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

SECOND AFFIDAVIT OF DAVID BENJAMIN MENKES

Dated 24 July 2014

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I, David Benjamin Menkes, academic psychiatrist of Hamilton, solemnly and sincerely affirm:

1. I previously provided an affidavit dated 23 June 2014 and I refer to its contents.

2. I have read the affidavits of Stewart Jessamine and Paul Prendergast.

3. I have been asked by the plaintiff to comment on Dr Jessamine's affidavit.

4. 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.

5. At paragraph 19 Dr Jessamine suggests that the regulatory status of "elemental fluoride" (the element fluorine, because of its extraordinary electronegativity, typically exists in ionized form as fluoride) depends on presentation (form and packaging) of the chemical, concentration of the product, and its intended use.

6. These criteria appear to differ from the summary in Medsafe's Regulatory Guidelines for Medicines as set out in the extract below. The key criteria are therapeutic claim (implied or expressed) **or** whether the active ingredient has a pharmacological action.

> The medicines legislation controls products used in humans for a therapeutic purpose. Products used for a therapeutic purpose can be categorised as medicines, related products, herbal remedies or medical devices...
> A product is considered to be intended for a therapeutic purpose if a therapeutic claim is stated or implied in the product labelling or promotional material, or where the active ingredient(s) clearly has a pharmacological action. (p 1)

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7. As I have already explained in my first affidavit, HFA and SSF have a claimed and intended therapeutic purpose and their active ingredient, fluoride, has a known pharmacological mechanism of action. Accordingly, these fluoride-releasing salts satisfy both criteria for therapeutic purpose, as outlined in paragraph 6.

8. Dr Jessamine suggests at paragraph 24 of his affidavit, that a narrow interpretation of "therapeutic purpose" would apply to water, fluoride and chlorine.

9. I disagree. While water prevents dehydration, and dehydration can be serious or even fatal, water is not considered a medicine because it is a food, essential to life. Thus giving water to a seriously dehydrated person could be considered therapeutic, but not in a medicinal sense.

10. Chlorine is commonly used to treat drinking water, in order to kill bacteria and other microorganisms and thereby prevent water-borne disease. It is not administered to a person to treat disease. If a person contracted an infection from water-borne bacteria, they would not be treated with chlorine.

11. In my opinion only one of the three - water, chlorine, and fluoride – can have a medicinal therapeutic purpose, namely the latter.

12. Fluoride is also the only substance of the three that, in various preparations, has been classified in New Zealand as a medicine.

13. Dr Jessamine says at paragraph 25 that a "reductionist approach" to interpretation would mean that close to everything could meet the definition of medicine, including oxygen in the air.

14. This statement is misleading because oxygen in the air, like water (see paragraph 9), is essential to life. Oxygen is thus not classified as a medicine, although concentrated

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oxygen can be prescribed by doctors and given therapeutically to seriously ill patients with hypoxia.

15. Dr Jessamine says at paragraph 27 that "*the Ministry of Health has never considered fluoridation of water, to the levels prescribed in New Zealand, to lead to the manufacture or creation of a medicine*".

16. This argument ignores the fact that artificial fluoridation uses public water supplies to deliver a pharmacologically active substance with a therapeutic purpose to one or more human beings. Fluoridation of water thus satisfies the core principles of what constitutes a medicine and its administration, consistent with relevant definitions in the Medicines Act of "administer", "medicine" and "therapeutic purpose".

17. I agree with Dr Jessamine that water itself is not a medicine but this is not the issue in question. The key point is that artificial fluoridation uses community water supplies to deliver a medicine.

18. Medicines are often delivered through an aqueous solution. For example, 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 vomiting, 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 Jessamine is also correct in stating (paragraph 30) that a substance with medicinal qualities is not necessarily a medicine in all its forms, and gives the example of lithium in paint or batteries.

20. This principle undoubtedly also applies to fluoride which, like lithium, occurs in many different forms. However, the key point again is that when used to fluoridate drinking water, fluoride is for all intents and purposes being used as a medicine with a specific therapeutic purpose for those consuming the water.

21. Batteries or paint containing lithium indeed do not have a therapeutic purpose or a therapeutic claim; the same can be said of many fluoride-containing compounds. However, certain lithium-releasing salts (e.g. lithium carbonate) have a therapeutic purpose and are used as medicines, and the same can reasonably be said of the fluoride releasing salts HFA and SSF (see paragraph 16).

22. HFA and SSF are used for the same purpose (prevention of dental caries) and exert the same pharmacological effect as sodium fluoride, another fluoride-releasing salt.

23. Sodium fluoride tablets (1.1 mg, each containing 0.5 mg elemental fluoride) are classified as a pharmacy-only medicine in New Zealand and are recommended as a substitute fluoride source for people in areas without artificial water fluoridation.

24. Based on an average consumption of 2 litres of water a day (refer paragraph 46 of Mr Prendergast's affidavit), a person in a fluoridated community ingests through the water supply a daily dose of fluoride equivalent to 3 to 4 fluoride tablets (1.5 – 2.0 mg of elemental fluoride). As indicated in the product information sheet, these tablets can be taken dissolved in water, making their administration (as well as their therapeutic purpose and pharmacological mechanism) essentially identical to consuming water in fluoridated areas at concentrations currently recommended in New Zealand (0.7 – 1.0 mg/litre).

25. At paragraph 31 Dr Jessamine refers to margarine which claims to lower cholesterol. Margarine is a food and is excluded from the definition of a medicine. Fluoride, however, is not essential for human development, physiology or reproduction, and thus cannot be considered a nutrient or food.

26. Dr Jessamine argues in paragraph 33 of his affidavit that fluoride-releasing compounds such as HFA or SSF cannot be considered medicines since they are supplied in industrial size containers.

27. I disagree with this argument. For example, a New Zealand registered prescription medicine, the anaesthetic gas nitrous oxide, is supplied in industrial size containers, in this case ranging from 1.09 – 18.14 cubic metres.

28. Dr Jessamine also says at paragraph 33 that such industrial size containers are not "recognisable medicinal dose forms". This characteristic also applies to nitrous oxide, but this in no way diminishes its use or status as a medicine.

29. The size or shape of the container supplying a medicine thus does not determine its classification. What matters is how it is used, for what purpose, and whether it has a recognised pharmacological mechanism of action (refer paragraph 16).

30. An essential characteristic of the use of medicines is dose control, in order to optimise the balance between intended and adverse effects.[1]

31. Consistent with this principle, artificial water fluoridation requires concentrations in the target range (0.7 – 1.0 ppm) in order to provide what is thought to be an adequate dose of fluoride to prevent tooth decay while minimising risks of harm. Dose control also explains why sodium fluoride tablets are contraindicated for those living in areas with artificial water fluoridation (refer paragraphs 23 and 24).

32. At paragraph 34 Dr Jessamine suggests that because concentrated fluoride compounds are never directly consumed in an undiluted form by human beings they are not supplied wholly or principally for administration to a human being for a therapeutic purpose.

33. This is incorrect in my view. Many medicines require dilution before they are administered and act upon the human body. To avoid cardiac arrest, for example, potassium chloride solution (0.75 g/10 mL) **must** be diluted in an aqueous solution before intravenous injection.

34. Similarly, many chemotherapeutic drugs or volatile anaesthetics require dilution in water or air, respectively, before they can be administered safely. In each of these cases, dilution is part of normal therapeutic practice and the fact that these agents are supplied in a concentrated form in no way challenges their classification or use as medicines.

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

D Richards

Affirmed at Hamilton this 24th day of July 2014

Before me: E Ho Kam
Deputy Registrar
District/High Courts
Hamilton

Deputy Registrar of District Court of New Zealand