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 PATRICK DAVID SLOAN

Dated 23 June 2014

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Wynn Williams Lawyers
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I, Patrick David Sloan, director of Christchurch affirm:

1. This is my second affidavit.

2. Its purpose is to:

   2.1. Explain briefly the key reasons why the plaintiff objects to fluoridation and does not agree that it has been proven to be safe and effective as claimed by the defendant in its statement of defence.

   2.2. Provide further documents in support of the plaintiff's claim.

Efficacy and safety not established and there are alternatives

3. It is accepted by the plaintiff that the merits of fluoridation are not directly relevant in this claim. However, the plaintiff considers it important to put on the record its strong disagreement with the defendant's claim that fluoridation is safe and effective.

4. The best single point of reference setting out the flaws in fluoridation is the academic text *The Case Against Fluoride* by Professor Paul Connett, James Beck and Spedding Micklem.

5. However, the following summarises the plaintiff's position.

How strong is the evidence that swallowing fluoride reduces tooth decay

6. Fluoridation advocates claim that the evidence that swallowing fluoride reduces tooth decay is very strong.

7. However, if you look at the actual science it is a different story.

8. It is well known that fluoridation was endorsed by the US Public Health Service in 1950 before testing of the effects of fluoridation were

completed. The American Medical Association and American Dental Association came out in support shortly afterwards.[1]

9. The effectiveness of swallowing fluoride to reduce tooth decay has never been demonstrated via a randomised control trial (RCT), the gold standard of epidemiology.[2]

10. That no RCT has ever been carried out during the more than 60 years that fluoridation has been practised is astonishing. There has been ample time for proponents to conduct such trials but they have never attempted to do so.

11. Two key US studies – both government funded and conducted by pro-fluoridation researchers – do not produce convincing evidence of benefit.

12. A very large study, administered by the National Institute for Dental Research, examined the permanent teeth of 39,000 children (aged 5 – 17) from 84 communities. The average saving in Decayed Missing and Filled Surfaces (DMFS) when comparing children in fluoridated and non-fluoridated communities was 0.6 of one tooth surface, and this was not shown to be statistically significant.[3]

13. Even if it were statistically significant the average saving is remarkably small.

14. As part of the "Iowa Study", where children's tooth decay has been tracked from birth, researchers examined the relationship between tooth decay and individual exposure to fluoride from all sources, including water, food and dental products. They were attempting to find the so-

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[1] Scientific knowledge in controversy: the social dynamics of the fluoridation debate, Brian Martin, 1991, pp 1 to 3

[2] NHS Centre for Review and Dissemination *A Systematic Review of Water Fluoridation* The University of York, Report 18

[3] J A Brunelle and J P Carlos *Recent Trends in Dental Caries in U.S. Children and the Effect of Water Fluoridation* Journal of Dental Research Volume 69, p 723-727, February 1990

called "optimal dose" needed to reduce tooth decay. However, they concluded that "achieving a caries-free status may have relatively little to do with fluoride intake".[4]

The most likely explanation for the weak evidence of benefit

15. When fluoridation first began in the 1940's, it was believed that fluoride's main benefit came from ingesting fluoride during the early years of life.

16. However now even fluoridation advocates have acknowledged that the predominant benefit of fluoride is post eruptive and topical, not systemic.[5] In other words, fluoride works on the outside of the tooth not from inside the body.

17. Ingestion is not required for caries prevention and consequently there cannot be any optimal intake.

18. Further this acknowledgement that fluoride's predominant benefit is topical removes the whole rationale for fluoridating water and forcing it on people who don't want it.

19. Fluoridation proponents suggest swallowing is required because fluoride is supplied to the oral cavity via ductal saliva. However, the CDC has stated that the concentration of fluoride in saliva is too low in concentration to provide any cariostatic effect.[6]

20. A further explanation for apparent (albeit weak) benefit may be attributable to the fact that fluoridation delays tooth eruption and thus delays decay.

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[4] John J Warren and others *Considerations on Optimal Fluoride Intake Using Dental Fluorosis and Dental Caries Outcomes – A Longitudinal Study* Journal of Public Health Dentistry Vol 69, No.2, Spring 2009

[5] Centers for Disease Control and Prevention. 1999 Morbidity and Mortality Weekly Report 48: 933-940, and 2001 Morbidity and Mortality Weekly Report 50 (RR14): 1 - 42

[6] Ibid, p3

21. A 2005 study confirmed that there is an approximately one year delay in tooth eruption due to fluoridation and that this varies between individuals possibly on a genetic basis. The study also found that once the delay in eruption is adjusted for there is no difference in tooth decay rates.[7]

Other countries

22. Most countries (including 97% of Europe) neither fluoridate their water nor their salt.

23. However, WHO figures indicate that tooth decay in 12-year olds is coming down as fast in non-fluoridated countries as fluoridated ones.[8]

24. Although the prevalence of caries varies between countries, levels everywhere have fallen greatly in the past three decades and national rates of caries are now universally low. This trend has occurred regardless of the concentration of fluoride in water or the use of fluoridated salt and probably reflects use of fluoridated toothpastes and other factorsincluding nutrition.[9]

Tooth decay in low-income families can be achieved

25. Many countries have been able to reduce tooth decay in low-income families using cost-effective programmes without water fluoridation.

26. The Scottish Childsmile programme[10] involves:

    26.1. Teaching toothbrushing in nursery schools;

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[7] A Komarek and E Lesaffre *A Bayesian analysis of multivariate doubly-interval-censored dental data* Biostatistics (2005) 6,1 pp 145 to 155

[8] K Cheng, I Chalmers and S Sheldon *Adding fluoride to water supplies* BMJ 6 October 2007, volume 335

[9] Ibid

[10] www.child-smile.org.uk

26.2. Advising parents on better diets;

26.3. Annual check-ups;

26.4. Fluoride varnishes where necessary.

27. The number of 12 year olds without caries has increased to over 70% using these methods and in the process costs have been cut by half.

28. Tooth decay is primarily caused by poor diet and poor oral hygiene. Sugar in particular is a leading cause of decay. Making education not fluoridation the centre of the fight against tooth decay has the advantage of attacking the cause of obesity, an issue which threatens to cost health services billions of dollars over the coming decades.

Dental fluorosis an acknowledged harm

29. Dental fluorosis is an acknowledged adverse effect of excessive ingestion of fluoride. It is a defect in the tooth enamel and is a symptom of fluoride toxicity.

30. On this basis alone the claim that fluoridation is safe is wrong.

31. It is my understanding that dental fluorosis occurs because fluoride ions interfere with the normal function of the ameloblasts (enamel forming cells), generally between 10 – 20 months of age, when enamel formation is taking place.

32. This raises the question as to what it is doing to other parts of the body, eg as it accumulates in the bone and tissue. However to my knowledge, fluoridation researchers fail to look for association between dental fluorosis and other adverse health effects on bones and tissue.

33. According to the CDC (2010) 41% of American children aged 12 to 15 have dental fluorosis.[11]

34. In New Zealand the prevalence of fluorosis in 9 year old Auckland children was 29.1 percent and 14.7 percent for children in non-fluoridated areas.[12]

35. Fluoridation promoters, however, refuse to admit other potential harms of fluoridation and in fact claim it is safe.

36. A 2006 report by the NRC found that fluoridation at 4 ppm (only 4 times higher than the current maximum fluoridation concentration) did not protect human health and posed known risks in terms of dental fluorosis, skeletal fluorosis and risk of bone fractures. Other risks such as neurotoxicity, genotoxicity, carcinogenity and endocrine effects were identified. This panel also indicated that bottle-fed babies are exceeding the EPA's safe reference dose when drinking fluoridated water.[13]

Fluoride impacts the brain

37. There are many animal and human studies that indicate that fluoride is a neurotoxin.[14]

38. In 2012 a team from Harvard University reviewed 27 studies that showed an association between fairly modest exposure to fluoride and lowered IQ in children.[15]

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[11] Eugenio D Beltran-Aguilar and others *Prevalence and Severity of Dental Fluorosis in the United States, 1999-2004*, NCHS Data Brief, No 53, November 2010

[12] Philip J Schluter and others *Prevalence of enamel defects and dental caries among 9-year old Auckland children* New Zealand Dental Journal December 2008, pp 145 to 152

[13] *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, NRC 2006

[14] www.FluorideAlert.org/issues/health/brain

[15] A L Choi, P Grandjean *Statement on fluoride paper* Harvard Press Release, Cambridge MA, Harvard University 2012

39. In nine of these studies the so-called "high fluoride" village had fluoride levels less than 3 ppm.

40. Such results show that current fluoridation concentrations of 0.7 to 1 ppm do not provide an adequate safety margin to protect all children from neurological damage manifesting as lowered IQ when drinking artificially fluoridated water.

41. Applying a safety factor of 10 would require the reduction of fluoride concentration to close to zero.

Additional comments

42. The plaintiff is also opposed to fluoridation on the basis that it is in conflict with principles of modern pharmacology and that the fluoride supplies are sourced from the phosphate fertiliser industry and contain heavy metal contaminants.

43. The criticisms are that fluoridation fails to provide any precise control of administered fluoride dosages to individuals. The ingested doses of fluoride vary appreciably across individuals depending on water consumption, intake of fluoride–containing foods and use of fluoride-containing dental products.

44. Also fluoride can be absorbed through the skin by showering or bathing in fluoridated water. I am not aware of any research that accounts for intake of fluoride through dermal exposure.

45. It is of considerable concern that arsenic, mercury and lead are permitted to be added to the drinking water supply. Even though traces of these substances may be in the water already and cannot be removed, they should not be deliberately added to water.

46. There have been no studies to my knowledge of what a person's cumulative ingestion of lead and arsenic and mercury may be through water fluoridation.

47. Further most of the reticulated water supply is not drunk and much of it ends up in the environment including on gardens and in waterways. There has been no study to my knowledge of the cumulative effects on the environment of fluoride, arsenic, mercury and lead from the water supply.

Additional documents

48. Attached and marked "A" is the Fluoride Flipbook which is information obtained from the Ministry of Health's website.

49. The Ministry asserts at p 5 that fluoride is not a medicine.

50. This is surprising given that fluoride is listed in the Medicines Regulations 1984 as a pharmacy-only, prescription and restricted medicine.

51. The Ministry also fails on p 4 of the Flipbook to acknowledge the fluoride for water fluoridation comes from the superphosphate industry and includes heavy metal contaminants. The implication of their statement is that the fluoride sources used in water fluoridation are not an industrial waste product.

52. However, in paragraph 8 of the statement of defence it is acknowledged that HFA is a byproduct of the superphosphate industry. And at paragraph 12.5 of the statement of defence it is acknowledged that fluoride compounds added to water supplies may contain heavy metal contaminants.

53. Through its lawyers, the plaintiff asked the defendant's lawyer for documents that informed its current approach of not treating HFA and SSF as a medicine.

54. The response was that there were no such documents.

55. This seemed surprising and so our lawyers made further enquiries which are attached and marked "B".

56. As at the date of affirming this affidavit, a response has not been received.

AFFIRMED at Christchurch this

23rd day of June 2014

before me:

A Barrister and Solicitor of the High Court of New Zealand

TIMOTHY DEREK HOLTON
SOLICITOR
CHRISTCHURCH

'A'

THIS is the Exhibit marked with the letter "A" referred to in the annexed affidavit of PATRICK DAVID SLOAN AFFIRMED/SWORN at Christchurch this 13 day of June 2014 before me:

A Solicitor of the High Court of New Zealand

Water Fluoridation

What is fluoride?
Fluoride is a common natural element found in air, soil, fresh water, sea water, plants and lots of foods. It is known to have a protective effect on teeth when used at the right concentrations.

Fluoride helps to protect our teeth from decay by strengthening teeth and reversing or slowing the early stages of tooth decay.

In New Zealand, fluoride is found naturally in all water supplies, but mostly at a level too low to protect against tooth decay (dental caries).

What is water fluoridation?

Water fluoridation is the adjustment of natural fluoride levels in water supplies to a level that will give extra protection against tooth decay.

The recommended level of fluoride in New Zealand community water supplies is 0.7 to 1 part per million (or 0.7 to 1 milligram per litre), and is sometimes called the "optimal level". This is the lowest amount at which the benefits to dental health can be achieved, while minimising any risk of fluorosis or white flecking on teeth (see pages 2-3).

Why do we fluoridate water?

The Ministry of Health, and many international health bodies, recommend that fluoride levels in drinking water be adjusted to optimal levels to improve and protect oral health.

Tooth decay can have a significant impact on appearance, self-esteem, social interaction and the ability to speak and chew. Un-treated decay may cause pain, dental abscesses or serious infection. Treating decay is costly and can be unpleasant and painful. However tooth decay is largely preventable.

Drinking optimally fluoridated water is a safe, simple and effective way to help prevent and reduce tooth decay in the whole population.

Who benefits?

More New Zealanders are keeping their teeth for life. Water fluoridation can benefit all people with natural teeth regardless of age, income or education level. It gives the greatest benefits to children and especially those most at risk of tooth decay.

How is water fluoridated?

Fluoride is added to the water supply by feeder and pump systems that are specially designed to add carefully controlled amounts. Once dissolved in water, the added fluoride is no different to naturally-occurring fluoride. Local water authorities have constant monitoring systems which include checking the amount of fluoride in water regularly. Local Councils must ensure their water supplies meet the standards in New Zealand Drinking Water Standards 2005 (revised 2008).

Water fluoridation is effective

Data collected in the United States in the 1930s and 1940s demonstrated that children drinking water with very little or no naturally-occurring fluoride had higher decay rates than children consuming water with higher levels of fluoride.

This led to the establishment of water fluoridation programmes to top-up fluoride to optimal levels. The effectiveness of water fluoridation has been reported in scientific literature for well over 60 years.

The protective action of fluoride on teeth is well documented. Water fluoridation delivers the benefits of fluoride across a population. It is intended to support good oral hygiene, such as cleaning your teeth with a fluoride toothpaste at least twice a day (morning and night), and complements other forms of fluoride use, such as professionally applied varnishes.

The prestigious US-based Centers for Disease Control and Prevention describes water fluoridation as one of the 10 most important public health advances and disease prevention measures of the twentieth century[1].

The Public Health Commission has estimated that water fluoridation prevents between 2.4 - 12.0 decayed, missing or filled teeth in the average person over a lifetime, or between 58,000 and 267,000 decayed, missing and filled teeth in New Zealand per year[2].

New Zealand research published in 2004 confirmed that decay severity was 31% lower in 5-year-old and 41% lower in 12-year-old children living in fluoridated Wellington than in non-fluoridated Canterbury[3]. Regional differences in patterns of decay exist for a number of social and clinical reasons, but the overwhelming result is that water fluoridation provides dental protection. This beneficial effect of fluoride is still evident despite the wide availability of fluoride toothpaste.

Water fluoridation is safe

Extensive studies of water fluoridation and human health have been undertaken in many countries over many years. A review of these studies in 2007 confirmed again that fluoridation at optimal levels, is safe and effective[4].

The 2007 review found no clear evidence of a link between fluoridation and bone or other cancers, and little or no effect on the risk of fractures. There was also no reliable evidence to link water fluoridation with conditions such as Down's Syndrome, allergic conditions, mutations and enzyme dysfunction.

The World Cancer Research Fund has noted that there is no substantial evidence that suggests that fluoride (as consumed in water or foods) has any significant effect on the risk of any cancer[5].

A 2010 review by the European Commission that looked at the risk and benefit of fluoridated drinking water found that it is generally considered beneficial[6].

The Ministry of Health monitors the scientific literature on the effects of water fluoridation to ensure its policy is in line with international best practice. Key resource documents are available on the Ministry of Health website: www.moh.govt.nz/fluoride.

Fluorosis

Dental fluorosis occurs when young children are exposed to excessive amounts of fluoride when their teeth are developing. Dental fluorosis is a known side effect of water fluoridation. However, in New Zealand, only the mildest forms of fluorosis are linked with optimally fluoridated water, and these don't have cosmetic or functional impact on the tooth or individual.

Research has reviewed the level of dental fluorosis in New Zealand. Studies published in 2005 and 2008 found that very mild fluorosis levels have been fairly stable since the 1980s[7].

[1] CDC *MMWR*, October 22, 1999;48(41);933–940, the other 9 measures include vaccinations, family planning, control of infectious diseases, reducing coronary heart disease and stroke, safer and healthier foods, healthier mothers and babies, motor vehicle safety measures, safer workplaces and recognising tobacco use as a health hazard.

[2] Public Health Commission, 1994, *Water Fluoridation in New Zealand: an analysis and monitoring report.*

[3] Lee M and Dennison PJ, 2004, *Water fluoridation and dental caries in 5-and 12-year-old children from Canterbury and Wellington* New Zealand Dental Journal 100(1):10-15.

[4] NHMRC, 2007, *A systematic review of the efficacy and safety of water fluoridation.* Canberra, National Health and Medical Research Council, Australian Government. For a summary view see NHMRC Public Statement: Efficacy and Safety of Fluoridation.

[5] World Cancer Research Fund/American Institute for Cancer Research, 2001, *Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective*, Washington, p150.

[6] Scientific Committee on Health and Environmental Risks, European Commission, 2010, Critical review of any new evidence on the hazard profile, health effects and human exposure to fluoride and the fluoridating agents of drinking water.

[7] *Mackay and Thomson, 2005,* Enamel defects and dental caries among Southland children. *New Zealand Dental Journal 101.(2):35-43, Schluter et al, 2008,* Prevalence of enamel defects and dental caries among 9-year-old Auckland children, *New Zealand Dental Journal,104(4):145-152.*

In New Zealand mild to moderate fluorosis may occur if children eat large amounts of toothpaste or incorrectly use fluoride tablets[8]. Some countries overseas have extremely high levels of naturally occurring fluoride in their drinking water which can cause severe fluorosis. New Zealand does not have this problem

Water fluoridation is cost-effective

Fluoridation is one of the most cost-effective ways to reduce dental decay in communities. The financial costs of treating dental disease are high, while the costs of water fluoridation are relatively low.

In 1999, a group of independent scientists and economists advised that the economic argument for water fluoridation is very strong, especially for communities with lower socio-economic status. In a town of around 50,000 people, fluoridation would prevent an estimated 74,200 cases of decay over 30 years. On those figures it was conservatively estimated it would cost around $4.20 to prevent each case of decay. Without fluoridation it would cost around $117.25 to treat each case of decay[9]. This shows that treating decay is around 30 times more expensive than preventing it with water fluoridation.

Fluoridated water and infant formula

There has been concern about the amount of fluoride young babies may consume if they are fed infant formula made up with fluoridated water.

In New Zealand, fluoride levels are well controlled in both water and infant formula, through the New Zealand Drinking Water Standards and the Australia New Zealand Food Standards Code. Fluoride is not permitted to be added to infant formula made in New Zealand, although it may be present in very small amounts in the base ingredients.

Recent clinical advice on the use of fluorides in New Zealand, confirms there are no safety concerns with using fluoridated tap water to make up infant formula[10].

What about personal choice?

Some people see water fluoridation as a form of mass medication, which takes away their individual rights.

In 1980, the Human Rights Commission stated that "in all circumstances ... it is considered that the question of fluoridation of water supplies by public authorities does not constitute a denial of human rights."[11]

In 1964, the Privy Council considered water fluoridation and stated that "the addition of fluoride adds no impurity and the water remains not only water but pure water and becomes greatly improved and still natural water containing no foreign elements."[12]

Water treatment devices for the home, such as reverse osmosis filters and steam distillers can be used if people wish to remove fluoride from their drinking water. Bottled water may or may not be fluoridated – check the label for details.

[8] Fluoride tablets are no longer recommended (except on the advice of a dental professional) because of the risk of fluorosis.

[9] *ESR, 1999* ,The Cost-Effectiveness of Fluoridating Water Supplies in New Zealand, *Institute of Environmental Science and Research Limited.*

[10] *New Zealand Guidelines Group, 2009,* Guidelines for the Use of Fluorides, *Wellington.*

[11] *Agenda item no 9, Proceedings of the Human Rights Commission, 13 August 1980.*

[12] *Privy Council Appeal no. 25 of 1964, Her Majesty's Attorney General of NZ v the Mayor, Councilors and Citizens of the City of Lower Hutt .*

Where does fluoride for water fluoridation come from?

Some people claim that fluoridating water is a way for industry to dump waste products; however this is not true. Industries such as aluminium smelters, oil refineries, steel production, brickworks and ceramic factories may release fluoride through their processes. However this material is not a source of fluoride for water fluoridation.

In New Zealand, fluoride for water treatment is supplied as sodium fluoride, sodium silicofluoride or hydrofluorosilicic acid. Some is manufactured locally and some is sourced overseas. Whatever the source or the form, the fluoride has to meet strict quality and purity standards.

Is it toxic?

In its concentrated form, fluoride is toxic, as is the concentrated chlorine used to kill bacteria in drinking water. That is why the containers have hazard markings on them. Once diluted to optimal levels, the added fluoride is not harmful and does not change the nature or purity of water.

An adult would have to drink many thousands of glasses of fluoridated water in one sitting to get a lethal dose of fluoride. However this amount of water would be lethal in itself.

Fluoride does not accumulate in the body. The level of fluoride in your blood reflects the level in the water you drink and the food you consume.

Why do some countries not use water fluoridation?

Some countries have natural fluoride levels that provide protection. At least 50 million people live in areas with naturally occurring fluoride in their water at around the optimal level. Technical reasons mean that some countries are not able to add fluoride to their water systems and some use alternatives such as fluoridated salt.

Even though some countries do not use water fluoridation, fluoride is still the key ingredient for the prevention and minimisation of tooth decay, through means such as fluoridated toothpaste, salt, tablets, varnishes or gels. Some countries also spend more on oral health services for their populations.

Key International health agencies, such as the World Health Organization, continue to recommend water fluoridation.

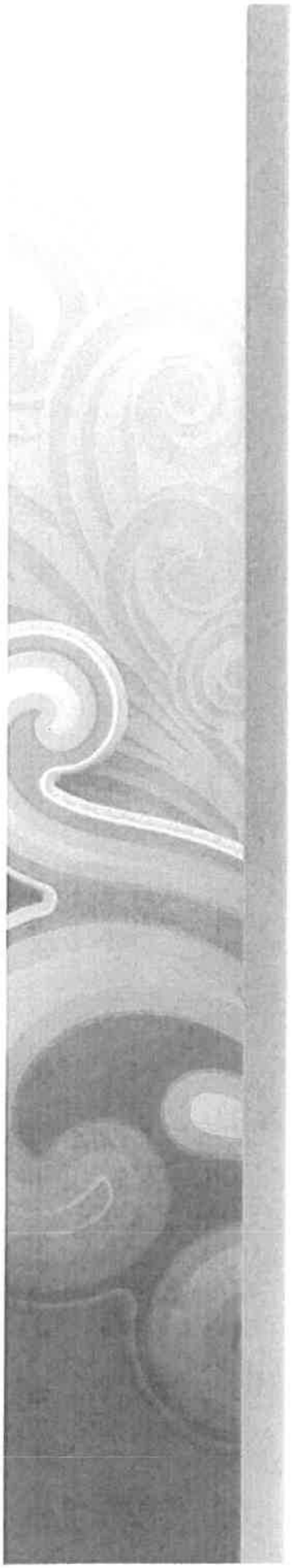
Finding unbiased information on fluoridation

The internet holds a lot of information about water fluoridation but the quality and reliability of information is often difficult for the lay person to assess. Many scientific articles are contained in journals that are subscription-based and may not be readily available to the public. Assessing health benefits and risks can be complicated, and research can appear contradictory or inconclusive.

Websites opposing water fluoridation often quote research with little regard for context, validation or subsequent reviews that have discounted questionable research.

There are research papers that question the efficacy or safety of fluoridation – however in many cases such research may be of poor quality, be inconclusive, not comparable to New Zealand's situation, or be only one result compared to a large body of evidence that has different results.

The Ministry of Health regularly scans the international literature to ensure its policy position takes account of significant scientific findings. The Ministry of Health webpage has information about fluoridation, links to relevant research papers and key international agency statements on water fluoridation, and other oral health issues; see www.moh.govt.nz/fluoride.



Summary

The table below summarises the key issues discussed in this paper and addresses concerns often raised by people seeking more information, or by those strongly opposed to fluoridation.

Questions?	Response
Is water fluoridation effective?	• Yes. Even where use of fluoride toothpaste is widespread, recent studies confirm that water fluoridation continues to provide benefits across the whole population, and especially to children and those most at risk of tooth decay. • Key international dental and general health agencies continue to support water fluoridation as a safe, effective way to protect teeth.
Does water fluoridation cause serious illness or disease?	• No. Recent systematic reviews of the scientific evidence over the last 60 years confirm that there are no significant health concerns arising from optimally fluoridated water.
Can you get severe fluorosis from optimally fluoridated water?	• No. Optimally fluoridated water does not lead to severe fluorosis. • Very mild to mild fluorosis may result, but it generally makes the teeth whiter and does not require treatment. • Levels of very mild fluorosis in New Zealand are fairly stable.
Is water fluoridation a form of mass medication?	• No. Fluoride is not a medicine – it is a naturally occurring element. Topping up fluoride to optimal levels does not change the nature or purity of water. • Individuals who object can opt out by using special filters for their drinking water.
Where does the fluoride come from?	• Fluoride used for drinking water comes mostly from soils and rocks. The manufactured product needs to meet strict quality and purity standards.

Questions?	Response
Is the fluoride used for drinking water toxic?	• While concentrated fluoride is toxic, it is not harmful when appropriately diluted. The same applies to chlorine, which is also commonly added to drinking water. • Once added to water, the added fluoride is no different to naturally-occurring fluoride. • An adult would have to drink several thousand glasses of fluoridated water in one sitting to get a lethal dose of fluoride.
Why don't some other countries fluoridate their water?	• Some countries have natural fluoride levels that provide protection. • Some countries cannot fluoridate water for technical reasons, but may use salt fluoridation schemes, or may support dental health in other ways. • The World Health Organization continues to recommend water fluoridation as a safe, effective way to protect dental health across the population

Fluoride

Further information www.moh.govt.nz/fluoride

MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

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'B'

Lisa Hansen

From: Lisa Hansen
Sent: Monday, 16 June 2014 9:30 a.m.
To: 'Jane Foster'
Subject: RE: New Health
Attachments: SKM_C364e0614061608390.pdf

AFFIRMED

THIS is the Exhibit marked with the letter .. B. .. referred to in the annexed affidavit of PATRICK DAVID SLOAN SWORN at Christchurch this 23 day of June 2014 before me:

A Solicitor of the High Court of New Zealand

Dear Jane

Thanks for your email.

Your response is surprising. Is New Health to infer that the Ministry has never turned its mind to whether HFA and SSF might be a medicine? Alternatively is New Health to infer that your advice is that it is a medicine.

Can you please confirm that the Ministry has not considered whether HFA and SSF are a medicine.

And/or can you please provide all and any documents that show HFA and SSF are a medicine.

If the Ministry were to evaluate HFA and SSF now using the criteria it applies to assess a dietary supplement, it would be compelled to conclude that they were medicines.

If a dietary supplement contains a scheduled ingredient (ie under the Medicines Regulations 1984) or makes a therapeutic claim or has a therapeutic purpose, it would be considered to be a medicine.

HFA and SSF satisfy these criteria. They contain fluoride which is listed in the Medicines Regulations 1984 as a prescription, pharmacy-only and restricted medicine, and have a therapeutic purpose.

I refer to an email exchange between Eric Blankenbyl and Tony Wang (of Medsafe) to illustrate the point (attached).

Perhaps the Ministry has deliberately refrained from evaluating HFA and SSF under the Medicines Act because concluding HFA and SSF were medicines would put at risk the Ministry's strong promotion of fluoridation.

Can you please confirm that if HFA and SSF were medicines this would compromise the Ministry's policy of supporting fluoridation.

Can you also please advise whether there are any products which are intended to be consumed by an individual that contain either a scheduled ingredient and/or have a therapeutic purpose and which are not medicines.

Can you please reply to the highlighted questions by no later than **Thursday 19 June 2014** as the responses may be required to be included in the further evidence adduced by the plaintiff.

Many thanks
Kind regards
Lisa

From: Jane Foster [mailto:Jane.Foster@crownlaw.govt.nz]
Sent: Friday, 13 June 2014 2:52 p.m.
To: Lisa Hansen
Cc: Susannah Shaw
Subject: New Health

Kia ora Lisa,

In regards to your request for the Ministry to provide by today any documents that informed their current approach of not treating HFA and SSF as a medicine I can now advise that the Ministry is not aware of any such documents.

We will contact you next week regarding the other documents you requested by way of informal discovery.
Na

Jane Foster
Crown Counsel
Crown Law ***Te Tari Ture o te Karauna***
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Fax: +64-4-473-3482
www.crownlaw.govt.nz

Lisa Hansen

From: Eric Blankenbyl
Sent: Saturday, 14 June 2014 9:00 a.m.
To: 'Lisa Hansen'
Cc: dsloan@ihug.co.nz
Subject: RE: MOH definition of a medicine:

Hi Lisa, I am forwarding you this reply from the MOH FYI. You are welcome to use it if you wish.

Kind Regards,

Eric Blankenbyl.

From: Tony_Wang@moh.govt.nz [mailto:Tony_Wang@moh.govt.nz] **On Behalf Of** dietarysupplements@moh.govt.nz
Sent: Thursday, 5 June 2014 12:00 p.m.
To: Eric Blankenbyl
Subject: RE: Prohibited ingredients list

Dear Eric,

The scientific genus name for Comfrey is *Symphytum*. When using our searchable database you should also check under the scientific name, and not just common name of the plant. I can advise you that in this case, Comfrey is not scheduled under the Medicines Regulations as a prescription, restricted, or pharmacy only medicine.

However, just because the ingredient is not listed does not assure that it is safe or effective for its intended purpose. As mentioned in the previous email, the categorisation of the product that you intend to import/sell/market (whether a cosmetic, dietary supplement, herbal medicine, medicine) depends on whether the ingredient/plant component has an implied therapeutic purpose, and whether you are making any therapeutic claims around the use of the product.

For example, creams for topical use may be marketed in New Zealand as either cosmetics, medicines or related products. Which category your product falls into depends on how you intend the product to be used and what sort of ingredients the product contains.

Cosmetics

A product marketed as a cosmetic must comply with the definition of a cosmetic in the Medicines Act 1981, with Regulations 24 and 26-36 of the Medicines Regulations 1984 and with the Cosmetic Products Group Standard 2006, which is published by the Environmental Protection Authority (EPA) at www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/cosmetic.aspx.

According to the Medicines Act, a cosmetic is for the purpose of beautifying, improving, protecting, altering or cleansing the hair, skin or complexion of human beings. (A copy of the Medicines Act and Regulations can be downloaded from www.legislation.govt.nz.)

You do not need to apply for approval to distribute a cosmetic in New Zealand. It remains the responsibility of the sponsor to ensure that the product is made to an acceptable quality and is safe to use.

Medicines/related products

In contrast to cosmetics, medicines and related products need to have consent from the Minister of Health prior to distribution. Medicines are defined in the Medicines Act 1981 as products that are administered to a human being for a **therapeutic purpose**. Information required in the application includes data demonstrating the safety, efficacy and quality of the ingredients and the final product. Data to demonstrate product stability during the proposed shelf-life would also need to be submitted. The product will need to be made in a facility that complies with an appropriate standard of Good Manufacturing Practice (GMP). Further information on the application process (and associated fee) is available on our website at www.medsafe.govt.nz/regulatory/fees.asp and

www.medsafe.govt.nz/regulatory/guidelines.asp. A copy of the Medicines Act is available from www.legislation.govt.nz.

Claims

Provided the product does not contain ingredients that are scheduled or have an implied therapeutic purpose, how you decide to position the product will centre on the type of claims you wish to make. **If you wish to position your product as a cosmetic then therapeutic claims will not be suitable.** We appreciate that it can be difficult to determine whether a claim implies a therapeutic purpose and, therefore, we advise that people seek independent advice.

The Association of New Zealand Advertisers offers a Therapeutic Advertising Pre-vetting System (TAPS, www.anza.co.nz/Category?Action=View&Category_id=262). For a fee an adjudicator will assess your labels and advertising material and advise if it is compliant with NZ legislation. They will also offer advice on how statements could be modified for products that do not have consent from the Minister. Many people have found this to be a useful service. Alternatively there are a number of regulatory affairs consultants who specialise in advertising compliance. A list is available on our website at www.medsafe.govt.nz/regulatory/consultants.asp.

Another useful resource is the TAPS website (www.anza.co.nz/Category?Action=View&Category_id=265). This website contains some guidelines on therapeutic claims and provides examples of claims that do not imply a therapeutic purpose.

I hope you find this information useful.

Tony Wang
Advisor - Science
Medicines Assessment
Medsafe
Ministry of Health
DDI: 04 819 6831

http://www.medsafe.govt.nz
mailto:Tony_Wang@moh.govt.nz

From: "Eric Blankenbyl" <straussherbs@xtra.co.nz>
To: <dietarysupplements@moh.govt.nz>,
Date: 04/06/2014 02:55 p.m.
Subject: RE: Prohibited ingredients list

Hi Tony, Thank you for your response. I have searched the links you provided for Comfrey without success. Does that mean it is not restricted or prohibited?

Kind Regards,

Eric.

From: Tony_Wang@moh.govt.nz [mailto:Tony_Wang@moh.govt.nz] **On Behalf Of** dietarysupplements@moh.govt.nz
Sent: Tuesday, 3 June 2014 9:43 a.m.
To: Eric Blankenbyl
Subject: Re: Prohibited ingredients list

Dear Eric,

Thank you for your email. There are lists available of ingredients that are prohibited/ restricted for use in dietary

supplements, however they are located in different parts of the NZ legislation with differences in the intent of their listing (i.e. some lists are permissive (allows for use in dietary supplements at daily doses below...) and some are restrictive (cannot use in dietary supplements)).

You can check the following resources to determine:

- whether the ingredient or plant components are restricted under the Dietary Supplements Regulations 1985 (a copy of the regulations is available from www.legislation.govt.nz).
- whether the ingredient/plant component is scheduled under the Misuse of Drugs Act 1975 as a controlled drug, or under the Medicines Regulations 1984 as a prescription medicine, pharmacy-only medicine or restricted (pharmacist-only) medicine. (copies of the regulations are available from www.legislation.govt.nz).
- You must also make sure that the products do not contain any scheduled substances. You can do this by using our searchable database (www.medsafe.govt.nz/profs/class/classintro.asp) to check the ingredients in each product to make sure they do not contain any substances scheduled as prescription medicines, restricted (pharmacist-only) medicines or pharmacy-only medicines under the Medicines Regulations 1984. I recommend that you search under both the name you know the ingredient by and any synonyms. If you do this and you get a "not found" result, it is unlikely that the ingredient is scheduled. As an example, citicoline is not scheduled under the Medicines Regulations.

You will also need to consider the following matters when deciding whether it is appropriate to include an ingredient in a dietary supplement:

- whether the product containing the ingredient/plant components meet the definition of a dietary supplement, as defined in regulation 2A of the Dietary Supplements Regulations (e.g. is it intended as a supplement to a substance normally derived from food?)
- whether the ingredient/plant component has an implied or stated therapeutic purpose (e.g. certain strengths of paracetamol are unscheduled, but this ingredient has a therapeutic purpose and is not intended to supplement the diet so could not be used in a dietary supplement)
- whether a product containing the ingredient/plant component is safe for its intended purpose at the proposed quantity to be ingested.

Dietary supplements must also comply with all other regulations in the Dietary Supplements Regulations 1985. This legislation describes a number of requirements for dietary supplements including, but not limited to, labelling requirements and also prohibiting dietary supplements being promoted for a therapeutic purpose.

I hope this answers your question.

Regards

Tony Wang
Advisor - Science
Medicines Assessment
Product Regulation
Medsafe
Ministry of Health
DDI: 04 819 6831

http://www.medsafe.govt.nz
mailto:Tony_Wang@moh.govt.nz

From: "Eric Blankenbyl" <straussherbs@xtra.co.nz>
To: <dietarysupplements@moh.govt.nz>.
Date: 30/05/2014 08:55 a.m.
Subject: Prohibited ingredients list

Good morning,

Can you please direct me to the list of ingredients that are restricted or prohibited for use in dietary supplements in NZ?

Kind Regards
Eric Blankenbyl