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, an incorporated society having its registered office in Christchurch**
	Plaintiff
AND	**ATTORNEY-GENERAL for and on behalf of the Minister of Health**
	Defendant

STATEMENT OF CLAIM

Dated 2 April 2014

Solicitor
Wynn Williams Lawyers
Homebase
Unit B 195 Marshland Road
Shirley
P O Box 4341
Christchurch
Ph: (03) 379 7622
Fax: (03) 353 0247
Solicitor: Jonathan Gillard

Counsel:
Lisa Hansen
Level 8, Wakefield House
90 The Terrace
PO Box 8045
Wellington 6143
Ph: 914 1052
Fax: (04) 473 3179
Email: l.hansen@barristerscomm.com

The Plaintiff by its solicitor says:

Parties

1. The plaintiff is an incorporated society having its registered office in Christchurch.

2. The plaintiff is a consumer-focused health organisation which aims to advance and protect the best interests and health freedoms of consumers.

3. The defendant is sued for and on behalf of the Minister of Health.

4. The Minister of Health, through the Ministry of Health's business unit Medsafe, is responsible for the regulation of therapeutic products in New Zealand.

The plaintiff

5. The plaintiff's purpose includes:

    5.1. To provide representation for the consumers of health products and services in New Zealand.

    5.2. To ensure that good quality health information is made available to consumers, at all times.

    5.3. To ensure that a consumer has the right to select such health services and products as may be beneficial to the consumer in the consumer's opinion.

    5.4. To promote sensible regulation of health products and services in the interests of New Zealand consumers.

Fluoridation of water supplies

6. Some local authorities in New Zealand add fluoride-releasing compounds to their water supplies to a total level of between 0.7 and 1 part per million (ppm) fluoride.

7. The fluoride compounds purchased by local authorities and used to add to water supplies are primarily hydrofluosilicic acid (HFA) and sodium silicofluroide (SSF).

8. HFA is a by-product of the manufacture of phosphate fertilisers. Phosphate rock, which contains fluoride and silica, is treated with sulphuric acid. This produces two gases: silicon tetrafluoride and hydrogen fluoride. These gases are passed through scrubbers where they react with water to form hydrofluosilicic acid.

9. SSF is generally produced from the addition of sodium carbonate or sodium chloride to HFA.

10. The claimed purpose of adding HFA and SSF to water supplies is therapeutic, namely to reduce the incidence of tooth decay.

11. The Ministry of Health strongly supports and promotes water fluoridation.

12. The plaintiff is opposed to fluoridation of water supplies by local authorities for reasons that include but not limited to:

    12.1. Fluoridation removes a consumer's freedom of choice.

    12.2. Fluoride is potentially harmful to health.

    12.3. Fluoridation of water supplies is not an effective way of providing fluoride for the purposes of preventing dental caries.

12.4. Fluoridation of communal water supplies in order to deliver fluoride to individuals conflicts with several core principles of modern pharmacology.

12.5. The fluoride added to water supplies is sourced from industrial by-products and contains heavy metal contaminants including arsenic, mercury and lead.

Plaintiff's legal challenge to fluoridation

13. In 2013 the plaintiff issued judicial review proceedings against the South Taranaki District Council challenging its December 2012 decision to add fluoride to its Waverley and Patea water supplies.

14. The plaintiff argued that there was no power in the Local Government Act 2002 to fluoridate, that water fluoridation breached s 11 of the New Zealand Bill of Rights Act 1990 (NZBORA) and was neither prescribed by law nor reasonably justified under s 5 of the NZBORA.

15. In a decision dated 7 March 2014 the High Court dismissed the plaintiff's claim (*New Health NZ Inc v South Taranaki District Council* [2014] NZHC 395) (the decision).

16. On 26 March 2014 the plaintiff lodged an appeal against the decision in the Court of Appeal.

Consequences of the decision

17. In the decision the judge held that water fluoridation has a therapeutic medical purpose, namely preventing tooth decay.

18. A necessary consequence of this finding is that the chemical compounds used in water fluoridation – HFA and SSF - are a "medicine" under the Medicines Act 1981.

19. Section 3 of the Medicines Act 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.

20. "Administer" means administer to a human being, either –

(a) Orally or by injection or by introduction into the body in any other way; or

(b) By external application, whether by direct contact with the body or not; -

and every reference to administering a substance is a reference to administering it 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 (s 2 of the Medicines Act).

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

22. Dental decay is a disease.

23. HFA and SSF are sold to and distributed by local authorities wholly and principally for the purpose of being introduced into the human body via the water supply in order to prevent dental decay.

Before being used for water fluoridation HFA and SSF must be approved as medicines under the Medicines Act and the manufacturer requires a licence from the Director General of Health

24. Under the Medicines Act a manufacturer of a medicine requires a licence from the Director General of Health: ss 17 and Part 3 of the Medicines Act.

25. A person who contravenes s 17 of the Medicines Act commits an offence and is liable on conviction to a fine not exceeding $40,000.

26. The Director-General has not granted a licence under Part 3 of the Medicines Act to any manufacturer of HFA and SSF.

27. Under s 20(2) of the Medicines Act no person shall sell or distribute by way of gift or loan or sample or in any other way, any medicine before the consent of the Minister of Health to the distribution of the medicine has been notified in the *Gazette*.

28. A person who contravenes s 20(2) commits an offence and if a body corporate is liable to a fine not exceeding $100,000.

29. The process for obtaining the Minister's consent is contained in ss 21 and 22 of the Medicines Act.

30. The Minister of Health has not granted consent to the distribution of HFA and SSF under the Medicines Act.

WHEREFORE the plaintiff claims:

(a) A declaration that when sold to and supplied or distributed by local authorities for the purpose of water fluoridation, HFA and SSF are medicines under the Medicines Act.

(b) A declaration that the Minister of Health is required to consent to the distribution of HFA and SSF under the Medicines Act and that unless and until such consent is granted, any person who sells or distributes HFA and SSF for water fluoridation breaches s 20 of the Medicines Act.

(c) A declaration that before HFA and SSF are sold and supplied to local authorities for water fluoridation purposes, the manufacturers of HFA and SSF require a licence under Part 3 of the Medicines Act.

(d) A declaration that the Minister of Health ought to take all necessary steps to ensure that HFA and SSF are only sold to local authorities and distributed by local authorities in accordance with the Medicines Act.

(e) Such other orders as the Court deems fit.

(f) Costs.

THIS statement of claim is filed by Jonathan Gillard, solicitor for the plaintiff, whose address for service is at the offices of Wynn Williams Lawyers, Homebase, Unit B 195 Marshland Road, Shirley, Christchurch.

Documents for service on the abovenamed plaintiff may be left at that address for service; or

a) Posted to the solicitor at P O Box 4341 Christchurch; or

b) Transmitted to the solicitor by facsimile on 03 353 0247 with a confirmation copy to be sent by post.