IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY CIV 2014-485-4138

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	ATTORNEY-GENERAL for and on behalf of the Minister of Health
	Defendant

AFFIDAVIT OF DAVID BENJAMIN MENKES

Dated 23 June 2014

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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 pharmacological and other 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 the chemicals used in artificial fluoridation of community water supplies have the properties of a medicine as defined by the Medicines Act 1981 and could thus be said to be used as a medicine.

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 to a target range of between 0.7 and 1.0 parts per million (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.

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11. The intended purpose of CWF is to prevent dental caries, based on the action of fluoride ions which, in sufficient concentration, can inhibit demineralisation and promote remineralisation 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 acidic environment promotes caries by promoting the demineralization of 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.

Do HFA and SSF function as medicines when used in CWF?

13. Section 3 of the Medicines Act 1981 defines "medicine" as any substance or article, other than a medical device that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose.

14. "Therapeutic purpose" includes treating or preventing disease (Section 4 of the Medicines Act).

15. Dental caries is a disease and it is my opinion that HFA and SSA when used in water fluoridation have a 'therapeutic purpose' as defined in the Medicines Act.

16. Section 2 of the Medicines Act defines "administer" to include 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 to be administered.

17. In my opinion these characteristics of drug administration apply to HFA and SSF when used in CWF to increase the concentration of fluoride and thereby promote its delivery to and ingestion by human beings. It is thus my view that HFA and SSF function as medicines when used in CWF.

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18. This view 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).

19. I understand the definitions of "medicine" and "therapeutic purpose" will be amended from 1 July 2014. The definition of medicine will read:

> (1) In this Act, unless the context otherwise requires, **medicine**—
>
> (a) means any substance or article that—
>
> (i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and
>
> (ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and
>
> (b) includes any substance or article—
>
> (i) that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or
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> (ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but
>
> (c) does not include—
>
> (i) a medical device; or
>
> (ii) any food within the meaning of section 2 of the Food Act 1981; or
>
> iii) any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or
>
> (iv) any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or
>
> (v) any animal remedy; or
>
> (vi) any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act."

20. The definition of "therapeutic purpose" will read:

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> In this Act, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:
>
> (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
>
> (b) influencing, inhibiting, or modifying a physiological process; or
>
> (c) testing the susceptibility of persons to a disease or ailment; or
>
> (d) influencing, controlling, or preventing conception; or
>
> (e) testing for pregnancy; or
>
> (f) investigating, replacing, or modifying parts of the human anatomy.

21. It is my opinion that HFA or SSF are used to achieve their principal intended action by increasing the concentration of fluoride ions, thus affecting mineralisation of tooth enamel and thereby preventing dental caries. This action on the human body is achieved by pharmacological means and thus satisfies the requirements of the revised definition of a medicine described in paragraph 19.

22. The caries-preventive action of fluoride is mainly topical in that fluoride ions in sufficient concentration interact with the surface of the tooth enamel and can thereby inhibit demineralisation and promote remineralisation.

23. As well as intended to prevent disease, the fluoride-releasing compounds HFA and SSF when used in CWF could also be said to come within subparagraph (b) of the definition of "therapeutic purpose", in that they are used for the purpose of influencing, inhibiting, or modifying a physiological process (refer paragraphs 21 and 22).

24. As used in New Zealand, CWF also can be seen to have a further characteristic of the use of medicines, namely the dose-response relationship. The current target range of 0.7 – 1.0 ppm fluoride in tap water, achieved by the careful addition of HFA or SSF to communal water supplies, is based on the Ministry's view that this range offers the optimum balance between desired effects 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.

25. To date it appears that Medsafe, the New Zealand drugs regulator, has not specifically described HFA and SSF as medicines, even though a variety of other fluoride-releasing products are so classified. For example, the NZ Formulary lists sodium fluoride tablets as a pharmacy-only medicine indicated for the prophylaxis of dental caries.[1]

26. Ingesting two 1.1 mg sodium fluoride tablets supplies a person with approximately 1.0 mg of elemental fluoride, the same dose as obtained by consuming 1 litre of fluoridated water (at the upper target concentration of 1.0 ppm) or 1.43 litres of water fluoridated with HFA or SSF to the lower target of 0.7 ppm.

27. In my opinion there is no valid medical or pharmacological reason why the delivery of the same dose of the active principle fluoride should be considered to reflect use of a medicine in one form (sodium fluoride tablets) and not in the other (water fluoridated with HFA or SSF), particularly when, as in the example given in paragraph 26, both reflect a typical daily dose and are supplied by a fluoride-releasing salt with the same therapeutic purpose.

28. There is thus no essential difference, in therapeutic intent or pharmacological mechanism, between ingesting the same dose of fluoride by tablet or by artificially fluoridated water. Both can be said to reflect the use of a medicine, particularly in light of the fact sodium fluoride tablets should, according to Ministry guidelines, be "chewed or sucked, or dissolved in drinking liquid".[2]

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

[2] www.health.govt.nz/system/files/documents/publications/guidelines-for-the-use-of-fluoride-nov09.pdf

29. To reiterate, HFA and SSF, when used for CWF, have the characteristics of medicines namely because their use is intended to cause "a pharmacological effect" (mineralisation of tooth enamel via the release of fluoride ions), and they are "used in one or more humans primarily for a therapeutic purpose" (prevention of dental caries).

30. While HFA and SSF are, for all intents and purposes, used as medicines in CWF, they are not pharmaceutical grade. Rather they are of a less pure and cheaper 'water treatment grade' (www.waternz.org.nz/).

31. CWF can be distinguished, in my opinion, from the practice of fortifying foodstuffs with essential nutrients, such as iodine or folic acid in bread, due to the fact that fluoride is not a dietary nutrient. Both fluoride-releasers (such as HFA and SSF) and essential nutrients may be used to prevent disease, but the former are used as medicines 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.

32. As with certain other atomic elements (notably lithium, but also antimony, bromide, gold, mercury, strontium) the salts of which 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-releasing salts cannot be considered nutrients or dietary supplements.

33. According to international guidelines, levels of fluoride in drinking water that are said to help prevent tooth decay are in the range of 0.7 – 1.0 ppm.[3] Because the natural levels of fluoride in fresh water in most parts of NZ are considered too low to have a

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

measurable effect on tooth mineralisation, the Ministry of Health recommends that the levels of fluoride in community water supplies be 'adjusted' to 0.7 - 1.0 ppm. In NZ and in the European Community, 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.

34. I have also considered whether the fact that fluoride exists in the environment, and is found naturally in groundwater, means that compounds that release it into drinking water could not be considered medicines. In my opinion this is incorrect. First, as noted in paragraphs 25 and 28, various fluoride-releasing compounds are scheduled as medicines and, in the case of sodium fluoride tablets, can be taken dissolved in water. Second, salts that release certain other atomic elements, which in their ionized form are found naturally in water, have also been used as medicines (refer paragraph 32 above) and, in sufficient concentration, are known to be toxic. Fluoride, like other elemental ions that are released by medicinal salts, can be considered therapeutic or toxic, depending on the dose.

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AFFIRMED at Hamilton this

23rd day of June 2014

before me:

M Wairari

M Wairari
Deputy Registrar
District/High Court
Hamilton

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

A

THIS is the Exhibit marked with the letter "A" referred to in the annexed affidavit of David Benjamin Menkes SWORN at Hamilton this 23rd day of June 2014 before me:
M Walan
Deputy Registrar
District/High Court
Hamilton
A Solicitor of the High Court of New Zealand

CURRICULUM VITAE (brief) June 2014

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

Collegium Internationale Neuropsychopharmacologicum (CINP)
Cochrane Collaboration Adverse Effects Methods Group
Healthy Skepticism
International Society of Drug Bulletins (www.isdbweb.org)
International Society of Pharmacovigilance
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/staff/staff_details.aspx?staffDetailsID=30139

(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: 94**

(c) **Refereed abstracts and letters: 43**

7. **Postgraduate supervision since 2009**

Examination committees for Masterate (Otago, 2013) and PhD (Auckland, 2012)

Co-supervision (with Graham Mellsop) of MD thesis "Real life outcomes of antipsychotic prescribing in New Zealand", Sangeeta Dey, 2012 to present

8. **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

Scientific Committee member, Australasian Mental Health Outcomes Conference "Into Uncharted Territory", Auckland, 17-19 November 2010.
Also presented a paper at this meeting

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

Conference Committee, RANZCP New Zealand Conferences (Wellington 2012, Auckland 2013, Dunedin 2014). My involvement included developing and implementing:

1. 'Evidence Alley', a set of exhibits supporting evidence-based decision making in psychiatry
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 DHB, 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

D Menkes

David B Menkes