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

SECOND AFFIDAVIT OF DAVID BENJAMIN MENKES

Dated 4 November 2013

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

Purpose of my evidence

1) I have previously provided an affidavit dated 2 August 2013 and I refer to its contents. In that affidavit I provided an opinion that artificial fluoridation of community water supplies up to 1 ppm could be said to constitute medical treatment and I considered the implications of this for informed consent.

2) In this affidavit I further address these issues, responding specifically to the affidavits of Professor John McMillan, Drs Robin Whyman and Stewart Jessamine.

3) 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 practitioner and 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.

Does water fluoridation constitute medical treatment?

4) Professor McMillan says that CWF is not medical treatment by providing a personal example in paragraph 12, "*The paracetamol in my office drawer is classed as a medicine. But when I offer some to my colleague with a mild headache I'm not providing medical treatment. I'm not a healthcare professional of any kind and cannot be considered to be providing medical treatment*".

5) In my opinion this statement is misleading because a medicine can be prescribed or administered by a health professional, and that same medicine can also be taken voluntarily by an individual, for the same indication and effect, with or without prescription. The term "medical treatment" applies equally in cases where treatment with a medicine was, or reasonably could have been, prescribed by a doctor. In the case of paracetamol, this medicine is often prescribed by doctors in hospital and other

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healthcare settings, as well as sold over the counter. When used appropriately for a medically-recognized indication, e.g., to relieve headache or fever, it can be considered a medical treatment. If used otherwise, for non-approved indications (skin rash or diarrhoea, for example) or for other purposes such as suicide, it would not be considered medical treatment.

6) Professor McMillan further mentions (paragraph 14) that his GP provides "medical treatment" when she binds his sprained ankle. This is also misleading because such treatment rarely requires medical expertise and indeed is usually performed by nurses or physiotherapists, not doctors. "Medical treatment" with medicines, described in the preceding paragraph, can be distinguished from other therapeutic activities that require a doctor to order, supervise, or perform directly. Examples of such medical treatments include surgery, radiotherapy, and electroconvulsive therapy.

7) Professor McMillan further offers the opinion (paragraph 15) that "*a central defining feature of medical treatment is that it is performed by physicians who are providing a regime of clinical care to a patient*". Although medical practitioners (including physicians) may perform medical treatments in this manner, McMillan's definition is both narrow and misleading. As described in the preceding two paragraphs, many medical treatments are prescribed by doctors but administered by other health professionals, or by patients themselves, remote from the medical encounter. Moreover, medical treatments are not restricted to individual patients as McMillan implies, and are sometimes administered to groups of people. Examples include immunisation or antibiotics to control infectious disease; depending on circumstances, these interventions can be targeted to individuals, multiple specific contacts,[1] or whole populations.[2] The latter examples, directed by doctors but not administered by them personally, are relevant to the consideration of whether CWF constitutes medical treatment, as described below and in my 1st affidavit.

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[1] Terranella A et al. Pregnancy dose Tdap and postpartum cocooning to prevent infant pertussis: a decision analysis. *Pediatrics* 2013; 131:e1748-56.

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

8) Dr Robin Whyman says that CWF does not constitute medical treatment because (paragraph 38a) "*fluoridation of water is…a supplement rather than a medication*". He bases his view on the fact that fluoride is found naturally in the environment.

9) I disagree with this reasoning. Many naturally occurring elemental ions (notably lithium; also gold, mercury, bromide) can, like fluoride, be used as medicines. Also like fluoride, these ions can be toxic or medicinal, depending on the dose. Further clarity about what is, and is not, a dietary supplement can be found in a standard medical definition,[3] "a product taken orally that contains one or more ingredients that are intended to supplement one's diet and are not considered food". Clearly fluoride is not a food, nor is it a nutrient (as demonstrated below, and in my 1st affidavit) so it, like lithium, cannot properly be regarded as a dietary supplement.

10) Dr Whyman says (paragraph 38b) that fluoridation is analogous to adding iodine to salt. Again I disagree. Iodine is an essential nutrient, necessary for the function of thyroid, and accordingly is often added to salt or prescribed as a dietary supplement. In the complete absence of dietary iodine, there develops a progressive deficiency state and, ultimately, death. To re-iterate, fluoride is not a nutrient: there is no recognized deficiency state, nor is there a requirement for fluoride in any aspect of human physiology, reproduction, or development. Indeed, breastfed infants are effectively protected from potentially toxic levels of fluoride in mother's blood by the active and specific exclusion of fluoride from breast milk.[4]

11) Nonetheless, some authorities have, as Dr Whyman notes, published 'nutrient reference values' for fluoride (also his paragraph 72). In my opinion this is a misleading use of the term "nutrient" for the above reasons. A recent European Food Safety Authority statement sheds light on this issue: evidence is presented confirming that fluoride is **not** a nutrient, but nonetheless an 'adequate intake' of 0.05 mg/kg/day is proposed in light

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[3] www.merriam-webster.com/medical/dietary%20supplement

[4] Ekstrand J, et al. No evidence of transfer of fluoride from plasma to breast milk. *British Medical Journal* 1981; 283: 761-2.

of its use to prevent dental caries.[5] Further clarity on this issue comes from a comprehensive report by the World Health Organisation.[6] This report considers several categories, including *essential trace elements* (iodine, zinc, selenium, copper, molybdenum, chromium), and *trace elements that are probably essential* (manganese, silicon, nickel, boron, vanadium). By contrast, fluoride (together with lead, cadmium, mercury, arsenic, aluminium, and lithium) are classified instead as *potentially toxic elements, some possibly with essential functions.* Several of the latter category of trace elements (as described above and in my 1st affidavit) can be toxic or used as medicines, depending on the dose.

12) It is an unfortunate characteristic of this latter category of trace elements that, when used as medicines, the therapeutic index (ratio of toxic to therapeutic dose, also called the margin of safety), tends to be quite low, complicating their use. Fluoride and lithium are good examples, with the former having an upper safe limit of 10 mg/day for healthy young men, which is only 2.5 times the recommended 'adequate intake' (see above) for caries prevention[7]. Lithium (2.0) and some other prescription medicines (e.g., digoxin 2.2, warfarin 2.5) share this problem of a low therapeutic index, whereas other drugs (e.g., tricyclic antidepressants and aspirin 5.0-6.0; beta-blockers and paracetamol 10-12) have higher therapeutic indices,[8] and some (e.g., benzylpenicillin, in the absence of penicillin allergy) are exceptionally high, since doses much higher than needed for therapeutic efficacy are known to be safe.

13) Dr Whyman further says (in paragraph 39) that CWF is not medical treatment but a population health measure that works in a preventive way. I do not agree with this distinction as these are not exclusive categories. As demonstrated in paragraph 7 above,

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[5] Scientific Opinion on Dietary Reference Values for Fluoride. European Food Safety Authority. www.efsa.europa.eu/de/consultationsclosed/call/130502.htm

[6] Trace Elements in Human Nutrition and Health. www.who.int/nutrition/publications/micronutrients/9241561734/en/index.html

[7] http://en.wikipedia.org/wiki/Recommended_Dietary_Allowance#Current_recommendations

[8] Regenthal R et al. Drug levels: Therapeutic and toxic serum/plasma concentrations of common drugs. *Journal of Clinical Monitoring and Computing* 1999; 15: 529-544

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other preventive population health measures, such as community immunisation and mass drug administration, can clearly be regarded as medical treatments.

14) The fact that artificial fluoridation in NZ may replicate naturally occurring fluoride exposure in some parts of the world, as pointed out by Dr Whyman in paragraph 38a, is unquestionably true. However, his claim that fluoride in CWF should therefore be classified as a supplement, not a medicine, is incorrect. A corresponding claim could be made regarding lithium-containing waters which also occur naturally and variably in the environment. But it would be absurd to suggest that its natural occurrence means that lithium shouldn't be considered a prophylactic medicine or that its use can't constitute medical treatment; to this day lithium remains an important and effective medical treatment for severe mood disorders.

15) Dr Jessamine is technically correct when he says (his paragraph 14) that "*Medsafe has never considered the fluoridation of water, to the levels prescribed in New Zealand, to lead to the creation of a medicine*". However, as presented in my 1st affidavit, several aspects of fluoride delivered by CWF clearly fulfil the definition and spirit of the Medicines Act 1981, especially in that this practice delivers a **pharmacologically active substance** which is **administered to one or more human beings** (Section 3) for a **therapeutic purpose -- preventing disease** (Section 4).

16) Dr Jessamine is also correct in stating (paragraph 15) that a substance with therapeutic qualities is not necessarily a medicine in all its forms, and gives the example of lithium in paint or batteries. This principle undoubtedly also applies to fluoride which, like lithium, occurs in many different forms. However, the key point is that when used to fluoridate drinking water to a pharmacologically active concentration (0.7-10 ppm), fluoride is for all intents and purposes being used as a medicine with a specific therapeutic purpose for those consuming the water.

17) Dr Jessamine further gives the example (paragraph 16) of gin and tonic not being medicinal, despite tonic containing a known medicine, quinine. I agree; in this case a quinine-containing beverage is being used for purposes which are more accurately viewed as dietary or recreational, and in any case the available dose of quinine is unlikely to confer any specific benefit or harm. The point again is that CWF is the deliberate

administration, directed by doctors and other health professionals, of a pharmacologically active substance for a defined therapeutic purpose; the same cannot be said of gin and tonic, margarine substitutes, or other foods.

18) Dr Jessamine concludes with the point (paragraph 17) that "*a substance is not a medicine unless it is supplied wholly or principally for a therapeutic purpose*" and proposes that water is supplied by local authorities mainly for dietary, not therapeutic, purposes. This is unquestionably true. However, if the water is artificially fluoridated to 0.7-1.0 ppm, the water itself can be properly viewed as the delivery vehicle used to administer a medicinal substance (fluoride), added *wholly or principally for a therapeutic purpose*, to the whole population supplied by that water scheme. Other examples from current medical practice illustrate this point further; acutely dehydrated or hypotensive patients treated with intravenous saline in emergency settings often also receive specific medicines dissolved in the saline (such as chlorpromazine for severe migraine with emesis, or adrenaline for anaphylactic shock). In these cases the principal purpose of the saline infusion is hydration, but the added medicines also have specific therapeutic purposes, and their classification and use as medicines is in no way diminished by the fact that they are administered in an aqueous solution given for another primary purpose.

19) Dr Whyman and Professor McMillan (paragraphs 41 and 13, respectively) both opine that routine tooth-brushing does not constitute medical treatment, and I agree; it can more reasonably be described as self-care and good hygiene. However, the use of high-fluoride toothpaste, gels, varnishes, and mouthwashes can be considered medical treatment, as these are generally prescribed by health professionals. Likewise, in my opinion CWF can also be considered medical treatment, as its use is specifically decided upon, advocated and directed by doctors for a specific therapeutic purpose using a pharmacologically active substance. These principles of medical treatment apply to CWF even if the fluoride delivered by the practice is yet to be technically classified as a medicine (paragraph 15, above), and fits with the definitions considered in my 1st affidavit.

20) A further principle of modern medical treatment is dose control, in order to optimise the balance between intended and adverse effects;[9] consistent with this principle, CWF requires careful control of fluoride concentrations in the target range (0.7 – 1.0 ppm). Due to significant inter-individual variation in water consumption, dietary and dental habits, the connection between fluoride water concentration and ingested doses is unfortunately inconsistent, posing risks of inefficacy and toxicity for individuals at the lower and upper ends, respectively, of the dose distribution.[10]

Informed consent

21) Professor McMillan asserts that CWF does not constitute involuntary treatment but rather poses an "inconvenience" for those who wish to avoid it -- by the use of filters, rainwater collections systems, or bottled water (his paragraphs 17, 18, 22). While this may be true to some extent for some citizens (those aware that their tap water is fluoridated, wish to avoid added fluoride, and have the time and means to take such measures) it certainly does not apply to many others – notably those with economic or social disadvantage – for whom avoiding fluoridated water would be difficult if not impossible.

22) Avoiding fluoridated water at home may be an expensive "inconvenience" but in my opinion totally avoiding fluoridated food and beverages would be almost impossible and certainly would impose severe restrictions on one's lifestyle. One would not, for example, be able to consume food or beverages made with fluoridated water from cafes, restaurants, supermarkets or friends' homes.

23) While acknowledging the BORA's requirement that everyone has the right to refuse medical treatment, Professor McMillan asserts that this doesn't apply to CWF, since drinking fluoridated water isn't "done" to a person. I think this is misleading. Many medical treatments are self-administered or given to others by non-medical personnel,

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[9] Richards D, Aronson J. *Oxford Handbook of Practical Drug Therapy*. Oxford University Press, 2005

[10] Fluoride in Drinking Water: A Scientific Review of EPA's Standards: The National Academies Press; 2006.

for example when prescribed antibiotics are swallowed by the individual, or given to a family member. In this case the prescribing clinician believes the patient's condition would improve with treatment, just as influential health professionals in the MoH and DHBs believe that oral health will be improved if people drink fluoridated water. The fundamental difference is not whether the manoeuvre is medical treatment, but rather whether it is done to treat or prevent illness, and whether it applies to individuals or populations. In the latter case, as described above, refusing or withdrawing consent is logistically difficult, if not impossible. As noted in my 1st affidavit, there are precedents for other mass drug administration programmes – and which have posed pharmacological and ethical challenges for similar reasons as CWF. The evidential standard, in terms of benefit/harm ratio, required for medical interventions should properly be *higher* when population rather than individual treatment is considered; a more stringent standard is also required to warrant prophylaxis compared to treating established illness. These ethical requirements thus set a high bar to warrant population-based preventive treatments such as CWF.[11]

24) In his paragraph 23 Professor McMillan states "*Libertarians might argue that every public health measure should require individual consent, consequently, universal public health measures that have a profound impact on health and carry no risk of harm, would become impermissible without universal consent*". This rhetorical statement appears extreme, but does allow useful distinctions to be drawn. For example, purification and disinfection of communal drinking water could be considered a universal public health measure, given its widespread adoption in developed societies. Few would seriously challenge its positive benefit/harm ratio, even given the comparatively tiny risks posed by, for instance, chlorination as a means of disinfection. By contrast, CWF is not intended to make water safe to consume, but rather (as detailed above, and in my 1st affidavit) to treat people with a pharmacologically active substance for a therapeutic purpose -- prevention of dental caries. CWF also differs from purification/disinfection of drinking water inasmuch as the former cannot be considered universal; most countries do not fluoridate

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[11] Cheng KK, et al. Adding fluoride to water supplies. *British Medical Journal* 2007; 335: 699-702.

their water, and an increasing number have abandoned the practice for health and/or ethical reasons. Community immunisation programmes are, like CWF, intended to reach as many individuals as possible in a population for the purposes of disease prevention. The differences, however, are profound: a) immunisation protects both treated individuals as well others by promoting 'herd immunity' and limiting transmission of disease (CWF confers no such indirect benefit); b) compared to CWF, immunisation confers both more benefit and also possibly more risk to individuals, but the **net benefit** of routine immunisation to population health is unquestionably positive (the net benefit of CWF is controversial and, even in the best case scenario, modest in comparison);[12] c) despite the strong evidence in favour of routine immunisation, and the benefits it confers to the community as a whole, individuals in NZ have the right to refuse this prophylactic treatment for themselves or their children. As outlined above, it is difficult if not impossible for many individuals to avoid fluoridated water.

25) In his paragraphs 25-33, Professor McMillan questions the arguments in my 1st affidavit regarding Awofeso's analysis,[13] particularly as it relates to the ethical basis for treatment without consent (according to the principles developed by Childress et al).[14] For example, he contends in his paragraphs 27 and 28 that I have mis-represented Childress et al's notions of effectiveness and proportionality. Reviewing my affidavit and the relevant paragraphs from Awofeso and Childress et al. indicates that no real issues are at stake here; 'risks' and 'harms' of treatment without consent are clearly understood to include attendant moral considerations such as compromised autonomy.

26) Professor McMillan proceeds (in his paragraphs 29-32) to question Awofeso's interpretation of the latter's cited references regarding the effects of CWF. There is little, if any, specific criticism. It appears that McMillan disagrees with Awofeso's

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[12] ibid.

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

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

conclusion that that CWF cannot be ethically justified, but does not provide a cogent counter-opinion.

27) In his paragraphs 33 and 36-38, Professor McMillan summarises the Nuffield Council's ethical position on CWF, referring in particular to its 6 point 'stewardship' model. This describes the *'public health aims of the state'* to include (in points 4-6 respectively): *not intervening without consent of those affected, minimising interventions that affect important areas of personal life,* and *not coercing ordinary adults to lead healthy lives.* Each of these principles is directly challenged by CWF. The Council also recognises the incomplete and uncertain evidence of both benefits and harms of CWF (McMillan paragraphs 38 and 41), based on the York Review, and which is also summarised in the British Medical Journal.[15]

28) In NZ, as overseas, the benefits of CWF are modest and not able to be demonstrated in some studies. For example, 2011 Ministry of Health data on dental decay for five-year-old children indicate that for those living in fluoridated areas (n=44,653) the percentage with caries-free teeth was 59.91% while for those living in non-fluoridated areas (n=18,804) the percentage with caries-free teeth was virtually identical at 59.18%.[16] Similarly, a study of 39,207 school children in the USA in 1986–1987 found no statistically significant difference in the incidence of decay-free teeth at any age between 5 and 17 years, with the percentage of decay-free children in the fluoridated areas being 34.5% while that for the non-fluoridated areas was 35.1%.[17] The evidence that CWF reduces health inequalities is, unfortunately, even weaker than the evidence for CWF overall.[18] The evidential 'gold standard' for establishing the efficacy and safety of health interventions is the randomised controlled trial (RCT); such a trial of CWF has yet to be reported in NZ or overseas.

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[15] Cheng KK, et al. Adding fluoride to water supplies. *British Medical Journal* 2007; 335: 699-702.

[16] Ministry of Health. Age 5 and Year 8 oral health data from the School Dental Services. Wellington: Ministry of Health. [updated 2012 Dec 6; cited 2013 Jul 1]. www.health.govt.nz/nz-health-statistics/health-statistics-and-data-sets/oral-health-data-and-stats/age-5-and-year-8-oral-health-data-school-dental-services

[17] Yiamouyiannis JA. Water fluoridation and tooth decay: results from the 1986–1987 national survey of U.S. schoolchildren. *Fluoride* 1990:23:55-67.

[18] Cheng KK, et al. Adding fluoride to water supplies. *British Medical Journal* 2007; 335: 699-702.

29) Several concerns, relevant to net benefit of CWF, relate to its problematic pharmacology. These concerns, in summary, include:

i) CWF confers the systemic (whole body) exposure of entire populations, and attendant risks of harm, from an agent whose predominant benefit is from topical contact with the teeth. Fluoridated toothpaste and other dental products are known to be effective based on RCT evidence and, unless swallowed, avoid the problem of systemic exposure.

ii) the low therapeutic index of fluoridated water poses particular difficulty given the variable doses that individuals ingest, depending on how much they drink.[19] A principle of pharmacology is that systemically administered drugs with a low therapeutic index should be dosed carefully, and are generally either standardised by weight (as in mg/kg/day) or are subject to blood monitoring.[20] Indeed, the recommended fluoride dose ('acceptable intake', see above) to optimize benefit/harm ratio is given as 0.05 mg/kg/day, but this refers to ingestion and is rather illogical in light of fluoride's topical mechanism of action. In any event, as described above, delivering fluoride in drinking water precludes accurate dosing. The other recommended precaution when administering drugs with low therapeutic index, blood level monitoring, is used rarely, if ever, with CWF.

iii) Because of this dosing problem, formula-fed infants in fluoridated areas receive higher mg/kg doses than anyone else, and may be especially vulnerable to toxicity given their rapid brain and other development (as noted above, the human breast actively excludes fluoride from milk). Patients with chronic renal failure are unable to excrete fluoride effectively and are prone to toxicity as a result. Individuals with iodine deficiency are also more sensitive, in this case to fluoride-induced thyroid dysfunction. In my view, it is unacceptable that special

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[19] Fluoride in Drinking Water: A Scientific Review of EPA's Standards: The National Academies Press; 2006.

[20] Richards D, Aronson J. *Oxford Handbook of Practical Drug Therapy*. Oxford University Press, 2005

protection for these vulnerable sub-populations is not generally considered or implemented in areas with CWF.

30) In his paragraphs 47 and 48 Professor McMillan makes his position clear. He concludes that CWF does not constitute medical treatment. However, if it is found to be medical treatment, then he doesn't consider CWF to violate the right to refuse treatment. If it is found to violate this right, then he considers CWF to be a justified limitation of that right. In other words, he supports CWF regardless of these considerations – ostensibly on the basis of evidence that he concedes is unclear and incomplete regarding both benefits and harms.

31) In his concluding paragraphs (49 and 50), Professor McMillan asserts that treatment without consent is necessary for improving oral health in Waverley and Patea, and that CWF is the "most effective way" of addressing oral health inequalities. As noted above, there is scant high quality evidence to support the latter view, and Professor McMillan neglects to identify the availability of other strategies to address the problem such as improving diet (by restricting sugary foods and beverages, for example) and promoting dental hygiene in families and schools. As Childress et al, Awofeso, and the Nuffield Report all make clear, the availability of alternative measures (particularly those with less impact on personal autonomy) are crucial to include in the ethical appraisal of public health interventions that preclude individual consent.

AFFIRMED at Hamilton this 04th

day of November 2013

before me:

A Elkington
Deputy Registrar
District/High Court
Hamilton

Deputy Registrar

A Barrister and ~~Solicitor~~ of the High Court of New Zealand