures (Connett, 2001) have been reported in scholarly journals. Also relevant is the cost of fluoridating public water supplies, of which less than 2 per cent is ingested. For example, the water supply of Calgary, Alberta (population 1.2 million), is fluoridated at an annual cost of $CA750,000 (60 cent per capita). Recently, Calgary's municipal water plant discontinued water fluoridation in part to avoid a $CA6 million upgrade to its fluoridation machines. In the USA, the cost

of artificial water fluoridation varies from 80 cents to $8 per individual per annum, depending on the population size and design of water plant. Although the cost of professionally administered topical fluorides is higher in per capita terms compared with the cost of fluoridation (Lo *et al.*, 2011), the cost of addition of fluoride to toothpaste is much lower than the per capita cost of artificial water fluoridation (George, 2011). However, if the costs of water fluoridation are related to individuals who would most likely benefit (admittedly a difficult cohort to determine but will include infants and most older adults), the cost of water fluoridation is much higher. It appears that the modest anticipated benefits from artificial water fluoridation are not proportional to the significant adverse economic and health consequences of this strategy, such as cost of artificial fluoridation, aesthetic and psychological effects of dental fluorosis (Mwaniki *et al.*, 1994) and a likelihood of higher risks of bone fractures and hypothyroidism. Topical applications of fluoride may provide all presumed benefits of artificial water fluoridation and lower the risk of systemic and local adverse effects, provided that it is adequately supervised and appropriate concentrations of fluoride used for different age cohorts (Marinho *et al.*, 2009). Most fluoride toothpastes also contain triclosan, which helps to reduce gingivitis, a risk factor for gingivitis and dental caries among children (Brambilla, 2001). Given the multiple, more efficient and potentially less harmful forms of fluoride administration, the fluoride preventing benefits of artificial fluoridation appear disproportionately less than the financial cost and potential health hazards from this form of fluoride delivery. Given the high fluoride content of fluoridated toothpaste, it is important that the use of high-dose fluoride toothpaste in children should be supervised to minimize the risk of swallowing of toothpaste during brushing (Anand, 2011).

Necessity

The consensus view on fluorine in relation to dental health is that it is necessary for optimal dental structure and for facilitating resistance against tooth decay. Systematic reviews have shown that water fluoridation reduces the prevalence of dental caries (i.e., per cent with dmft/Delayed, Missing and Filled Teeth (DMFT) > 0) by 14.6 per cent and that fluoride mouth rinses reduce the prevalence of dental caries by the same magnitude (Petersen and Lennon, 2004). In addition to natural and artificial sources of fluoride in water, other sources in most communities include toothpaste, canned juices, carbonated beverages, infant formulas, milk, tea soda drinks and mouth rinses. It is estimated that an average 6 kilogram child who consumes 1 litre of milk daily in the USA may obtain 20 per cent of her or his daily fluoride intake from this source alone (Liu *et al.*, 1995). Further, it is not only in developed nations that the total fluoride exposure in the population is high. Most societies have high local sources of fluoride. In Tanzania, for example, a commonly used meat tenderizer (*Magadi*) has high fluoride content and contributes significantly to high dental fluorosis levels in the population (Yoder *et al.*, 1998). In Sri Lanka, fluorosis levels of 43 per cent have been associated with high levels—up to 5.9 parts per million—of fluoride in well water (van der Hoek *et al.*, 2003). In most poor regions, well water is a common water source, and this source is generally fluoride dense (Shomar *et al.*, 2004). Given the increasing awareness of the various sources of fluoride in the community, it would appear that artificial water fluoridation is not a necessary tool for assuring optimal fluoride levels among community members. Indeed, the consistent caries decline in both communities where water is fluoridated and those with no water fluoridation indicate that multiple sources provide adequate water fluoridation, thus making it unnecessary to artificially fluoridate water (Aoba and Fejerskov, 2002).

Least Infringement

The least infringement principle states that ethical conflicts may be resolved in favour of an intervention if it results in the least possible infringement of individual or population autonomy bodily integrity, as well as community health, among all available alternatives. With regards to artificial water fluoridation, it is an intrusive strategy as its implementation results in mandatory consumption of artificially fluoridated water, even for those who may be harmed by this intervention, such as individuals with fluoride allergy, infants aged 6 months or less and individuals with chronic renal disease. Its infringement on individual autonomy is higher than with other sources of fluoride, which individuals may choose to use or not use. Its infringement on bodily integrity may or may not be higher than other sources of fluoride. However, unlike with water fluoridation, risks from other fluoride sources are easier to manage. For example, supervised use of high fluoride toothpaste may be prescribed for children aged less than 6 years. Other targeted strategies such use of xylitol gum and reducing sugar ingestion have been shown to be effective in reducing dental caries (American Academy of Pediatric Dentistry, 2010). With water fluoridation, however,

such choices may only be achieved if individuals de-fluoridate public water supplies at great expense. Although the only accepted adverse consequence of water fluoridation on bodily integrity is fluorosis, involuntary storage of large amounts of fluoride in bones and thyroid glands is unlikely to be conducive to optimal health. From a precautionary principle perspective, it is ethical to reduce access of excessive fluoride intake, given the potential of harm to the body. Water fluoridation fails the precautionary principle test (Commission of the European Communities, 2000). While adverse impacts of fluoride stored in the bones, pineal and thyroid glands (about 50 per cent of ingested fluoride) on community health remain largely unproven, risk perception is an important consideration in this regard. It is known that the public generally perceives risks to be more worrying and less acceptable if such risks are involuntary and result from 'man-made' sources rather than natural sources (Department of Health, 1998). Water fluoridation belongs to this category of 'unacceptable risks'. The easy and widespread availability of other fluoride delivery channels that infringe less on individual autonomy bodily integrity and community health—perceived or real—impairs the ethical justification of water fluoridation.

Public Justification

This implies transparency by public authorities in justifying the continued practice of water fluoridation to an increasingly skeptical public, as well as allowing affected parties' input in policy formulation. In Carnarvon, Western Australia, for example, earlier studies already indicate that natural fluoride concentrations in the public water supplies are high, and fluorosis is common among adolescents. There is no proof that government officials who are promoting fluoridation in this community conducted extensive water quality analyses and dental fluorosis surveys to see what the levels of dental fluorosis are in the communities before they fluoridate, even though they know that fluoride levels from water and food sources indicate whether children are being overdosed or not. Public justification of water fluoridation is anchored in the 'common good' utilitarian principle—that is, the best outcome for the greatest number. While this principle is valid in some public health contexts such as mandatory wheat flour fortification with folic acid or salt with iodine in nations like Australia (Broughton, 1984; Australian Institute of Health and Welfare, 2011b), it cannot be justified in the case of water fluoridation given the wide availability of alternative sources whose intake are easier to regulate. In the case of Carnarvon, it is disingenuous to justify raising average water fluoride levels from its natural calcium fluoride level of 0.5 to 0.7 parts per million with addition of fluosilicic acid, which is inferior to naturally occurring calcium fluoride as a caries prevention agent. Furthermore, the fluosilicic acid brands used in artificially fluoridating Australia's water supplies are known to be contaminated with lead, arsenic and mercury—major public health hazards for which no safe level exists (Incitec Pivot, 2006). Another common public justification for water fluoridation—equity in reaching the poor who may not be able to otherwise access fluoride sources (Burt, 2002)—is arguable. A study on fluoridated toothpaste affordability revealed that the proportion of annual household expenditure ranged from 0.02 per cent in the UK to 4 per cent in Zambia to buy the annual average amount of lowest cost toothpaste per head (Goldman *et al.*, 2008). However, this may be addressed through advocacy to subsidize the cost of fluoride toothpaste, instead of fluoridating public water supplies, such as in Nepal where an advocacy project increased the market share of fluoridated toothpaste to less than 10 to 90 per cent within 3 years (Yee *et al.*, 2003). To date, there is no evidence to support the assertion that water fluoridation reduced social disparities in caries incidence in Australia or internationally (Pizzo *et al.*, 2007; Evans *et al.*, 1984). Evans et al advised

> *'so far, the relationship between fluoridation and socioeconomic status on caries experience remains equivocal. A note of caution is sounded regarding the interpretation of such results, and the difficulties faced when comparing studies is discussed'.*

Similar conclusions were reached in the York Review (McDonaugh *et al.*, 2000). It is more likely that dental hygiene, access to quality dental care, smoking, poverty and poor nutrition will have a greater influence on socioeconomic disparities in dental caries prevalence than water fluoridation. For example, despite fluoridation being the norm among prisoners in New South Wales, Australia, their past dental health, smoking, methamphetamine addiction and poor nutrition have left them with significantly worse dental profile compared with the majority of New South Wales residents (Osborn *et al.*, 2003). Also, despite over 90 per cent of Australia's public water supplies being fluoridated, since the late 1990s the prevalence of dental decay had increased, particularly among children in low socioeconomic households where the number of caries was 1.5 times that of those in better-off areas (Metherell, 2012).

Ironically, the most well-known adverse effect of artificial water fluoridation, that is, dental fluorosis is inequitably distributed, with poorer children more likely to develop dental fluorosis (due in part to malnutrition) than children from socioeconomically communities (Janakiran, 2009). However, rather than addressing the legitimate concerns of the public with regards to the ethics of fluoridation, pro-fluoridation activists dismiss anti-water fluoridation advocates as misinformed trouble makers intent on undermining public health (Armfield, 2007).

Conclusion

Ethical justification analysis constitutes an important parameter for resolving scientific, legal and public health controversies related to artificial water fluoridation. The above review suggests that artificial water fluoridation cannot be justified on major ethical parameters such as effectiveness, proportionality, necessity, least infringement and public justification. This leads to the question 'Why do a handful of countries including Australia invest substantial amounts of resources in an intervention of contemporary limited value on ethical grounds?' A major reason may be the need to 'close ranks' against advocacy groups and not concede 'victory' to them. Advocacy groups against artificial water fluoridation have, for decades, been derided as ignorant, and it may be viewed as humiliating for the scientific community to concur with anti-water fluoridation campaigners. A second reason is the general inertia with policy disinvestment, which pervades the Australian health sector. Most pro-artificial water fluoridation policy makers tend to be hesitant about policy disinvestment perhaps because it is contrary to 'the way we do it here' culture—the infrastructure has been designed for the fluoridation process, and discontinuing the practice might imply unpalatable changes in operational arrangements (Elshaug *et al.*, 2007). Irrespective of the reasons for reluctance to revise water fluoridation policies, its impact is to slow public health progress in addressing issues that may be related to fluorosis, such as de-fluoridation in areas with high natural fluoride levels in water and more exhaustive investigations of bone and thyroid diseases that may be linked to high-fluoride ingestion in areas such as Bartlett, Texas (Horowitz and Heifetz, 1972) and Tenant Creek, Northern Territory. The cases of water de-fluoridation in Australia are rare, despite wide variations in fluoride levels of natural water systems, and availability of effective defluoridation methods (South Australia's Research Centre on Water Quality and Treatment, 2009). Communities living in areas of high natural water fluoride continue to endure its hazards, perhaps in part because of a perception that de-fluoridation programs might damage the credibility of artificial water fluoridation programs.

More research on the ethics of water fluoridation is required, given increasing difficulty in justifying this public health intervention on ethical grounds in the 21st century. Important research questions in this regard include the following: How can risks and benefits of water fluoridation be compared in Australian communities? In fluoridated areas, do low-income earners have the same average levels of tooth decay as middle- and high-income earners? What are the long-term adverse effects of artificial water fluoridation at a range of 0.7–1.2 parts per million?

Perhaps, the most ideal interventions to prevent dental caries in future may not involve the use of fluorides, thus resolving the ethical debate. For example, probiotics such as *Lactobacillus paracasei* (*Pro-t-Action*) have been shown to have a specific effect on *Streptococcus mutans* and other caries-causing bacteria. This probiotic can easily be incorporated into toothpaste and has not been shown to have any other effect on humans other than destruction of caries-causing bacteria. This promising approach to caries prevention deserves urgent investment to develop it into a global caries prevention strategy (Cannon, 2011).

The US Health authorities have taken the first retreat from water fluoridation in half a century by recommending that the maximum amount of fluoride in public water supplies be set at 0.7 parts per million with effect from February 2011 (United States Department of Health and Human Services, 2011). However, no policy position was provided regarding communities with natural water fluoride above 0.7 parts per million. The Australian health authorities insist on continuing to artificially fluoridate water within the 0.7–1.2 parts per million band. At least on ethical grounds, a reconsideration of current artificial water fluoridation policies is warranted, and a parliamentary debate is a good start to such policy review in Australia.

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DVGW
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DVGW Statement on the Fluoridation of Drinking Water

Recent events have caused the DVGW to review its 1974 statement on the fluoridation of drinking water and to publish an updated version.

Fluoridated drinking water has been available since the end of the sixties to consumers in several cities in the former GDR, including Chemnitz, Magdeburg and Erfurt. The legal basis for this was the Second Implementing Regulation of the "Ordinance Regulating the Hygienic Monitoring of Central Water Supply Systems – Hygienic Monitoring of Drinking Water Fluoridation" (Law Gazette of the GDR, Part II, 1970, 659). Due to the transitional regulations of Dec. 18, 1990 implementing EC law (Federal Law Gazette I, 1990, 2915-2926) drinking water continued to be supplied under the old law in the territory of the former GDR until Dec. 31, 1992.

The addition of fluoride to drinking water in the old federal Länder is addressed in Section 37 para 2 no. 5 of the Act on the general reform of food legislation (Act on food and materials coming into contact with food – Lebensmittel- und Bedarfsgegenständegesetz, LMBG) of 1974 (Federal Law Gazette, Part I, 1974, 1945-1966). According to this law, the "addition of fluorides to drinking water to prevent caries" may be permitted upon request in individual cases as an exception to the legal provisions if the facts justify the assumption that there are no health risks. The Land governments are authorized to regulate the conditions and the procedure for such exceptions more precisely in statutory rules and orders. The governments of the Länder include appropriate authorities responsible for the approval of such exceptions.

Since the effective date of the LMBG on Jan. 1, 1975, no Land government has laid down such statutory rules and orders.

After the water supply companies in the new federal Länder ceased the practice of adding fluorides to drinking water, relevant professional bodies have expressed the fear that this could result in an increase in the incidence of caries.

Therefore the DVGW feels bound to publish a new statement, even though there is no new basic evidence since the mid-seventies that would induce the DVGW to revise its position as stated at that time. Two comprehensive studies of the literature illustrate this. These studies assess scientific publications on the subject of drinking water fluoridation over the last fifteen years.

These studies of the literature will be included in the DVGW series of publications on water for the information of water supply companies and specialists in the population.

The position of the DVGW concerning drinking water fluoridation is as follows:

1. Drinking water is a food. It is the duty of water companies to supply drinking water that meets all requirements of a food. This means that drinking water must be of such a quality that there are no known adverse health effects resulting from its consumption or use.

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Compliance with DIN 2000 and the Drinking Water Ordinance guarantee this.

It is not the task of water supply companies to add substances to drinking water intended as prophylactics against illness not caused by drinking water.

The DVGW therefore is against the addition of fluorides to drinking water.

2. Caries is not the manifestation of a fluoride deficiency, but is the result of a generally false nutrition and inefficient dental hygiene. Unwholesome habits resulting in caries are not eliminated by the fluoridation of drinking water; on the contrary, they are promoted.

3. The suggested optimal fluoride concentration of 1 mg per litre is very close to the dose with which long term detrimental effects in people cannot be excluded. The limit of fluoride as specified in the Drinking Water Ordinance is 1,5 mg per litre.

   The very small difference between the concentration regarded as beneficial as a prophylactic and the limit value in drinking water cannot be justified in view of different habits and therefore differing consumption of drinking water and the uncontrolled intake of fluorides from other sources. The safety of a lifelong accumulation of fluoride in the human body as a result of increased intake is disputed in medical science throughout the world.

4. Less than 1 per cent of the fluoride contained in drinking water would act as a prophylactic. More than 99 per cent would be discharged with waste water directly into the environment. This additional fluoride emission into waters is unacceptable for ecological reasons.

5. The consumer cannot avoid fluoridated drinking water made available by public water supply. This mandatory intake of fluoride violates the basic right to bodily freedom from injury and free development of personality provided by the Basic Law of the Federal Republic of Germany.

6. Fluoride intake for the prevention of caries is more effective with specific measures taken by the individual than by fluoridation of drinking water.

7. An assessment of risks vs. benefits involving both the health aspects and ecological consequences justifies DVGW's rejection of the fluoridation of drinking water.